



Notice of Intent to Adopt Rules

1. General Information

| | | |
|--|-----------------------------|--------------------------|
| a. Agency/Board Name <i>See attached list for references</i> | | |
| b. Agency/Board Address | c. Agency/Board City | d. Agency/Board Zip Code |
| e. Name of Contact Person | f. Contact Telephone Number | |
| g. Contact Email Address | | |
| h. Date of Public Notice: | | i. Comment Period Ends: |
| j. Program(s) <i>See attached list for references</i> | | |

2. Rule Type and Information

a. Choose all that apply: New Rules* Amended Rules Repealed Rules
** "New" rules means the first set of regular rules to be promulgated by the Agency after the Legislature adopted a new statutory provision or significantly amended an existing statute.*

If "New," provide the Enrolled Act number and year enacted:

b. Provide the Chapter Number, and Short Title of Each Chapter being Created/Amended/Repealed *(if more than 5 chapters are being created/amended/repealed, please use the Additional Rule Information form and attach it to this certification)*

| | |
|-----------------|--------------|
| Chapter Number: | Short Title: |
| Chapter Number: | Short Title: |
| Chapter Number: | Short Title: |
| Chapter Number: | Short Title: |
| Chapter Number: | Short Title: |

c. The Statement of Reasons is attached to this certification.

d. N/A In consultation with the Attorney General's Office, the Agency's Attorney General representative concurs that strike and underscore is not required as the proposed amendments are pervasive (Section 5 of the Rules on Rules).

e. A copy of the proposed rules* may be obtained:

By contacting the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: _____

* If Item "d" above is not checked, the proposed rules shall be in strike and underscore format.

3. Public Comments and Hearing Information

a. A public hearing on the proposed rules has been scheduled. Yes No

| | | | | | |
|--|-----------|-------|-------|-------|-----------|
| | If "Yes:" | Date: | Time: | City: | Location: |
| | | | | | |

b. What is the manner in which interested person may present their views on the rulemaking action?
 By submitting written comments to the Agency at the physical and/or email address listed in Section 1 above.
 At the following URL: _____

A public hearing will be held if requested by 25 persons, a government subdivision, or by an association having not less than 25 members.
Requests for a public hearing may be submitted:
 To the Agency at the physical and/or email address listed in Section 1 above.
 At the following URL: _____

c. Any person may urge the Agency not to adopt the rules and request the Agency to state its reasons for overruling the consideration urged against adoption. Requests for an agency response must be made prior to, or within thirty (30) days, after adoption of the rule, addressed to the Agency and Contact Person listed in Section 1 above.

4. Federal Law Requirements

a. These rules are created/amended/repealed to comply with federal law or regulatory requirements. Yes No

| | | |
|--|-----------|--|
| | If "Yes:" | Applicable Federal Law or Regulation Citation: |
| | | |

Indicate one (1):
 The proposed rules meet, but do not exceed, minimum federal requirements.
 The proposed rules exceed minimum federal requirements.

Any person wishing to object to the accuracy of any information provided by the Agency under this item should submit their objections prior to final adoption to:
 To the Agency at the physical and/or email address listed in Section 1 above.
 At the following URL: _____

5. State Statutory Requirements

a. Indicate one (1):
 The proposed rule change *MEETS* minimum substantive statutory requirements.
 The proposed rule change *EXCEEDS* minimum substantive statutory requirements. Please provide a statement explaining the reason the rules exceeds the requirements:

6. Authorization

a. I certify that the foregoing information is correct.

| | |
|--|--|
| <i>Printed Name of Authorized Individual</i> | |
| <i>Title of Authorized Individual</i> | |
| <i>Date of Authorization</i> | |

Distribution List:

- Attorney General and LSO: Hard copy of Notice of Intent; Statement of Reasons; Clean copy of the rules; and Strike-through and underline version of rules (if applicable).
- Secretary of State: Electronic version of Notice of Intent sent to rules@state.wy.us

Statement of Reasons

The Department of Workforce Services, Wyoming OSHA Division in conjunction with Wyoming OSHA Commission respectfully requests to modify and amend the 1910 General Industry and 1926 Construction Standards.

Amending and modifying the 1910 General Industry Standards and 1926 Construction Standard for its Hazard Communication Standard (HCS): This rulemaking action is to modify its Hazard Communication Standard (HCS) to conform to the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals (GHS). OSHA has determined that the modification will significantly reduce costs and burdens while also improving the quality and consistency of information provided to employers and employees regarding chemical hazards and associated protective measures. This improved information will enhance the effectiveness of the HCS in ensuring that employees are apprised of the chemical hazards to which they may be exposed, and in reducing the incidence of chemical-related occupational illnesses and injuries. The modification to the standard include revised criteria for classification of chemical hazards; revised labeling provisions that include requirements for use of standardized signal words, pictograms, hazard statements, and precautionary statements; a specified format for safety data sheets; and related revisions to definitions of terms used in the standard, and requirements for employee training on labels and safety data sheets. OSHA also is modifying provisions of other standards, including standards for flammable and combustible liquids, process safety management, and most substance-specific health standards, to ensure consistency with the modified HCS requirements. The consequences of these modifications will be to improve safety, to facilitate global harmonization of standards, and to produce hundreds of millions of dollars in annual savings.

Subpart D - Occupational Health and Environmental Controls

| | |
|---|--|
| 1926.50 | Medical services and first aid. |
| 1926.51 | Sanitation. |
| 1926.52 | Occupational noise exposure. |
| 1926.53 | Ionizing radiation. |
| 1926.54 | Nonionizing radiation. |
| 1926.55 | Gases, vapors, fumes, dusts, and mists. |
| 1926.56 | Illumination. |
| 1926.57 | Ventilation. |
| 1926.58 | [Reserved] |
| 1926.59 | Hazard communication. |
| 1926.60 | Methylenedianiline. |
| Appendix A to Section 1926.60 Substance Data Sheet, for 4-4'-Methylenedianiline | |
| Appendix B to Section 1926.60 Substance Technical Guidelines, MDA | |
| Appendix C to Section 1926.60 Medical Surveillance Guidelines for MDA | |
| Appendix D to Section 1926.60 Sampling and Analytical Methods for MDA Monitoring and Measurement Procedures | |
| Appendix E to Section 1926.60 Qualitative and Quantitative Fit Testing Procedures | |
| 1926.61 | Retention of DOT markings, placards and labels. |
| 1926.62 | Lead. |
| 1926.64 | Process safety management of highly hazardous chemicals. |
| 1926.65 | Hazardous waste operations and emergency response. |
| 1926.66 | Spray finishing using flammable and combustible materials. |

SUBPART D -- Occupational Health and Environmental Controls

Authority: ~~40 U.S.C. 3701 et seq.; 29 U.S.C. 653, 655, 657; and Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), 3-2000 (65 FR 50017), 5-2002 (67 FR 65008), 5-2007 (72 FR 31160), or 4-2010 (75 FR 55355), as applicable; and 29 CFR 1911.~~

~~Sections 1926.58, 1926.59, 1926.60, and 1926.65 also issued under 5 U.S.C. 553 and 29 CFR 1911.~~

~~Section 1926.61 also issued under 49 U.S.C. 1801-1819 and 5 U.S.C. 553.~~

~~Section 1926.62 of 29 CFR also issued under 42 U.S.C. 4853.~~

~~Section 1926.65 of 29 CFR also issued under 29 U.S.C. 655 note, and 5 U.S.C.~~

~~[55 FR 50687, Dec. 10, 1990; 57 FR 49272, Oct. 30, 1992; 58 FR 26627, May 4, 1993; 58 FR 34218, June 24, 1993; 58 FR 35310, June 30, 1993; 59 FR 6170, Feb. 9, 1994; 59 FR 17479,~~

April 13, 1994; 59 FR 36695, July 19, 1994; 59 FR 43268, Aug. 22, 1994; 59 FR 65947, Dec. 22, 1994; 61 FR 9227, March 7, 1996; 61 FR 31427, June 20, 1996; 62 FR 1493, Jan. 10, 1997; 63 FR 1152, Jan. 8, 1998; 63 FR 33450, June 18, 1998; 70 FR 1143, Jan. 5, 2005; 71 FR 16674, April 3, 2006; 71 FR 50191, August 24, 2006; 73 FR 75588, Dec. 12, 2008; 76 FR 33611, June 8, 2011]

40 U.S.C. 3701 et seq.; 29 U.S.C. 653, 655, 657; and Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), 3-2000 (65 FR 50017), 5-2002 (67 FR 65008), 5-2007 (72 FR 31160), or 4-2010 (75 FR 55355), as applicable; and 29 CFR 1911.

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Section 1926.65 of 29 CFR also issued under 29 U.S.C. 655 note, and 5 U.S.C. [55 FR 50687, Dec. 10, 1990; 57 FR 49272, Oct. 30, 1992; 58 FR 26627, May 4, 1993; 58 FR 34218, June 24, 1993; 58 FR 35310, June 30, 1993; 59 FR 6170, Feb. 9, 1994; 59 FR 17479, April 13, 1994; 59 FR 36695, July 19, 1994; 59 FR 43268, Aug. 22, 1994; 59 FR 65947, Dec. 22, 1994; 61 FR 9227, March 7, 1996; 61 FR 31427, June 20, 1996; 62 FR 1493, Jan. 10, 1997; 63 FR 1152, Jan. 8, 1998; 63 FR 33450, June 18, 1998; 70 FR 1143, Jan. 5, 2005; 71 FR 16674, April 3, 2006; 71 FR 50191, August 24, 2006; 73 FR 75588, Dec. 12, 2008; 76 FR 33611, June 8, 2011; 76 FR 80740, Dec. 27, 2011]

1926.50 Medical services and first aid. STD 1-8.2

(a) The employer shall insure the availability of medical personnel for advice and consultation on matters of occupational health.

(b) Provisions shall be made prior to commencement of the project for prompt medical attention in case of serious injury.

(c) In the absence of an infirmary, clinic, hospital, or physician, that is reasonably accessible in terms of time and distance to the worksite, which is available for the treatment of injured employees, a person who has a valid certificate in first-aid training from the U.S. Bureau of Mines, the American Red Cross, or equivalent training that can be verified by documentary evidence, shall be available at the worksite to render first aid.

(d)

(1) First-aid supplies shall be easily accessible when required.

(2) The contents of the first-aid kit shall be placed in a weatherproof container with individual sealed packages for each type of item, and shall be checked by the employer before being sent out on each job and at least weekly on each job to ensure that the expended items are

replaced.

(e) Proper equipment for prompt transportation of the injured person to a physician or hospital, or a communication system for contacting necessary ambulance service, shall be provided.

(f) In areas where 911 is not available, the telephone numbers of the physicians, hospitals, or ambulances shall be conspicuously posted.

(The information collection requirements contained in paragraph (f) were approved by the Office of Management and Budget under control number 1218-0093.)

(g) Where the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use.

Appendix A to § 1926.50 -- First aid Kits (Non-Mandatory)

First aid supplies are required to be easily accessible under paragraph Sec. 1926.50(d)(1). An example of the minimal contents of a generic first aid kit is described in American National Standard

(ANSI) Z308.1-1978 "Minimum Requirements for Industrial Unit-Type First-aid Kits". The contents of the kit listed in the ANSI standard should be adequate for small work sites. When larger operations or multiple operations are being conducted at the same location, employers should determine the need for additional first aid kits at the worksite, additional types of first aid equipment and supplies and additional quantities and types of supplies and equipment in the first aid kits.

In a similar fashion, employers who have unique or changing first-aid needs in their workplace, may need to enhance their first-aid kits. The employer can use the OSHA 200 log, OSHA 101's or other reports to identify these unique problems. Consultation from the local Fire/Rescue Department, appropriate medical professional, or local emergency room may be helpful to employers in these circumstances. By assessing the specific needs of their workplace, employers can ensure that reasonably anticipated supplies are available. Employers should assess the specific needs of their worksite periodically and augment the first aid kit appropriately.

If it is reasonably anticipated employees will be exposed to blood or other potentially infectious materials while using first-aid supplies, employers should provide personal protective equipment (PPE). Appropriate PPE includes gloves, gowns, face shields, masks and eye protection (see "Occupational Exposure to Blood borne Pathogens", 29 CFR 1910.1030(d)(3)) (56 FR 64175).

1926.51 Sanitation.

(a) Potable water.

STEP (1) An adequate supply of potable water shall be provided in all places of employment.

(2) Portable containers used to dispense drinking water shall be capable of being tightly

closed, and equipped with a tap. Water shall not be dipped from containers. STEP

(3) Any container used to distribute drinking water shall be clearly marked as to the nature of its contents and not used for any other purpose. STEP

(4) The common drinking cup is prohibited. STEP

(5) Where single service cups (to be used but once) are supplied, both a sanitary container for the unused cups and a receptacle for disposing of the used cups shall be provided. STEP

(6) Potable water means water that meets the standards for drinking purposes of the State or local authority having jurisdiction, or water that meets the quality standards prescribed by the U.S. Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR part 141).

(b) Nonpotable water.

(1) Outlets for nonpotable water, such as water for industrial or firefighting purposes only, shall be identified by signs meeting the requirements of Subpart G of this part, to indicate clearly that the water is unsafe and is not to be used for drinking, washing, or cooking purposes. STEP

(2) There shall be no cross-connection, open or potential, between a system furnishing potable water and a system furnishing nonpotable water. STEP

(c) Toilets at construction jobsites.

(1) Toilets shall be provided for employees according to the following table: STEP

Table D-1

| Number of employees | |
|---------------------|--|
| 20 or less..... | 1 |
| 20 or more..... | 1 toilet seat and 1 urinal per 40 workers. |
| 200 or more..... | 1 toilet seat and 1 urinal per 50 workers. |

(2) Under temporary field conditions, provisions shall be made to assure not less than one toilet facility is available. STEP

(3) Job sites, not provided with a sanitary sewer, shall be provided with one of the

following toilet facilities unless prohibited by local codes: STEP

- (i) Privies (where their use will not contaminate ground or surface water);
- (ii) Chemical toilets;
- (iii) Recirculating toilets;
- (iv) Combustion toilets.

(4) The requirements of this paragraph (c) for sanitation facilities shall not apply to mobile crews having transportation readily available to nearby toilet facilities.

(d) Food handling.

(1) All employees' food service facilities and operations shall meet the applicable laws, ordinances, and regulations of the jurisdictions in which they are located. STEP

(2) All employee food service facilities and operations shall be carried out in accordance with sound hygienic principles. In all places of employment where all or part of the food service is provided, the food dispensed shall be wholesome, free from spoilage, and shall be processed, prepared, handled, and stored in such a manner as to be protected against contamination.

(e) Temporary sleeping quarters. When temporary sleeping quarters are provided, they shall be heated, ventilated, and lighted. STEP

(f) Washing facilities.

(1) The employer shall provide adequate washing facilities for employees engaged in the application of paints, coating, herbicides, or insecticides, or in other operations where contaminants may be harmful to the employees. Such facilities shall be in near proximity to the worksite and shall be so equipped as to enable employees to remove such substances. STEP

(2) General. Washing facilities shall be maintained in a sanitary condition.

(3) Lavatories.

(i) Lavatories shall be made available in all places of employment. The requirements of this subdivision do not apply to mobile crews or to normally unattended work locations if employees working at these locations have transportation readily available to nearby washing facilities which meet the other requirements of this paragraph.

(ii) Each lavatory shall be provided with hot and cold running water, or tepid running water.

(iii) Hand soap or similar cleansing agents shall be provided.

(iv) Individual hand towels or sections thereof, of cloth or paper, air blowers or clean individual sections of continuous cloth toweling, convenient to the lavatories, shall be provided.

(4) Showers.

(i) Whenever showers are required by a particular standard, the showers shall be provided in accordance with paragraphs (f)(4) (ii) through (v) of this section.

(ii) One shower shall be provided for each 10 employees of each sex, or numerical fraction thereof, who are required to shower during the same shift.

(iii) Body soap or other appropriate cleansing agents convenient to the showers shall be provided as specified in paragraph (f)(3)(iii) of this section.

(iv) Showers shall be provided with hot and cold water feeding a common discharge line.

(v) Employees who use showers shall be provided with individual clean towels.

(g) Eating and drinking areas. No employee shall be allowed to consume food or beverages in a toilet room nor in any area exposed to a toxic material.

(h) Vermin control. Every enclosed workplace shall be so constructed, equipped, and maintained, so far as reasonably practicable, as to prevent the entrance or harborage of rodents, insects, and other vermin. A continuing and effective extermination program shall be instituted where their presence is detected.

(i) Change rooms. Whenever employees are required by a particular standard to wear protective clothing because of the possibility of contamination with toxic materials, change rooms equipped with storage facilities for street clothes and separate storage facilities for the protective clothing shall be provided.

1926.52 Occupational noise exposure.

(a) Protection against the effects of noise exposure shall be provided when the sound levels exceed those shown in Table D-2 of this section when measured on the A-scale of a standard sound level meter at slow response. STEP

(b) When employees are subjected to sound levels exceeding those listed in Table D-2 of this section, feasible administrative or engineering controls shall be utilized. If such controls fail to reduce sound levels within the levels of the table, personal protective equipment as required in Subpart E, shall be provided and used to reduce sound levels within the levels of the table. STEP

(c) If the variations in noise level involve maxima at intervals of 1 second or less, it is to be considered continuous.

(d)

(1) In all cases where the sound levels exceed the values shown herein, a continuing, effective hearing conservation program shall be administered. STEP

TABLE D-2 - PERMISSIBLE NOISE EXPOSURES

| Duration per day, hours | Sound level dBA slow response |
|-------------------------|-------------------------------------|
| 8..... | 90 |
| 6..... | 92 |
| 4..... | 95 |
| 3..... | 97 |
| 2..... | 100 |
| 1 1/2..... | 102 |
| 1..... | 105 |
| 1/2..... | 110 |
| 1/4 or less..... | 115 |

(2)

(i) When the daily noise exposure is composed of two or more periods of noise exposure of different levels, their combined effect should be considered, rather than the individual effect of each. Exposure to different levels for various periods of time shall be computed according to the formula set forth in paragraph (d)(2)(ii) of this section.

(ii) $F(e) = \frac{T(1)}{L(1)} + \frac{T(2)}{L(2)} + \dots + \frac{T(n)}{L(n)}$

where:

F(e)=The equivalent noise exposure factor.

T=The period of noise exposure at any essentially constant level.

L=The duration of the permissible noise exposure at the constant level (from Table D-2).

If the value of F(e) exceeds unity (1) the exposure exceeds permissible levels.

(iii) A sample computation showing an application of the formula in paragraph (d)(2)(ii) of this section is as follows. An employee is exposed at these levels for these periods:

110 db A 1/4 hour.

100 db A 1/2 hour.

90 db A 1 1/2 hours.

$$F(e)=(1/4 \text{ divided by } 1/2)+(1/2 \text{ divided by } 2)+(1 \ 1/2 \text{ divided by } 8)$$

$$F(e)=0.500+0.25+0.188$$

$$F(e)=0.938$$

Since the value of F(e) does not exceed unity, the exposure is within permissible limits.

(e) Exposure to impulsive or impact noise should not exceed 140 dB peak sound pressure level.
STEP

1926.53 Ionizing radiation.

(a) In construction and related activities involving the use of sources of ionizing radiation, the pertinent provisions of the Atomic Energy Commission's Standards for Protection Against Radiation (10 CFR Part 20), relating to protection against occupational radiation exposure, shall apply.

(b) Any activity which involves the use of radioactive materials or X-rays, whether or not under license from the Atomic Energy Commission, shall be performed by competent persons specially trained in the proper and safe operation of such equipment. In the case of materials used under Commission license, only persons actually licensed, or competent persons under direction and supervision of the licensee, shall perform such work. STEP

(c) [Reserved]

Note: The requirements applicable to construction work under paragraphs (c) through (r) of this section are identical to those set forth at paragraphs (a) through (p) of [1910.1096](#) of this chapter.

[44 FR 8577, Feb. 9, 1979; 44 FR 20940, Apr. 6, 1979, as amended at 58 FR 35084 & 35310; June 30, 1993; 61 FR 5507, Feb. 13, 1996; 61 FR 31427, June 20, 1996]

1926.54 Nonionizing radiation.

(a) Only qualified and trained employees shall be assigned to install, adjust, and operate laser equipment. STEP

(b) Proof of qualification of the laser equipment operator shall be available and in possession of the operator at all times. STEP

(c) Employees, when working in areas in which a potential exposure to direct or reflected laser light greater than 0.005 watts (5 milliwatts) exists, shall be provided with antilaser eye protection devices as specified in Subpart E of this part. STEP

(d) Areas in which lasers are used shall be posted with standard laser warning placards. STEP

(e) Beam shutters or caps shall be utilized, or the laser turned off, when laser transmission is not actually required. When the laser is left unattended for a substantial period of time, such as during lunch hour, overnight, or at change of shifts, the laser shall be turned off. STEP

(f) Only mechanical or electronic means shall be used as a detector for guiding the internal alignment of the laser. STEP

(g) The laser beam shall not be directed at employees. STEP

(h) When it is raining or snowing, or when there is dust or fog in the air, the operation of laser systems shall be prohibited where practicable; in any event, employees shall be kept out of range of the area of source and target during such weather conditions. STEP

(i) Laser equipment shall bear a label to indicate maximum output. STEP

(j) Employees shall not be exposed to light intensities above:

(1) Direct staring: 1 micro-watt per square centimeter; STEP

(2) Incidental observing: 1 milliwatt per square centimeter; STEP

(3) Diffused reflected light: 2 1/2 watts per square centimeter. STEP

(k) Laser unit in operation should be set up above the heads of the employees, when possible. STEP

(l) Employees shall not be exposed to microwave power densities in excess of 10 milliwatts per square centimeter. STEP

1926.55 Gases, vapors, fumes, dusts, and mists.

(a) Exposure of employees to inhalation, ingestion, skin absorption, or contact with any material or substance at a concentration above those specified in the "Threshold Limit Values of Airborne Contaminants for 1970" of the American Conference of Governmental Industrial Hygienists, shall be avoided. See Appendix A to this section.

STEP

(b) To achieve compliance with paragraph (a) of this section, administrative or engineering controls must first be implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or other protective measures shall be used to keep the exposure of employees to air contaminants within the limits prescribed in this section. Any equipment and technical measures used for this purpose must first be approved for each particular use by a competent industrial hygienist or other technically qualified person. Whenever respirators are used, their use shall comply with 1926.103. STEP

(c) Paragraphs (a) and (b) of this section do not apply to the exposure of employees to airborne asbestos dust. Whenever any employee is exposed to airborne asbestos, tremolite, anthophyllite, or actinolite dust, the requirements of 1910.1101 or 1926.58 of this title shall apply.

(d) Paragraphs (a) and (b) of this section do not apply to the exposure of employees to formaldehyde. Whenever any employee is exposed to formaldehyde, the requirements of 1910.1048 of this title shall apply.

Appendix A to 1926.55 - 1970 American Conference of Governmental Industrial Hygienists' Threshold Limit Values of Airborne Contaminants

Threshold Limit Values of Airborne Contaminants For Construction

| Substance | CAS No. \d\ | ppm \a\ | mg/m ³ \b\ | Skin Designation |
|---|-------------|---------|-----------------------|------------------|
| Abate; see Temephos..... | | | | |
| Acetaldehyde..... | 75-07-0 | 200 | 360 | -- |
| Acetic acid..... | 64-19-7 | 10 | 25 | -- |
| Acetic anhydride..... | 108-24-7 | 5 | 20 | -- |
| Acetone..... | 67-64-1 | 1000 | 2400 | -- |
| Acetonitrile..... | 75-05-8 | 40 | 70 | -- |
| 2-Acetylaminofluorine; see Sec. 1926.1114..... | 53-96-3 | | | |
| Acetylene..... | 74-86-2 | E | | |
| Acetylene dichloride; see 1,2-Dichloroethylene..... | | | | |
| Acetylene tetrabromide..... | 79-27-6 | 1 | 14 | -- |
| Acrolein..... | 107-02-8 | 0.1 | 0.25 | -- |
| Acrylamide..... | 79-06-1 | -- | 0.3 | X |
| Acrylonitrile; see Sec. 1926.1145..... | 107-13-1 | | | |
| Aldrin..... | 309-00-2 | -- | 0.25 | X |
| Allyl alcohol..... | 107-18-6 | 2 | 5 | X |
| Allyl chloride..... | 107-05-1 | 1 | 3 | -- |
| Allyl glycidyl ether (AGE)..... | 106-92-3 | (C)10 | (C)45 | -- |
| Allyl propyl disulfide..... | 2179-59-1 | 2 | 12 | -- |
| alpha-Alumina..... | 1344-28-1 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Alundum; see alpha-Alumina..... | | | | |
| 4-Aminodiphenyl; see Sec. 1926.1111..... | 92-67-1 | | | |
| 2-Aminoethanol; see Ethanolamine..... | | | | |
| 2-Aminopyridine..... | 504-29-0 | 0.5 | 2 | -- |
| Ammonia..... | 7664-41-7 | 50 | 35 | -- |
| Ammonium sulfamate..... | 7773-06-0 | | | |
| Total dust..... | | -- | 15 | -- |
| Respirable fraction..... | | -- | 5 | -- |
| n-Amyl acetate..... | 628-63-7 | 100 | 525 | -- |
| sec-Amyl acetate..... | 626-38-0 | 125 | 650 | -- |
| Aniline and homologs..... | 62-53-3 | 5 | 19 | X |
| Anisidine (o-, p-isomers)..... | 29191-52-4 | -- | 0.5 | X |
| Antimony and compounds (as Sb)..... | 7440-36-0 | -- | 0.5 | -- |
| ANTU (alpha Naphthylthiourea)..... | 86-88-4 | -- | 0.3 | -- |
| Argon..... | 7440-37-1 | E | | |
| Arsenic, inorganic compounds (as As); see Sec. 1926.1118..... | 7440-38-2 | -- | -- | -- |
| Arsenic, organic compounds (as As)..... | 7440-38-2 | -- | 0.5 | -- |
| Arsine..... | 7784-42-1 | 0.05 | 0.2 | -- |

| | | | | |
|---|-------------------------|-------------------------|--------|-------|
| Asbestos; see 1926.58..... | | | | |
| Azinphos-methyl..... | 86-50-0 | -- | 0.2 | X |
| Barium, soluble compounds (as Ba)..... | 7440-39-3 | -- | 0.5 | -- |
| Benzene \g\; see Sec. 1926.1128..... | 71-43-2 | | | |
| Benzidine; see Sec. 1926.1110..... | 92-87-5 | | | |
| p-Benzoquinone; see Quinone..... | | | | |
| Benzo(a)pyrene; see Coal tar pitch volatiles..... | | | | |
| Benzoyl peroxide..... | 94-36-0 | -- | 5 | -- |
| Benzyl chloride..... | 100-44-7 | 1 | 5 | -- |
| Beryllium and beryllium compounds (as Be)..... | 7440-41-7 | -- | 0.002 | -- |
| Biphenyl; see Diphenyl..... | | | | |
| Bisphenol A; see Diglycidyl ether..... | | | | |
| Boron oxide..... | 1303-86-2 | | | |
| Total dust..... | | -- | 15 | -- |
| Boron tribromide..... | 10294-33-4 | 1 | 10 | -- |
| Boron trifluoride..... | 7637-07-2 | (C)1 | (C)3 | -- |
| Bromine..... | 7726-95-6 | 0.1 | 0.7 | -- |
| Bromine pentafluoride..... | 7789-30-2 | 0.1 | 0.7 | -- |
| Bromoform..... | 75-25-2 | 0.5 | 5 | X |
| Butadiene (1,3-Butadiene); see 29 CFR 1910.1051; 29 CFR 1910.19(1)..... | 106-99-0 | 1 ppm/ 5 ppm STEL | | -- |
| Butanethiol; see Butyl mercaptan..... | | | | |
| 2-Butanone (Methyl ethyl ketone)..... | 78-93-3 | 200 | 590 | -- |
| 2-Butoxyethanol..... | 111-76-2 | 50 | 240 | X |
| n-Butyl acetate..... | 123-86-4 | 150 | 710 | -- |
| sec-Butyl acetate..... | 105-46-4 | 200 | 950 | -- |
| tert-Butyl acetate..... | 540-88-5 | 200 | 950 | -- |
| n-Butyl alcohol..... | 71-36-3 | 100 | 300 | -- |
| sec-Butyl alcohol..... | 78-92-2 | 150 | 450 | -- |
| tert-Butyl alcohol..... | 75-65-0 | 100 | 300 | -- |
| Butylamine..... | 109-73-9 | (C)5 | (C)15 | X |
| tert-Butyl chromate (as CrO3) see 1926.1126n..... | 1189-85-1 | | | |
| n-Butyl glycidyl ether (BGE)..... | 2426-08-6 | 50 | 270 | -- |
| Butyl mercaptan..... | 109-79-5 | 0.5 | 1.5 | -- |
| p-tert-Butyltoluene..... | 98-51-1 | 10 | 60 | -- |
| Cadmium (as Cd); see 1926.1127..... | 7440-43-9 | | | |
| Calcium carbonate..... | 1317-65-3 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Calcium oxide..... | 1305-78-8 | -- | 5 | -- |
| Calcium sulfate..... | 7778-18-9 | | | |
| Total dust..... | | -- | 15 | -- |
| Respirable fraction..... | | -- | 5 | -- |
| Camphor, synthetic..... | 76-22-2 | -- | 2 | -- |
| Carbaryl (Sevin)..... | 63-25-2 | -- | 5 | -- |
| Carbon black..... | 1333-86-4 | -- | 3.5 | -- |
| Carbon dioxide..... | 124-38-9 | 5000 | 9000 | -- |
| Carbon disulfide..... | 75-15-0 | 20 | 60 | X |
| Carbon monoxide..... | 630-08-0 | 50 | 55 | -- |
| Carbon tetrachloride..... | 56-23-5 | 10 | 65 | X |
| Cellulose..... | 9004-34-6 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Chlordane..... | 57-74-9 | -- | 0.5 | X |
| Chlorinated camphene..... | 8001-35-2 | -- | 0.5 | X |
| Chlorinated diphenyl oxide..... | 55720-99-5 | -- | 0.5 | -- |
| Chlorine..... | 7782-50-5 | 1 | 3 | -- |
| Chlorine dioxide..... | 10049-04-4 | 0.1 | 0.3 | |
| Chlorine trifluoride..... | 7790-91-2 | (C)0.1 | (C)0.4 | -- |
| Chloroacetaldehyde..... | 107-20-0 | (C)1 | (C)3 | -- |
| a-Chloroacetophenone (Phenacyl chloride)..... | 532-27-4 | 0.05 | 0.3 | -- |
| Chlorobenzene..... | 108-90-7 | 75 | 350 | -- |
| o-Chlorobenzylidene malononitrile..... | 2698-41-1 | 0.05 | 0.4 | -- |
| Chlorobromomethane..... | 74-97-5 | 200 | 1050 | -- |
| 2-Chloro-1,3-butadiene; see beta-Chloroprene..... | | | | |
| Chlorodiphenyl (42% Chlorine) (PCB)..... | 53469-21-9 | -- | 1 | X |
| Chlorodiphenyl (54% Chlorine) (PCB)..... | 11097-69-1 | -- | 0.5 | X |
| 1-Chloro,2,3-epoxypropane; see Epichlorohydrin..... | | | | |
| 2-Chloroethanol; see Ethylene chlorohydrin..... | | | | |
| Chloroethylene; see Vinyl chloride..... | | | | |
| Chloroform (Trichloromethane)..... | 67-66-3 | (C)50 | (C)240 | -- |
| bis(Chloromethyl) ether; see Sec. 1926.1108..... | 542-88-1 | | | |
| Chloromethyl methyl ether; see Sec. 1926.1106..... | 107-30-2 | | | |
| 1-Chloro-1-nitropropane..... | 600-25-9 | 20 | 100 | -- |
| Chloropicrin..... | 76-06-2 | 0.1 | 0.7 | -- |
| beta-Chloroprene..... | 126-99-8 | 25 | 90 | X |
| Chromic acid and chromates..... | | | | |
| (as CrO3)..... | Varies with compound | -- | 0.1 | -- |
| Chromium (II) compounds..... | | | | |
| (as Cr)..... | 7440-47-3 | -- | 0.5 | -- |
| Chromium (III) compounds..... | | | | |
| (as Cr)..... | 7440-47-3 | -- | 0.5 | -- |
| Chromium (VI) compounds see 1926.1126(o)..... | | | | |
| Chromium metal and insol. salts (as Cr)..... | 7440-47-3 | -- | 1 | -- |
| Chrysene; see Coal tar pitch volatiles..... | | | | |
| Coal tar pitch volatiles (benzene soluble fraction), | 65996-93-2 | -- | 0.2 | -- |

| | | | | | |
|---|-------------|--------|--------|----|----|
| anthracene, BaP, phenanthrene, acridine, chrysene, pyrene. | | | | | |
| Cobalt metal, dust, and fume (as Co)..... | 7440-48-4 | -- | 0.1 | -- | |
| Coke oven emissions; see Sec. 1926.1129..... | | | | | |
| Copper..... | 7440-50-8 | | | | |
| Fume (as Cu)..... | | -- | 0.1 | -- | |
| Dusts and mists (as Cu)..... | | -- | 1 | -- | |
| Corundum; see Emery..... | | | | | |
| Cotton dust (raw)..... | | -- | 1 | | |
| Crag herbicide (Sesone)..... | 136-78-7 | | | | |
| Total dust..... | | -- | | -- | |
| Respirable fraction..... | | -- | | -- | |
| Cresol, all isomers..... | 1319-77-3 | 5 | 22 | | X |
| Crotonaldehyde..... | 123-73-9; | 2 | 6 | | |
| | 4170-30-3 | | | | |
| Cumene..... | 98-82-8 | 50 | 245 | | X |
| Cyanides (as CN)..... | Varies with | -- | 5 | | X |
| | Compound | | | | |
| Cyanogen..... | 460-19-5 | 10 | -- | | -- |
| Cyclohexane..... | 110-82-7 | 300 | 1050 | | -- |
| Cyclohexanol..... | 108-93-0 | 50 | 200 | | -- |
| Cyclohexanone..... | 108-94-1 | 50 | 200 | | -- |
| Cyclohexene..... | 110-83-8 | 300 | 1015 | | -- |
| Cyclonite..... | 121-82-4 | -- | 1.5 | | X |
| Cyclopentadiene..... | 542-92-7 | 75 | 200 | | -- |
| DDT, see Dichlorodiphenyltrichloroethane..... | | | | | |
| DDVP, see Dichlorvos..... | | | | | |
| 2,4-D (Dichlorophenoxyacetic acid)..... | 94-75-7 | -- | 10 | | -- |
| Decaborane..... | 17702-41-9 | 0.05 | 0.3 | | X |
| Demeton (Systox)..... | 8065-48-3 | -- | 0.1 | | X |
| Diacetone alcohol (4-Hydroxy-4-methyl-2-pentanone)..... | 123-42-2 | 50 | 240 | | -- |
| 1,2-Diaminoethane; see Ethylenediamine..... | | | | | |
| Diazomethane..... | 334-88-3 | 0.2 | 0.4 | | -- |
| Diborane..... | 19287-45-7 | 0.1 | 0.1 | | -- |
| 1,2-Dibromo-3-chloropropane (DBCP); see Sec. 1926.1144.... | 96-12-8 | | | | -- |
| 1,2-Dibromoethane; see Ethylene dibromide..... | | | | | |
| Dibutyl phosphate..... | 107-66-4 | 1 | 5 | | -- |
| Dibutyl phthalate..... | 84-74-2 | -- | 5 | | -- |
| Dichloroacetylene..... | 7572-29-4 | (C)0.1 | (C)0.4 | | -- |
| o-Dichlorobenzene..... | 95-50-1 | (C)50 | (C)300 | | -- |
| p-Dichlorobenzene..... | 106-46-7 | 75 | 450 | | -- |
| 3,3'-Dichlorobenzidine; see Sec. 1926.1107..... | 91-94-1 | | | | |
| Dichlorodifluoromethane..... | 75-71-8 | 1000 | 4950 | | -- |
| 1,3-Dichloro-5,5-dimethyl hydantoin..... | 118-52-5 | -- | 0.2 | | -- |
| Dichlorodiphenyltrichloroethane (DDT)..... | 50-29-3 | -- | 1 | | X |
| 1,1-Dichloroethane..... | 75-34-3 | 100 | 400 | | -- |
| 1,2-Dichloroethane; see Ethylene dichloride..... | | | | | |
| 1,2-Dichloroethylene..... | 540-59-0 | 200 | 790 | | -- |
| Dichloroethyl ether..... | 111-44-4 | (C)15 | (C)90 | | X |
| Dichloromethane; see Methylene chloride..... | | | | | |
| Dichloromonofluoromethane..... | 75-43-4 | 1000 | 4200 | | -- |
| 1,1-Dichloro-1-nitroethane..... | 594-72-9 | (C)10 | (C)60 | | -- |
| 1,2-Dichloropropane; see Propylene dichloride..... | | | | | |
| Dichlorotetrafluoroethane..... | 76-14-2 | 1000 | 7000 | | -- |
| Dichlorvos (DDVP)..... | 62-73-7 | -- | 1 | | X |
| Dieldrin..... | 60-57-1 | -- | 0.25 | | X |
| Diethylamine..... | 109-89-7 | 25 | 75 | | -- |
| 2-Diethylaminoethanol..... | 100-37-8 | 10 | 50 | | X |
| Diethylene triamine..... | 111-40-0 | (C)10 | (C)42 | | X |
| Diethyl ether; see Ethyl ether..... | | | | | |
| Difluorodibromomethane..... | 75-61-6 | 100 | 860 | | -- |
| Diglycidyl ether (DGE)..... | 2238-07-5 | (C)0.5 | (C)2.8 | | -- |
| Dihydroxybenzene; see Hydroquinone..... | | | | | |
| Diisobutyl ketone..... | 108-83-8 | 50 | 290 | | -- |
| Diisopropylamine..... | 108-18-9 | 5 | 20 | | X |
| 4-Dimethylaminoazobenzene; see Sec. 1926.1115..... | 60-11-7 | | | | |
| Dimethoxymethane; see Methylal..... | | | | | |
| Dimethyl acetamide..... | 127-19-5 | 10 | 35 | | X |
| Dimethylamine..... | 124-40-3 | 10 | 18 | | -- |
| Dimethylaminobenzene; see Xylidine..... | | | | | |
| Dimethylaniline (N,N-Dimethylaniline)..... | 121-69-7 | 5 | 25 | | X |
| Dimethylbenzene; see Xylene..... | | | | | |
| Dimethyl-1,2-dibromo- 2,2-dichloroethyl phosphate..... | 300-76-5 | -- | 3 | | -- |
| Dimethylformamide..... | 68-12-2 | 10 | 30 | | X |
| 2,6-Dimethyl-4-heptanone; see Diisobutyl ketone..... | | | | | |
| 1,1-Dimethylhydrazine..... | 57-14-7 | 0.5 | 1 | | X |
| Dimethylphthalate..... | 131-11-3 | -- | 5 | | -- |
| Dimethyl sulfate..... | 77-78-3 | 1 | 5 | | X |
| Dinitrobenzene (all isomers)..... | | | 1 | | X |
| (ortho)..... | 528-29-0 | | | | |
| (meta)..... | 99-65-0 | | | | |
| (para)..... | 100-25-4 | | | | |
| Dinitro-o-cresol..... | 534-52-1 | -- | 0.2 | | X |
| Dinitrotoluene..... | 25321-14-6 | -- | 1.5 | | X |
| Dioxane (Diethylene dioxide)..... | 123-91-1 | 100 | 360 | | X |
| Diphenyl (Biphenyl)..... | 92-52-4 | 0.2 | 1 | | -- |
| Diphenylamine..... | 122-39-4 | -- | 10 | | -- |
| Diphenylmethane diisocyanate; see Methylene bisphenyl isocyanate..... | | | | | |

| | | | | |
|--|----------------------|--------|--------|-------|
| Dipropylene glycol methyl ether..... | 34590-94-8 | 100 | 600 | X |
| Di-sec octyl phthalate (Di-(2-ethylhexyl) phthalate)..... | 117-81-7 | -- | 5 | -- |
| Emery..... | 12415-34-8 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Endosulfan..... | 115-29-7 | -- | 0.1 | X |
| Endrin..... | 72-20-8 | -- | 0.1 | X |
| Epichlorohydrin..... | 106-89-8 | 5 | 19 | X |
| EPN..... | 2104-64-5 | -- | 0.5 | X |
| 1,2-Epoxypropane; see Propylene oxide..... | | | | |
| 2,3-Epoxy-1-propanol; see Glycidol..... | | | | |
| Ethane..... | 74-84-0 | E | | |
| Ethanethiol; see Ethyl mercaptan..... | | | | |
| Ethanolamine..... | 141-43-5 | 3 | 6 | -- |
| 2-Ethoxyethanol (Cellosolve)..... | 110-80-5 | 200 | 740 | X |
| 2-Ethoxyethyl acetate (Cellosolve acetate)..... | 111-15-9 | 100 | 540 | X |
| Ethyl acetate..... | 141-78-6 | 400 | 1400 | -- |
| Ethyl acrylate..... | 140-88-5 | 25 | 100 | X |
| Ethyl alcohol (Ethanol)..... | 64-17-5 | 1000 | 1900 | -- |
| Ethylamine..... | 75-04-7 | 10 | 18 | -- |
| Ethyl amyl ketone (5-Methyl-3-heptanone)..... | 541-85-5 | 25 | 130 | -- |
| Ethyl benzene..... | 100-41-4 | 100 | 435 | -- |
| Ethyl bromide..... | 74-96-4 | 200 | 890 | -- |
| Ethyl butyl ketone (3-Heptanone)..... | 106-35-4 | 50 | 230 | -- |
| Ethyl chloride..... | 75-00-3 | 1000 | 2600 | -- |
| Ethyl ether..... | 60-29-7 | 400 | 1200 | -- |
| Ethyl formate..... | 109-94-4 | 100 | 300 | -- |
| Ethyl mercaptan..... | 75-08-1 | 0.5 | 1 | -- |
| Ethyl silicate..... | 78-10-4 | 100 | 850 | -- |
| Ethylene..... | 74-85-1 | E | | |
| Ethylene chlorohydrin..... | 107-07-3 | 5 | 16 | X |
| Ethylenediamine..... | 107-15-3 | 10 | 25 | -- |
| Ethylene dibromide..... | 106-93-4 | (C)25 | (C)190 | X |
| Ethylene dichloride (1,2-Dichloroethane)..... | 107-06-2 | 50 | 200 | -- |
| Ethylene glycol dinitrate..... | 628-96-6 | (C)0.2 | (C)1 | X |
| Ethylene glycol methyl acetate; see Methyl cellosolve acetate..... | | | | |
| Ethyleneimine; see Sec. 1926.1112..... | 151-56-4 | | | |
| Ethylene oxide; see Sec. 1926.1147..... | 75-21-8 | | | |
| Ethylidene chloride; see 1,1-Dichloroethane..... | | | | |
| N-Ethylmorpholine..... | 100-74-3 | 20 | 94 | X |
| Ferbam..... | 14484-64-1 | | | |
| Total dust..... | | -- | 15 | -- |
| Ferrovandium dust..... | 12604-58-9 | -- | 1 | -- |
| Fibrous Glass..... | | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Fluorides (as F)..... | Varies with compound | -- | 2.5 | -- |
| Fluorine..... | 7782-41-4 | 0.1 | 0.2 | -- |
| Fluorotrichloromethane (Trichlorofluoromethane)..... | 75-69-4 | 1000 | 5600 | -- |
| Formaldehyde; see Sec. 1926.1148..... | 50-00-0 | | | |
| Formic acid..... | 64-18-6 | 5 | 9 | -- |
| Furfural..... | 98-01-1 | 5 | 20 | X |
| Furfuryl alcohol..... | 98-00-0 | 50 | 200 | -- |
| Gasoline..... | 8006-61-9 | | A \3\ | -- |
| Glycerin (mist)..... | 56-81-5 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Glycidol..... | 556-52-5 | 50 | 150 | -- |
| Glycol monoethyl ether; see 2-Ethoxyethanol..... | | | | |
| Graphite, natural, respirable dust..... | 7782-42-5 | (\2\) | (\2\) | (\2\) |
| Graphite, synthetic..... | | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Guthion; see Azinphos methyl..... | | | | |
| Gypsum..... | 13397-24-5 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Hafnium..... | 7440-58-6 | -- | 0.5 | -- |
| Helium..... | 7440-59-7 | E | | |
| Heptachlor..... | 76-44-8 | -- | 0.5 | X |
| Heptane (n-Heptane)..... | 142-82-5 | 500 | 2000 | -- |
| Hexachloroethane..... | 67-72-1 | 1 | 10 | X |
| Hexachloronaphthalene..... | 1335-87-1 | -- | 0.2 | X |
| n-Hexane..... | 110-54-3 | 500 | 1800 | -- |
| 2-Hexanone (Methyl n-butyl ketone)..... | 591-78-6 | 100 | 410 | -- |
| Hexone (Methyl isobutyl ketone)..... | 108-10-1 | 100 | 410 | -- |
| sec-Hexyl acetate..... | 108-84-9 | 50 | 300 | -- |
| Hydrazine..... | 302-01-2 | 1 | 1.3 | X |
| Hydrogen..... | 1333-74-0 | E | | |
| Hydrogen bromide..... | 10035-10-6 | 3 | 10 | -- |
| Hydrogen chloride..... | 7647-01-0 | (C)5 | (C)7 | -- |
| Hydrogen cyanide..... | 74-90-8 | 10 | 11 | X |
| Hydrogen fluoride (as F)..... | 7664-39-3 | 3 | 2 | -- |
| Hydrogen peroxide..... | 7722-84-1 | 1 | 1.4 | -- |
| Hydrogen selenide (as Se)..... | 7783-07-5 | 0.05 | .02 | -- |
| Hydrogen sulfide..... | 7783-06-4 | 10 | 15 | -- |

| | | | | |
|--|----------------------|---------|--------|----|
| Hydroquinone..... | 123-31-9 | -- | 2 | -- |
| Indene..... | 95-13-6 | 10 | 45 | -- |
| Indium and compounds (as In)..... | 7440-74-6 | -- | 0.1 | -- |
| Iodine..... | 7553-56-2 | (C)0.1 | (C)1 | -- |
| Iron oxide fume..... | 1309-37-1 | -- | 10 | -- |
| Iron salts (soluble) (as Fe)..... | Varies with compound | -- | 1 | -- |
| Isoamyl acetate..... | 123-92-2 | 100 | 525 | -- |
| Isoamyl alcohol (primary and secondary)..... | 123-51-3 | 100 | 360 | -- |
| Isobutyl acetate..... | 110-19-0 | 150 | 700 | -- |
| Isobutyl alcohol..... | 78-83-1 | 100 | 300 | -- |
| Isophorone..... | 78-59-1 | 25 | 140 | -- |
| Isopropyl acetate..... | 108-21-4 | 250 | 950 | -- |
| Isopropyl alcohol..... | 67-63-0 | 400 | 980 | -- |
| Isopropylamine..... | 75-31-0 | 5 | 12 | -- |
| Isopropyl ether..... | 108-20-3 | 500 | 2100 | -- |
| Isopropyl glycidyl ether (IGE)..... | 4016-14-2 | 50 | 240 | -- |
| Kaolin..... | 1332-58-7 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Ketene..... | 463-51-4 | 0.5 | 0.9 | -- |
| Lead, inorganic (as Pb); see 1926.62..... | 7439-92-1 | | | |
| Limestone..... | 1317-65-3 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Lindane..... | 58-89-9 | -- | 0.5 | X |
| Lithium hydride..... | 7580-67-8 | -- | 0.025 | -- |
| L.P.G. (Liquefied petroleum gas)..... | 68476-85-7 | 1000 | 1800 | |
| Magnesite..... | 546-93-0 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Magnesium oxide fume..... | 1309-48-4 | | | |
| Total particulate..... | | 15 | -- | -- |
| Malathion..... | 121-75-5 | | | |
| Total dust..... | | -- | 15 | X |
| Maleic anhydride..... | 108-31-6 | 0.25 | | |
| Manganese compounds (as Mn)..... | 7439-96-5 | -- | (C)5 | -- |
| Manganese fume (as Mn)..... | 7439-96-5 | -- | (C)5 | -- |
| Marble..... | 1317-65-3 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Mercury (aryl and inorganic)(as Hg)..... | 7439-97-6 | | 0.1 | X |
| Mercury (organo) alkyl compounds (as Hg)..... | 7439-97-6 | -- | 0.01 | X |
| Mercury (vapor) (as Hg)..... | 7439-97-6 | -- | 0.1 | X |
| Mesityl oxide..... | 141-79-7 | 25 | 100 | -- |
| Methane..... | 74-82-8 | E | | |
| Methanethiol; see Methyl mercaptan..... | | | | |
| Methoxychlor..... | 72-43-5 | | | |
| Total dust..... | | -- | 15 | -- |
| 2-Methoxyethanol (Methyl cellosolve)..... | 109-86-4 | 25 | 80 | X |
| 2-Methoxyethyl acetate (Methyl cellosolve acetate)..... | 110-49-6 | 25 | 120 | X |
| Methyl acetate..... | 79-20-9 | 200 | 610 | -- |
| Methyl acetylene (Propyne)..... | 74-99-7 | 1000 | 1650 | -- |
| Methyl acetylene-propadiene mixture (MAPP)..... | | 1000 | 1800 | -- |
| Methyl acrylate..... | 96-33-3 | 10 | 35 | X |
| Methylal (Dimethoxy-methane)..... | 109-87-5 | 1000 | 3100 | -- |
| Methyl alcohol..... | 67-56-1 | 200 | 260 | -- |
| Methylamine..... | 74-89-5 | 10 | 12 | -- |
| Methyl amyl alcohol; see Methyl isobutyl carbinol..... | | | | |
| Methyl n-amyl ketone..... | 110-43-0 | 100 | 465 | -- |
| Methyl bromide..... | 74-83-9 | (C)20 | (C)80 | X |
| Methyl butyl ketone; see 2-Hexanone..... | | | | |
| Methyl cellosolve; see 2-Methoxyethanol..... | | | | |
| Methyl cellosolve acetate; see 2-Methoxyethyl acetate..... | | | | |
| Methylene chloride; see Sec. 1910.1052..... | | | | |
| Methyl chloroform (1,1,1-Trichloroethane)..... | 71-55-6 | 350 | 1900 | -- |
| Methylcyclohexane..... | 108-87-2 | 500 | 2000 | -- |
| Methylcyclohexanol..... | 25639-42-3 | 100 | 470 | -- |
| o-Methylcyclohexanone..... | 583-60-8 | 100 | 460 | X |
| Methylene chloride..... | 75-09-2 | 500 | 1740 | -- |
| Methylenedianiline (MDA)..... | 101-77-9 | | | |
| Methyl ethyl ketone (MEK); see 2-Butanone..... | | | | |
| Methyl formate..... | 107-31-3 | 100 | 250 | -- |
| Methyl hydrazine (Monomethyl hydrazine)..... | 60-34-4 | (C)0 | (C)0.3 | X |
| | | | 5 | |
| Methyl iodide..... | 74-88-4 | 5 | 28 | X |
| Methyl isoamyl ketone..... | 110-12-3 | 100 | 475 | -- |
| Methyl isobutyl carbinol..... | 108-11-2 | 25 | 100 | X |
| Methyl isobutyl ketone; see Hexone..... | | | | |
| Methyl isocyanate..... | 624-83-9 | 0.02 | 0.05 | X |
| Methyl mercaptan..... | 74-93-1 | 0.5 | 1 | -- |
| Methyl methacrylate..... | 80-62-6 | 100 | 410 | -- |
| Methyl propyl ketone; see 2-Pentanone..... | | | | |
| Methyl silicate..... | 681-84-5 | (C)5 | (C)30 | -- |
| alpha-Methyl styrene..... | 98-83-9 | (C)100 | (C)480 | -- |
| Methylene bisphenyl isocyanate (MDI)..... | 101-68-8 | (C)0.02 | (C)0.2 | -- |
| Mica; see Silicates..... | | | | |
| Molybdenum (as Mo)..... | 7439-98-7 | | | |

| | | | | |
|--|------------|--------|-------|----|
| Soluble compounds..... | | -- | 5 | -- |
| Insoluble compounds..... | | | | |
| Total dust..... | | -- | 15 | -- |
| Monomethyl aniline..... | 100-61-8 | 2 | 9 | X |
| Monomethyl hydrazine; see Methyl hydrazine..... | | | | |
| Morpholine..... | 110-91-8 | 20 | 70 | X |
| Naphtha (Coal tar)..... | 8030-30-6 | 100 | 400 | -- |
| Naphthalene..... | 91-20-3 | 10 | 50 | -- |
| alpha-Naphthylamine; see Sec. 1926.1104..... | 134-32-7 | | | |
| beta-Naphthylamine; see Sec. 1926.1109..... | 91-59-8 | | | -- |
| Neon..... | 7440-01-9 | E | | |
| Nickel carbonyl (as Ni)..... | 13463-39-3 | 0.001 | 0.007 | -- |
| Nickel, metal and insoluble compounds (as Ni)..... | 7440-02-0 | -- | 1 | -- |
| Nickel, soluble compounds (as Ni)..... | 7440-02-0 | -- | 1 | -- |
| Nicotine..... | 54-11-5 | -- | 0.5 | X |
| Nitric acid..... | 7697-37-2 | 2 | 5 | -- |
| Nitric oxide..... | 10102-43-9 | 25 | 30 | -- |
| p-Nitroaniline..... | 100-01-6 | 1 | 6 | X |
| Nitrobenzene..... | 98-95-3 | 1 | 5 | X |
| p-Nitrochlorobenzene..... | 100-00-5 | -- | 1 | X |
| 4-Nitrodiphenyl; see Sec. 1926.1103..... | 92-93-3 | | | |
| Nitroethane..... | 79-24-3 | 100 | 310 | -- |
| Nitrogen..... | 7727-37-9 | E | | |
| Nitrogen dioxide..... | 10102-44-0 | (C)5 | (C)9 | -- |
| Nitrogen trifluoride..... | 7783-54-2 | 10 | 29 | -- |
| Nitroglycerin..... | 55-63-0 | (C)0.2 | (C)2 | X |
| Nitromethane..... | 75-52-5 | 100 | 250 | -- |
| 1-Nitropropane..... | 108-03-2 | 25 | 90 | -- |
| 2-Nitropropane..... | 79-46-9 | 25 | 90 | -- |
| N-Nitrosodimethylamine; see Sec. 1926.1116..... | 62-79-9 | | | -- |
| Nitrotoluene (all isomers)..... | | 5 | 30 | X |
| o-isomer..... | 88-72-2; | | | |
| m-isomer..... | 99-08-1; | | | |
| p-isomer..... | 99-99-0 | | | |
| Nitrotrichloromethane; see Chloropicrin..... | | | | |
| Nitrous oxide..... | 10024-97-2 | E | | |
| Octachloronaphthalene..... | 2234-13-1 | -- | 0.1 | X |
| Octane..... | 111-65-9 | 400 | 1900 | -- |
| Oil mist, mineral..... | 8012-95-1 | -- | 5 | -- |
| Osmium tetroxide (as Os)..... | 20816-12-0 | -- | 0.002 | -- |
| Oxalic acid..... | 144-62-7 | -- | 1 | -- |
| Oxygen difluoride..... | 7783-41-7 | 0.05 | 0.1 | -- |
| Ozone..... | 10028-15-6 | 0.1 | 0.2 | -- |
| Paraquat, respirable dust..... | 4685-14-7; | -- | 0.5 | X |
| | 1910-42-5; | | | |
| | 2074-50-2 | | | |
| Parathion..... | 56-38-2 | -- | 0.1 | X |
| Particulates not otherwise regulated..... | | | | |
| Total dust organic and inorganic..... | | -- | 15 | -- |
| PCB; see Chlorodiphenyl (42% and 54% chlorine)..... | | | | |
| Pentaborane..... | 19624-22-7 | 0.005 | 0.01 | -- |
| Pentachloronaphthalene..... | 1321-64-8 | -- | 0.5 | X |
| Pentachlorophenol..... | 87-86-5 | -- | 0.5 | X |
| Pentaerythritol..... | 115-77-5 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Pentane..... | 109-66-0 | 500 | 1500 | -- |
| 2-Pentanone (Methyl propyl ketone)..... | 107-87-9 | 200 | 700 | -- |
| Perchloroethylene (Tetrachloroethylene)..... | 127-18-4 | 100 | 670 | -- |
| Perchloromethyl mercaptan..... | 594-42-3 | 0.1 | 0.8 | -- |
| Perchloryl fluoride..... | 7616-94-6 | 3 | 13.5 | -- |
| Petroleum distillates (Naphtha)(Rubber Solvent)..... | | | A \3\ | -- |
| Phenol..... | 108-95-2 | 5 | 19 | X |
| p-Phenylene diamine..... | 106-50-3 | -- | 0.1 | X |
| Phenyl ether, vapor..... | 101-84-8 | 1 | 7 | -- |
| Phenyl ether-biphenyl mixture, vapor..... | | 1 | 7 | -- |
| Phenylethylene; see Styrene..... | | | | |
| Phenyl glycidyl ether (PGE)..... | 122-60-1 | 10 | 60 | -- |
| Phenylhydrazine..... | 100-63-0 | 5 | 22 | X |
| Phosdrin (Mevinphos)..... | 7786-34-7 | -- | 0.1 | X |
| Phosgene (Carbonyl chloride)..... | 75-44-5 | 0.1 | 0.4 | -- |
| Phosphine..... | 7803-51-2 | 0.3 | 0.4 | -- |
| Phosphoric acid..... | 7664-38-2 | -- | 1 | -- |
| Phosphorus (yellow)..... | 7723-14-0 | -- | 0.1 | -- |
| Phosphorus pentachloride..... | 10026-13-8 | -- | 1 | -- |
| Phosphorus pentasulfide..... | 1314-80-3 | -- | 1 | -- |
| Phosphorus trichloride..... | 7719-12-2 | 0.5 | 3 | -- |
| Phthalic anhydride..... | 85-44-9 | 2 | 12 | -- |
| Picric acid..... | 88-89-1 | -- | 0.1 | X |
| Pindone (2-Pivalyl-1,3-indandione)..... | 83-26-1 | -- | 0.1 | -- |
| Plaster of Paris..... | 26499-65-0 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Platinum (as Pt)..... | 7440-06-4 | | | |
| Metal..... | | -- | -- | -- |
| Soluble salts..... | | -- | 0.002 | -- |
| Polytetrafluoroethylene decomposition products..... | | | A 2 | |
| Portland cement..... | 65997-15-1 | | | |

| | | | | |
|--|-------------|--------|----------------|-------|
| Total dust..... | | -- | 15 | -- |
| Respirable fraction..... | | 5 | | -- |
| Propane..... | 74-98-6 | E | | |
| Propargyl alcohol..... | 107-19-7 | 1 | -- | X |
| beta-Propiolactone; see Sec. 1926.1113..... | 57-57-8 | | | |
| n-Propyl acetate..... | 109-60-4 | 200 | 840 | -- |
| n-Propyl alcohol..... | 71-23-8 | 200 | 500 | -- |
| n-Propyl nitrate..... | 627-13-4 | 25 | 110 | -- |
| Propylene dichloride..... | 78-87-5 | 75 | 350 | -- |
| Propylene imine..... | 75-55-8 | 2 | 5 | X |
| Propylene oxide..... | 75-56-9 | 100 | 240 | -- |
| Propyne; see Methyl acetylene..... | | | | |
| Pyrethrum..... | 8003-34-7 | -- | 5 | -- |
| Pyridine..... | 110-86-1 | 5 | 15 | -- |
| Quinone..... | 106-51-4 | 0.1 | 0.4 | -- |
| RDX; see Cyclonite..... | | | | |
| Rhodium (as Rh), metal fume and insoluble compounds..... | 7440-16-6 | -- | 0.1 | -- |
| Rhodium (as Rh), soluble compounds..... | 7440-16-6 | -- | 0.001 | -- |
| Ronnel..... | 299-84-3 | -- | 10 | -- |
| Rotenone..... | 83-79-4 | -- | 5 | -- |
| Rouge..... | | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Selenium compounds (as Se)..... | 7782-49-2 | -- | 0.2 | -- |
| Selenium hexafluoride (as Se)..... | 7783-79-1 | 0.05 | 0.4 | -- |
| Silica, amorphous, precipitated and gel..... | 112926-00-8 | (\2\) | (\2\) | (\2\) |
| Silica, amorphous, diatomaceous earth, containing less than 1% crystalline silica..... | 61790-53-2 | (\2\) | (\2\) | (\2\) |
| Silica, crystalline cristobalite, respirable dust..... | 14464-46-1 | (\2\) | (\2\) | (\2\) |
| Silica, crystalline quartz, respirable dust..... | 14808-60-7 | (\2\) | (\2\) | (\2\) |
| Silica, crystalline tripoli (as quartz), respirable dust..... | 1317-95-9 | (\2\) | (\2\) | (\2\) |
| Silica, crystalline tridymite, respirable dust..... | 15468-32-3 | (\2\) | (\2\) | (\2\) |
| Silica, fused, respirable dust..... | 60676-86-0 | (\2\) | (\2\) | (\2\) |
| Silicates (less than 1% crystalline silica)..... | | | | |
| Mica (respirable dust)..... | 12001-26-2 | (\2\) | (\2\) | (\2\) |
| Soapstone, total dust..... | | (\2\) | (\2\) | (\2\) |
| Soapstone, respirable dust..... | | (\2\) | (\2\) | (\2\) |
| Talc (containing asbestos); use asbestos limit; see 1926.58..... | | | | |
| Talc (containing no asbestos), respirable dust..... | 14807-96-6 | (\2\) | (\2\) | (\2\) |
| Tremolite, asbestiform; see 1926.58..... | | | | |
| Silicon carbide..... | 409-21-2 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Silver, metal and soluble compounds (as Ag)..... | 7440-22-4 | -- | 0.01 | -- |
| Soapstone; see Silicates..... | | | | |
| Sodium fluoroacetate..... | 62-74-8 | -- | 0.05 | X |
| Sodium hydroxide..... | 1310-73-2 | -- | 2 | -- |
| Starch..... | 9005-25-8 | | | |
| Total dust..... | | -- | 15 | -- |
| Respirable fraction..... | | -- | 5 | -- |
| Stibine..... | 7803-52-3 | 0.1 | 0.5 | -- |
| Stoddard solvent..... | 8052-41-3 | 200 | 1150 | -- |
| Strychnine..... | 57-24-9 | -- | 0.15 | -- |
| Styrene..... | 100-42-5 | (C)100 | (C)420 | -- |
| Sucrose..... | 57-50-1 | | | |
| Total dust..... | | -- | 15 | -- |
| Respirable fraction..... | | -- | 5 | -- |
| Sulfur dioxide..... | 7446-09-5 | 5 | 13 | -- |
| Sulfur hexafluoride..... | 2551-62-4 | 1000 | 6000 | -- |
| Sulfuric acid..... | 7664-93-9 | -- | 1 | -- |
| Sulfur monochloride..... | 10025-67-9 | 1 | 6 | -- |
| Sulfur pentafluoride..... | 5714-22-7 | 0.025 | 0.25 | -- |
| Sulfuryl fluoride..... | 2699-79-8 | 5 | 20 | -- |
| Systox, see Demeton..... | | | | |
| 2,4,5-T (2,4,5-trichlorophenoxyacetic acid)..... | 93-76-5 | -- | 10 | -- |
| Talc; see Silicates..... | | | | |
| Tantalum, metal and oxide dust..... | 7440-25-7 | -- | 5 | -- |
| TEDP (Sulfotep)..... | 3689-24-5 | -- | 0.2 | X |
| Teflon decomposition products..... | | | A ² | |
| Tellurium and compounds (as Te)..... | 13494-80-9 | -- | 0.1 | -- |
| Tellurium hexafluoride (as Te)..... | 7783-80-4 | 0.02 | 0.2 | -- |
| Temphos..... | 3383-96-8 | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| TEPP (Tetraethyl pyrophosphate)..... | 107-49-3 | -- | 0.05 | X |
| Terphenyls..... | 26140-60-3 | (C)1 | (C)9 | -- |
| 1,1,1,2-Tetrachloro-2,2-difluoroethane..... | 76-11-9 | 500 | 4170 | -- |
| 1,1,2,2-Tetrachloro-1,2-difluoroethane..... | 76-12-0 | 500 | 4170 | -- |
| 1,1,2,2-Tetrachloroethane..... | 79-34-5 | 5 | 35 | X |
| Tetrachloroethylene; see Perchloroethylene..... | | | | |
| Tetrachloromethane; see Carbon tetrachloride..... | | | | |
| Tetrachloronaphthalene..... | 1335-88-2 | -- | 2 | X |
| Tetraethyl lead (as Pb)..... | 78-00-2 | -- | 0.1 | X |
| Tetrahydrofuran..... | 109-99-9 | 200 | 590 | -- |
| Tetramethyl lead, (as Pb)..... | 75-74-1 | -- | 0.15 | X |
| Tetramethyl succinonitrile..... | 3333-52-6 | 0.5 | 3 | X |
| Tetranitromethane..... | 509-14-8 | 1 | 8 | -- |

| | | | | |
|---|------------|---------|---------|----|
| Tetryl (2,4,6-Trinitrophenylmethylnitramine)..... | 479-45-8 | -- | 1.5 | X |
| Thallium, soluble compounds (as Tl)..... | 7440-28-0 | -- | 0.1 | X |
| Thiram..... | 137-26-8 | -- | 5 | -- |
| Tin, inorganic compounds (except oxides) (as Sn)..... | 7440-31-5 | -- | 2 | -- |
| Tin, organic compounds (as Sn)..... | 7440-31-5 | -- | 0.1 | -- |
| Tin oxide (as Sn)..... | 21651-19-4 | -- | -- | -- |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Titanium dioxide..... | 13463-67-7 | -- | | -- |
| Total dust..... | | -- | | -- |
| Toluene..... | 108-88-3 | 200 | 750 | -- |
| Toluene-2,4-diisocyanate (TDI)..... | 584-84-9 | (C)0.02 | (C)0.14 | -- |
| o-Toluidine..... | 95-53-4 | 5 | 22 | X |
| Toxaphene; see Chlorinated camphene..... | | | | |
| Tremolite; see Silicates..... | | | | |
| Tributyl phosphate..... | 126-73-8 | -- | 5 | -- |
| 1,1,1-Trichloroethane; see Methyl chloroform..... | | | | |
| 1,1,2-Trichloroethane..... | 79-00-5 | 10 | 45 | X |
| Trichloroethylene..... | 79-01-6 | 100 | 535 | -- |
| Trichloromethane; see Chloroform..... | | | | |
| Trichloronaphthalene..... | 1321-65-9 | -- | 5 | X |
| 1,2,3-Trichloropropane..... | 96-18-4 | 50 | 300 | -- |
| 1,1,2-Trichloro-1,2,2-trifluoroethane..... | 76-13-1 | 1000 | 7600 | -- |
| Triethylamine..... | 121-44-8 | 25 | 100 | -- |
| Trifluorobromomethane..... | 75-63-8 | 1000 | 6100 | -- |
| Trimethyl benzene..... | 25551-13-7 | 25 | 120 | -- |
| 2,4,6-Trinitrophenol; see Picric acid..... | | | | |
| 2,4,6-Trinitrophenylmethylnitramine; see Tetryl..... | | | | |
| 2,4,6-Trinitrotoluene (TNT)..... | 118-96-7 | -- | 1.5 | X |
| Triorthocresyl phosphate..... | 78-30-8 | -- | 0.1 | -- |
| Triphenyl phosphate..... | 115-86-6 | -- | 3 | -- |
| Tungsten (as W)..... | 7440-33-7 | | | |
| Insoluble compounds..... | | -- | 5 | -- |
| Soluble compounds..... | | -- | 1 | -- |
| Turpentine..... | 8006-64-2 | 100 | 560 | -- |
| Uranium (as U)..... | 7440-61-1 | | | |
| Soluble compounds..... | | -- | 0.2 | -- |
| Insoluble compounds..... | | -- | 0.2 | -- |
| Vanadium..... | 1314-62-1 | | | |
| Respirable dust (as V2 O5)..... | | -- | (C)0.5 | -- |
| Fume (as V2 O5)..... | | -- | (C)0.1 | -- |
| Vegetable oil mist..... | | | | |
| Total dust..... | | -- | | -- |
| Respirable fraction..... | | -- | | -- |
| Vinyl benzene; see Styrene..... | | | | |
| Vinyl chloride; see Sec. 1926.1117..... | 75-01-4 | | | |
| Vinyl cyanide; see Acrylonitrile..... | | | | |
| Vinyl toluene..... | 25013-15-4 | 100 | 480 | -- |
| Warfarin..... | 81-81-2 | -- | 0.1 | -- |
| Xylenes (o-, m-, p-isomers)..... | 1330-20-7 | 100 | 435 | -- |
| Xylidine..... | 1300-73-8 | 5 | 25 | X |
| Yttrium..... | 7440-65-5 | -- | 1 | -- |
| Zinc chloride fume..... | 7646-85-7 | -- | 1 | -- |
| Zinc oxide fume..... | 1314-13-2 | -- | 5 | -- |
| Zinc oxide..... | 1314-13-2 | | | |
| Total dust..... | | -- | 15 | -- |
| Respirable fraction..... | | -- | 5 | -- |
| Zirconium compounds (as Zr)..... | 7440-67-7 | -- | 5 | -- |

Mineral Dusts

SILICA:

Crystalline
 Quartz. Threshold Limit calculated from the formula..... 250 (k)

 %SiO2+5

Cristobalite.....
 Amorphous, including natural diatomaceous earth..... 20
 SILICATES (less than 1% crystalline silica)
 Mica..... 20
 Portland cement..... 50
 Soapstone..... 20
 Talc (non-asbestiform)..... 20
 Talc (fibrous), use asbestos limit..... --

Graphite (natural)..... 15

Inert or Nuisance Particulates: (m) 50 (or 15 mg/m3 whichever is the smaller) of
 total dust <1% SiO2

[Inert or Nuisance Dusts includes all mineral, inorganic, and
 organic dusts as indicated by examples in TLV's Appendix D]

Conversion factors.....
 mppcf x 35.3 = million particles per cubic meter = particles per
 c.c.

Footnotes

- \1\ [Reserved]
 - \2\ See Mineral Dusts Table.
 - \3\ Use Asbestos Limit Sec. 1926.58.
 - \4\ See 1926.58.
 - * The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit.
 - ** As determined from breathing-zone air samples.
 - a Parts of vapor or gas per million parts of contaminated air by volume at 25 [deg]C and 760 torr.
 - b Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.
 - c [Reserved]
 - d The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given--not CAS numbers for the individual compounds.
 - e-f [Reserved]
 - g For sectors excluded from Sec. 1926.1128 the limit is 10 ppm TWA.
 - h [Reserved]
 - i [Reserved]
 - j Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques.
 - k The percentage of crystalline silica in the formula is the amount determined from airborne samples, except in those instances in which other methods have been shown to be applicable.
 - l [Reserved]
 - m Covers all organic and inorganic particulates not otherwise regulated. Same as Particulates Not Otherwise Regulated.
- The 1970 TLV uses letter designations instead of a numerical value as follows:
- A 1 [Reserved]
 - A 2 Polytetrafluoroethylene decomposition products. Because these products decompose in part by hydrolysis in alkaline solution, they can be quantitatively determined in air as fluoride to provide an index of exposure. No TLV is recommended pending determination of the toxicity of the products, but air concentrations should be minimal.
 - A 3 Gasoline and/or Petroleum Distillates. The composition of these materials varies greatly and thus a single TLV for all types of these materials is no longer applicable. The content of benzene, other aromatics and additives should be determined to arrive at the appropriate TLV.
 - E Simple asphyxiants. The limiting factor is the available oxygen which shall be at least 19.5% and be within the requirements addressing explosion in part 1926.
- [39 FR 22801, June 24, 1974, as amended at 51 FR 37007, Oct. 17, 1986; 52 FR 46312, Dec 4, 1987; 58 FR 35089, June 30, 1993; 61 FR 9227, March 7, 1996; 61 FR 56746, Nov. 4, 1996; 62 FR 1493, Jan. 10, 1997; 71 FR 10381, Feb. 28, 2006]

1926.56 Illumination.

(a) General. Construction areas, ramps, runways, corridors, offices, shops, and storage areas shall be lighted to not less than the minimum illumination intensities listed in Table D-3 while any work is in progress: **STEP**

TABLE D-3 - MINIMUM ILLUMINATION INTENSITIES IN FOOT-CANDLES

| Foot-Candles | Area of Operation |
|--------------|---|
| 5..... | General construction area lighting. |
| 3..... | General construction areas, concrete placement, excavation and waste areas, access ways, active storage areas, loading platforms, refueling, and field maintenance areas. |
| 5..... | Indoors: warehouses, corridors, hallways, and exitways. |
| 5..... | Tunnels, shafts, and general underground work areas: (Exception: minimum of 10 foot-candles is required at tunnel and shaft heading during drilling, mucking, and scaling. Bureau of Mines approved cap lights shall be acceptable for use in the tunnel heading) |

| | |
|---------|--|
| 10..... | General construction plant and shops (e.g., batch plants, screening plants, mechanical and electrical equipment rooms, carpenter shops, rigging lofts and active store rooms, mess halls, and indoor toilets and workrooms.) |
| 30..... | First aid stations, infirmaries, and offices. |

(b) Other areas. For areas or operations not covered above, refer to the American National Standard A11.1-1965, R1970, Practice for Industrial Lighting, for recommended values of illumination. STEP

1926.57 Ventilation.

(a) General. Whenever hazardous substances such as dusts, fumes, mists, vapors, or gases exist or are produced in the course of construction work, their concentrations shall not exceed the limits specified in 1926.55(a). When ventilation is used as an engineering control method, the system shall be installed and operated according to the requirements of this section.

(b) Local exhaust ventilation. Local exhaust ventilation when used as described in (a) shall be designed to prevent dispersion into the air of dusts, fumes, mists, vapors, and gases in concentrations causing harmful exposure. Such exhaust systems shall be so designed that dusts, fumes, mists, vapors, or gases are not drawn through the work area of employees. STEP

(c) Design and operation. Exhaust fans, jets, ducts, hoods, separators, and all necessary appurtenances, including refuse receptacles, shall be so designed, constructed, maintained and operated as to ensure the required protection by maintaining a volume and velocity of exhaust air sufficient to gather dusts, fumes, vapors, or gases from said equipment or process, and to convey them to suitable points of safe disposal, thereby preventing their dispersion in harmful quantities into the atmosphere where employees work.

STEP

(d) Duration of operations.

(1) The exhaust system shall be in operation continually during all operations which it is designed to serve. If the employee remains in the contaminated zone, the system shall continue to operate after the cessation of said operations, the length of time to depend upon the individual circumstances and effectiveness of the general ventilation system. STEP

(2) Since dust capable of causing disability is, according to the best medical opinion, of microscopic size, tending to remain for hours in suspension in still air, it is essential that the exhaust system be continued in operation for a time after the work process or equipment served by the same shall have ceased, in order to ensure the removal of the harmful elements to the required extent. For the same reason, employees wearing respiratory equipment should not remove same immediately until the atmosphere seems clear.

(e) Disposal of exhaust materials. The air outlet from every dust separator, and the dusts, fumes, mists, vapors, or gases collected by an exhaust or ventilating system shall discharge to the outside atmosphere. Collecting systems which return air to work area may be used if

concentrations which accumulate in the work area air do not result in harmful exposure to employees. Dust and refuse discharged from an exhaust system shall be disposed of in such a manner that it will not result in harmful exposure to employees.

STEP

(f) Abrasive blasting

(1) Definitions applicable to this paragraph

(i) Abrasive. A solid substance used in an abrasive blasting operation.

(ii) Abrasive-blasting respirator. A respirator constructed so that it covers the wearer's head, neck, and shoulders to protect him from rebounding abrasive.

(iii) Blast cleaning barrel. A complete enclosure which rotates on an axis, or which has an internal moving tread to tumble the parts, in order to expose various surfaces of the parts to the action of an automatic blast spray.

(iv) Blast cleaning room. A complete enclosure in which blasting operations are performed and where the operator works inside of the room to operate the blasting nozzle and direct the flow of the abrasive material.

(v) Blasting cabinet. An enclosure where the operator stands outside and operates the blasting nozzle through an opening or openings in the enclosure.

(vi) Clean air. Air of such purity that it will not cause harm or discomfort to an individual if it is inhaled for extended periods of time.

(vii) Dust collector. A device or combination of devices for separating dust from the air handled by an exhaust ventilation system.

(viii) Exhaust ventilation system. A system for removing contaminated air from a space, comprising two or more of the following elements (a) enclosure or hood, (b) duct work, (c) dust collecting equipment, (d) exhauster, and (e) discharge stack.

(ix) Particulate-filter respirator. An air purifying respirator, commonly referred to as a dust or a fume respirator, which removes most of the dust or fume from the air passing through the device.

(x) Respirable dust. Airborne dust in sizes capable of passing through the upper respiratory system to reach the lower lung passages.

(xi) Rotary blast cleaning table. An enclosure where the pieces to be cleaned are positioned on a rotating table and are passed automatically through a series of blast sprays.

(xii) Abrasive blasting. The forcible application of an abrasive to a surface by pneumatic pressure, hydraulic pressure, or centrifugal force.

(2) Dust hazards from abrasive blasting.

(i) Abrasives and the surface coatings on the materials blasted are shattered and pulverized during blasting operations and the dust formed will contain particles of respirable size. The composition and toxicity of the dust from these sources shall be considered in making an evaluation of the potential health hazards.

(ii) The concentration of respirable dust or fume in the breathing zone of the abrasive-blasting operator or any other worker shall be kept below the levels specified in 1926.55 or other pertinent sections of this part.

(iii) Organic abrasives which are combustible shall be used only in automatic systems. Where flammable or explosive dust mixtures may be present, the construction of the equipment, including the exhaust system and all electric wiring, shall conform to the requirements of American National Standard Installation of Blower and Exhaust Systems for Dust, Stock, and Vapor Removal or Conveying, Z33.1-1961 (NFPA 91-1961), and Subpart S of this part. The blast nozzle shall be bonded and grounded to prevent the build up of static charges. Where flammable or explosive dust mixtures may be present, the abrasive blasting enclosure, the ducts, and the dust collector shall be constructed with loose panels or explosion venting areas, located on sides away from any occupied area, to provide for pressure relief in case of explosion, following the principles set forth in the National Fire Protection Association Explosion Venting Guide. NFPA 68-1954.

(3) Blast-cleaning enclosures.

(i) Blast-cleaning enclosures shall be exhaust ventilated in such a way that a continuous inward flow of air will be maintained at all openings in the enclosure during the blasting operation.

(a) All air inlets and access openings shall be baffled or so arranged that by the combination of inward air flow and baffling the escape of abrasive or dust particules into an adjacent work area will be minimized and visible spurts of dust will not be observed.

(b) The rate of exhaust shall be sufficient to provide prompt clearance of the dust-laden air within the enclosure after the cessation of blasting. STEP

(c) Before the enclosure is opened, the blast shall be turned off and the exhaust system shall be run for a sufficient period of time to remove the dusty air within the enclosure.

(d) Safety glass protected by screening shall be used in observation windows, where hard deep-cutting abrasives are used.

(e) Slit abrasive-resistant baffles shall be installed in multiple sets at all small access openings where dust might escape, and shall be inspected regularly and replaced when needed.

(1) Doors shall be flanged and tight when closed.

(2) Doors on blast-cleaning rooms shall be operable from both inside and outside, except that where there is a small operator access door, the large work access door may be closed or opened from the outside only.

(4) Exhaust ventilation systems.

(i) The construction, installation, inspection, and maintenance of exhaust systems shall conform to the principles and requirements set forth in American National Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, Z9.2-1960, and ANSI Z33.1-1961.

(a) When dust leaks are noted, repairs shall be made as soon as possible.

STEP

(b) The static pressure drop at the exhaust ducts leading from the equipment shall be checked when the installation is completed and periodically thereafter to assure continued satisfactory operation. Whenever an appreciable change in the pressure drop indicates a partial blockage, the system shall be cleaned and returned to normal operating condition.

(ii) In installations where the abrasive is recirculated, the exhaust ventilation system for the blasting enclosure shall not be relied upon for the removal of fines from the spent abrasive instead of an abrasive separator. An abrasive separator shall be provided for the purpose.

(iii) The air exhausted from blast-cleaning equipment shall be discharged through dust collecting equipment. Dust collectors shall be set up so that the accumulated dust can be emptied and removed without contaminating other working areas.

(5) Personal protective equipment.

(i) Employers must use only respirators approved by NIOSH under 42 CFR part 84 for protecting employees from dusts produced during abrasive-blasting operations.

(ii) Abrasive-blasting respirators shall be worn by all abrasive-blasting operators:

(a) When working inside of blast-cleaning rooms, or

(b) When using silica sand in manual blasting operations where the nozzle and blast are not physically separated from the operator in an exhaust ventilated enclosure, or

(c) Where concentrations of toxic dust dispersed by the abrasive blasting may exceed the limits set in 1926.55 or other pertinent part sections of this part and the nozzle and blast are not physically separated from the operator in an exhaust-ventilated enclosure.

(iii) Properly fitted particulate filter respirators, commonly referred to as dust-filter respirators, may be used for short, intermittent, or occasional dust exposures such as cleanup, dumping of dust collectors, or unloading shipments of sand at a receiving point, when it is not feasible to control the dust by enclosure, exhaust ventilation, or other means. The respirators used must be approved by NIOSH under 42 CFR part 84 for protection against the specific type of dust encountered.

(a) Dust-filter respirators may be used to protect the operator of outside abrasive-blasting operations where nonsilica abrasives are used on materials having low toxicities.

(b) Dust-filter respirators shall not be used for continuous protection where silica sand is used as the blasting abrasive, or toxic materials are blasted.

(iv) A respiratory protection program as defined and described in 1926.103, shall be established wherever it is necessary to use respiratory protective equipment.

(v) Operators shall be equipped with heavy canvas or leather gloves and aprons or equivalent protection to protect them from the impact of abrasives. Safety shoes shall be worn to protect against foot injury where heavy pieces of work are handled.

(a) Safety shoes shall conform to the requirements of American National Standard for Men's Safety-Toe Footwear, Z41.1-1967.

(b) Equipment for protection of the eyes and face shall be supplied to the operator when the respirator design does not provide such protection and to any other personnel working in the vicinity of abrasive blasting operations. This equipment shall conform to the requirements of 1926.102.

(6) Air supply and air compressors. Air for abrasive-blasting respirators must be free of harmful quantities of dusts, mists, or noxious gases, and must meet the requirements for supplied-air quality and use specified in 29 CFR 1910.134(i).

(i) a trap and carbon filter are installed and regularly maintained, to remove oil, water, scale, and odor, STEP

(ii) a pressure reducing diaphragm or valve is installed to reduce the pressure down to requirements of the particular type of abrasive-blasting respirator, and STEP

(iii) an automatic control is provided to either sound an alarm or shut down the compressor in case of overheating. STEP

(7) Operational procedures and general safety. Dust shall not be permitted to accumulate on the floor or on ledges outside of an abrasive-blasting enclosure, and dust spills shall be cleaned up promptly. Aisles and walkways shall be kept clear of steel shot or similar abrasive which may create a slipping hazard. STEP

(8) Scope. This paragraph (a) applies to all operations where an abrasive is forcibly applied to a surface by pneumatic or hydraulic pressure, or by centrifugal force. It does not apply to steam blasting, or steam cleaning, or hydraulic cleaning methods where work is done without the aid of abrasives.

(g) Grinding, polishing, and buffing operations

(1) Definitions applicable to this paragraph

(i) Abrasive cutting-off wheels. Organic-bonded wheels, the thickness of which is not more than one forty-eighth of their diameter for those up to, and including, 20 inches in

diameter, and not more than one-sixtieth of their diameter for those larger than 20 inches in diameter, used for a multitude of operations variously known as cutting, cutting off, grooving, slotting, coping, and jointing, and the like. The wheels may be "solid" consisting of organic-bonded abrasive material throughout, "steel centered" consisting of a steel disc with a rim of organic-bonded material moulded around the periphery, or of the "inserted tooth" type consisting of a steel disc with organic-bonded abrasive teeth or inserts mechanically secured around the periphery.

(ii) Belts. All power-driven, flexible, coated bands used for grinding, polishing, or buffing purposes.

(iii) Branch pipe. The part of an exhaust system piping that is connected directly to the hood or enclosure.

(iv) Cradle. A movable fixture, upon which the part to be ground or polished is placed.

(v) Disc wheels. All power-driven rotatable discs faced with abrasive materials, artificial or natural, and used for grinding or polishing on the side of the assembled disc.

(vi) Entry loss. The loss in static pressure caused by air flowing into a duct or hood. It is usually expressed in inches of water gauge.

(vii) Exhaust system. A system consisting of branch pipes connected to hoods or enclosures, one or more header pipes, an exhaust fan, means for separating solid contaminants from the air flowing in the system, and a discharge stack to outside.

(viii) Grinding wheels. All power-driven rotatable grinding or abrasive wheels, except disc wheels as defined in this standard, consisting of abrasive particles held together by artificial or natural bonds and used for peripheral grinding.

(ix) Header pipe (main pipe). A pipe into which one or more branch pipes enter and which connects such branch pipes to the remainder of the exhaust system.

(x) Hoods and enclosures. The partial or complete enclosure around the wheel or disc through which air enters an exhaust system during operation.

(xi) Horizontal double-spindle disc grinder. A grinding machine carrying two power-driven, rotatable, coaxial, horizontal spindles upon the inside ends of which are mounted abrasive disc wheels used for grinding two surfaces simultaneously.

(xii) Horizontal single-spindle disc grinder. A grinding machine carrying an abrasive disc wheel upon one or both ends of a power-driven, rotatable single horizontal spindle.

(xiii) Polishing and buffing wheels. All power-driven rotatable wheels composed all or in part of textile fabrics, wood, felt, leather, paper, and may be coated with abrasives on the periphery of the wheel for purposes of polishing, buffing, and light grinding.

(xiv) Portable grinder. Any power-driven rotatable grinding, polishing, or buffing wheel mounted in such manner that it may be manually manipulated.

(xv) Scratch brush wheels. All power-driven rotatable wheels made from wire or bristles, and used for scratch cleaning and brushing purposes.

(xvi) Swing-frame grinder. Any power-driven rotatable grinding, polishing, or buffing wheel mounted in such a manner that the wheel with its supporting framework can be manipulated over stationary objects.

(xvii) Velocity pressure (vp). The kinetic pressure in the direction of flow necessary to cause a fluid at rest to flow at a given velocity. It is usually expressed in inches of water gauge.

(xviii) Vertical spindle disc grinder. A grinding machine having a vertical, rotatable power-driven spindle carrying a horizontal abrasive disc wheel.

(2) Application. Wherever dry grinding, dry polishing or buffing is performed, and employee exposure, without regard to the use of respirators, exceeds the permissible exposure limits prescribed in 1926.55 or other pertinent sections of this part, a local exhaust ventilation system shall be provided and used to maintain employee exposures within the prescribed limits.

(3) Hood and branch pipe requirements.

(i) Hoods connected to exhaust systems shall be used, and such hoods shall be designed, located, and placed so that the dust or dirt particles shall fall or be projected into the hoods in the direction of the air flow. No wheels, discs, straps, or belts shall be operated in such manner and in such direction as to cause the dust and dirt particles to be thrown into the operator's breathing zone.

(ii) Grinding wheels on floor stands, pedestals, benches, and special-purpose grinding machines and abrasive cutting-off wheels shall have not less than the minimum exhaust volumes shown in Table D-57.1 with a recommended minimum duct velocity of 4,500 feet per minute in the branch and 3,500 feet per minute in the main. The entry losses from all hoods except the vertical-spindle disc grinder hood, shall equal 0.65 velocity pressure for a straight takeoff and 0.45 velocity pressure for a tapered takeoff. The entry loss for the vertical-spindle disc grinder hood is shown in figure D-57.1 (following paragraph (b) of this section).

TABLE D-57.1 - GRINDING AND ABRASIVE CUTTING-OFF WHEELS

| Wheel diameter, inches (cm) | Wheel width, inches (cm) | Minimum exhaust volume (feet ³ /min.) |
|-----------------------------------|--------------------------|--|
| To 9 (22.86) | 1 1/2 (3.81) | 220 |
| Over 9 to 16 (22.86 to 40.64) | 2 (5.08) | 390 |
| Over 16 to 19 (40.64 to 48.26) | 3 (7.62) | 500 |
| Over 19 to 24 (48.26 to 60.96) | 4 (10.16) | 610 |
| Over 24 to 30 | | |

| | | |
|--|-----------|-------|
| (60.96 to 76.2) | 5 (12.7) | 880 |
| Over 30 to 36 (76.2 to 91.44) | 6 (15.24) | 1,200 |

For any wheel wider than wheel diameters shown in Table D-57.1, increase the exhaust volume by the ratio of the new width to the width shown.

Example:

If wheel width=4 1/2 inches, then

4.5 divided by 4 X 610=686 (rounded to 690).

(iii) Scratch-brush wheels and all buffing and polishing wheels mounted on floor stands, pedestals, benches, or special-purpose machines shall have not less than the minimum exhaust volume shown in Table D-57.2.

TABLE D-57.2 - BUFFING AND POLISHING WHEELS

| Wheel diameter, inches (cm) | Wheel width, inches (cm) | Minimum exhaust volume (feet(3)/min.) |
|--|--------------------------|---------------------------------------|
| To 9 (22.86) | 2 (5.08) | 300 |
| Over 9 to 16 (22.86 to 40.64) | 3 (7.62) | 500 |
| Over 16 to 19 (40.64 to 48.26) | 4 (10.16) | 610 |
| Over 19 to 24 (48.26 to 60.96) | 5 (12.7) | 740 |
| Over 24 to 30 (60.96 to 76.2) | 6 (15.24) | 1,040 |
| Over 30 to 36 (76.2 to 91.44) | 6 (15.24) | 1,200 |

(iv) Grinding wheels or discs for horizontal single-spindle disc grinders shall be hooded to collect the dust or dirt generated by the grinding operation and the hoods shall be connected to branch pipes having exhaust volumes as shown in Table D-57.3.

TABLE D-57.3 - HORIZONTAL SINGLE-SPINDLE DISC GRINDER

| Disc diameter, inches (cm) | Exhaust volume (feet(3)/min.) |
|-------------------------------------|-------------------------------|
| Up to 12 (30.48)..... | 220 |
| Over 12 to 19 (30.48 to 48.26)..... | 390 |
| Over 19 to 30 (48.26 to 76.2)..... | 610 |

| | |
|------------------------------------|-----|
| Over 30 to 36 (76.2 to 91.44)..... | 880 |
|------------------------------------|-----|

(v) Grinding wheels or discs for horizontal double-spindle disc grinders shall have a hood enclosing the grinding chamber and the hood shall be connected to one or more branch pipes having exhaust volumes as shown in Table D-57.4.

TABLE D-57.4 - HORIZONTAL DOUBLE-SPINDLE DISC GRINDER

| Disc diameter, inches (cm) | Exhaust volume (feet(3)/min.) |
|--------------------------------------|-------------------------------|
| Up to 19 (48.26)..... | 610 |
| Over 19 to 25 (48.26 to 63.5)..... | 880 |
| Over 25 to 30 (63.5 to 76.2)..... | 1,200 |
| Over 30 to 53 (76.2 to 134.62)..... | 1,770 |
| Over 53 to 72 (134.62 to 182.88).... | 6,280 |

(vi) Grinding wheels or discs for vertical single-spindle disc grinders shall be encircled with hoods to remove the dust generated in the operation. The hoods shall be connected to one or more branch pipes having exhaust volumes as shown in Table D-57.5.

TABLE D-57.5 - VERTICAL SPINDLE DISC GRINDER

| Disc diameter, inches (cm) | One-half or more of disc covered | | Disc not covered | |
|----------------------------------|----------------------------------|----------------------|------------------|----------------------|
| | Number (1) | Exhaust foot(3)/min. | Number(1) | Exhaust foot(3)/min. |
| Up to 20 (50.8)..... | 1 | 500 | 2 | 780 |
| Over 20 to 30 (50.8 to 76.2).... | 2 | 780 | 2 | 1,480 |
| Over 30 to 53 (76.2 to 134.62).. | 2 | 1,770 | 4 | 3,530 |
| Over 53 to 72 (134.62 to 182.88) | 2 | 3,140 | 5 | 6,010 |

Footnote(1) Number of exhaust outlets around periphery of hood, or equal distribution provided by other means.

(vii) Grinding and polishing belts shall be provided with hoods to remove dust and dirt generated in the operations and the hoods shall be connected to branch pipes having exhaust volumes as shown in Table D-57.6.

TABLE D-57.6 - GRINDING AND POLISHING BELTS

| Belts width, inches (cm) | Exhaust volume (feet ³ /min.) |
|-------------------------------------|--|
| Up to 3 (7.62)..... | 220 |
| Over 3 to 5 (7.62 to 12.7)..... | 300 |
| Over 5 to 7 (12.7 to 17.78)..... | 390 |
| Over 7 to 9 (17.78 to 22.86)..... | 500 |
| Over 9 to 11 (22.86 to 27.94)..... | 610 |
| Over 11 to 13 (27.94 to 33.02)..... | 740 |

(viii) Cradles and swing-frame grinders. Where cradles are used for handling the parts to be ground, polished, or buffed, requiring large partial enclosures to house the complete operation, a minimum average air velocity of 150 feet per minute shall be maintained over the entire opening of the enclosure. Swing-frame grinders shall also be exhausted in the same manner as provided for cradles. (See fig. G-3)

(ix) Where the work is outside the hood, air volumes must be increased as shown in American Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, Z9.2-1960 (section 4, exhaust hoods).

(4) Exhaust systems.

(i) Exhaust systems for grinding, polishing, and buffing operations should be designed in accordance with American Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, Z9.2-1960.

(ii) Exhaust systems for grinding, polishing, and buffing operations shall be tested in the manner described in American Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, Z9.2-1960.

(iii) All exhaust systems shall be provided with suitable dust collectors.

(5) Hood and enclosure design.

(i)

(a) It is the dual function of grinding and abrasive cutting-off wheel hoods to protect the operator from the hazards of bursting wheels as well as to provide a means for the removal of dust and dirt generated. All hoods shall be not less in structural strength than specified in the American National Standard Safety Code for the Use, Care, and Protection of Abrasive Wheels, B7.1-1970.

(b) Due to the variety of work and types of grinding machines employed, it is necessary to develop hoods adaptable to the particular machine in question, and such hoods shall be located as close as possible to the operation.

(ii) Exhaust hoods for floor stands, pedestals, and bench grinders shall be designed in accordance with figure G-2. The adjustable tongue shown in the figure shall be kept in working order and shall be adjusted within one-fourth inch of the wheel periphery at all times.

(iii) Swing-frame grinders shall be provided with exhaust booths as indicated in figure G-3.

(iv) Portable grinding operations, whenever the nature of the work permits, shall be conducted within a partial enclosure. The opening in the enclosure shall be no larger than is actually required in the operation and an average face air velocity of not less than 200 feet per minute shall be maintained.

(v) Hoods for polishing and buffing and scratch-brush wheels shall be constructed to conform as closely to figure D-57.4 as the nature of the work will permit.

(vi) Cradle grinding and polishing operations shall be performed within a partial enclosure similar to figure G-5. The operator shall be positioned outside the working face of the opening of the enclosure. The face opening of the enclosure should not be any greater in area than that actually required for the performance of the operation and the average air velocity into the working face of the enclosure shall not be less than 150 feet per minute.

(vii) Hoods for horizontal single-spindle disc grinders shall be constructed to conform as closely as possible to the hood shown in figure Figure D-57.6. It is essential that there be a space between the back of the wheel and the hood, and a space around the periphery of the wheel of at least 1 inch in order to permit the suction to act around the wheel periphery. The opening on the side of the disc shall be no larger than is required for the grinding operation, but must never be less than twice the area of the branch outlet.

(viii) Horizontal double-spindle disc grinders shall have a hood encircling the wheels and grinding chamber similar to that illustrated in figure Figure D-57.7. The openings for passing the work into the grinding chamber should be kept as small as possible, but must never be less than twice the area of the branch outlets.

(ix) Vertical-spindle disc grinders shall be encircled with a hood so constructed that the heavy dust is drawn off a surface of the disc and the lighter dust exhausted through a continuous slot at the top of the hood as shown in figure D-57.1.

(x) Grinding and polishing belt hoods shall be constructed as close to the operation as possible. The hood should extend almost to the belt, and 1-inch wide openings should be provided on either side. Figure D-57.8 shows a typical hood for a belt operation.

Figure D-57.1 -- Vertical Spindle Disc Grinder Exhaust Hood and Branch Pipe Connections

| Dia. D inches (cm) | Exhaust E | Volume Exhausted at 4,500 | Note |
|--------------------|-----------|---------------------------|------|
| | | | |

| Min. | Max. | No Pipes | Dia. | ft/min ft(3)/min | |
|---------------------|----------------------------------|----------|------------------------------|---------------------|--|
| | 20 (50.8) | 1 | 4 1/4 (10.795) | 500 | When one-half or more of the disc can be hooded, use exhaust ducts as shown at the left. |
| Over 20 (50.8)... | 30 (76.2) | 2 | 4 (10.16) | 780 | |
| Over 30 (76.2)... | 72 (182.88) | 2 | 6 (15.24) | 1,770 | |
| Over 53 (134.62)... | 72 (182.88) | 2 | 8 (20.32) | 3,140 | |
| | 20 (50.8) | 2 | 4 (10.16) | 780 | When no hood can be used over disc, use exhaust ducts as shown at left. |
| Over 20 (50.8)... | 20 (50.8) | 2 | 4 (10.16) | 780 | |
| Over 30 (76.2)... | 30 (76.2) | 2 | 5 1/2 (13.97) | 1,480 | |
| Over 53 (134.62)... | 53 (134.62) 72 (182.88) | 4 5 | 6 (15.24) 7 (17.78) | 3,530 6,010 | |

Entry loss=1.0 slot velocity pressure + 0.5 branch velocity pressure.
Minimum slot velocity=2,000 ft/min -- 1/2-inch (1.27 cm) slot width.

Figure D-57.2 -- Standard Grinder Hood

| Wheel dimension, inches (centimeters) | Exhaust | Volume |
|---------------------------------------|---------|--------|
|---------------------------------------|---------|--------|

| Diameter | | Width, Max | outlet, inches (centimeters) E | of air at 4,500 ft/min |
|-------------------|------------|--------------|---|---------------------------------|
| Min= d | Max= D | | | |
| | 9 (22.86) | 1 1/2 (3.81) | 3 | 220 |
| Over 9 (22.86)... | 16 (40.64) | 2 (5.08) | 4 | 390 |
| Over 16 (40.64).. | 19 (48.26) | 3 (7.62) | 4 1/2 | 500 |
| Over 19 (48.26).. | 24 (60.96) | 4 (10.16) | 5 | 610 |
| Over 24 (60.96).. | 30 (76.2) | 5 (12.7) | 6 | 880 |
| Over 30 (76.2)... | 36 (91.44) | 6 (15.24) | 7 | 1,200 |

Entry loss = 0.45 velocity pressure for tapered takeoff 0.65 velocity pressure for straight takeoff.

FIGURE D-57.3 A METHOD OF APPLYING AN EXHAUST ENCLOSURE TO SWING-FRAME GRINDERS

(For Figure D-57.3, see printed copy)

Figure D-57.4

Standard Buffing and Polishing Hood

| Wheel dimension, inches (centimeters) | | Width, Max | Exhaust outlet, inches E | Volume of air at 4,500 ft/min |
|---------------------------------------|------------|------------|-----------------------------------|---|
| Min= d | Max= D | | | |
| | 9 (22.86) | 2 (5.08) | 3 1/2 (3.81) | 300 |
| Over 9 (22.86)... | 16 (40.64) | 3 (5.08) | 4 | 500 |
| Over 16 (40.64).. | 19 (48.26) | 4 (11.43) | 5 | 610 |
| Over 19 (48.26).. | 24 (60.96) | 5 (12.7) | 5 1/2 | 740 |
| Over 24 (60.96).. | 30 (76.2) | 6 (15.24) | 6 1/2 | 1,040 |
| Over 30 (76.2)... | 36 (91.44) | 6 (15.24) | 7 | 1,200 |

Entry loss = 0.15 velocity pressure for tapered takeoff; 0.65 velocity pressure for straight takeoff.

FIGURE D-57.5 CRADLE POLISHING OR GRINDING ENCLOSURE

Entry loss= 0.45 velocity pressure for tapered takeoff.

(For Figure D-57.5, see printed copy)

Figure D-57.6 -- Horizontal Single-Spindle Disc Grinder

Exhaust Hood and Branch Pipe Connections

| Dia D inches (centimeters) | | Exhaust E dia. inches (cm) | Volume exhausted at 4,500 ft/min ft(3)/min |
|----------------------------|------------|-------------------------------------|--|
| Min. | Max. | | |
| | 12 (30.48) | 3 (7.6) | 220 |
| Over 12 (30.48)..... | 19 (48.26) | 4 (10.16) | 390 |
| Over 19 (48.26)..... | 30 (76.2) | 5 (12.7) | 610 |
| Over 30 (76.2)..... | 36 (91.44) | 6 (15.24) | 880 |

NOTE: If grinding wheels are used for disc grinding purposes, hoods must conform to structural strength and materials as described in 9.1.

Entry loss = 0.45 velocity pressure for tapered takeoff.

Figure D-57.7 -- Horizontal Double-Spindle Disc Grinder
Exhaust Hood and Branch Pipe Connections

| Disc dia.inches (centimeters) | | Exhaust E | | Volume exhausted at 4,500 ft/min. ft(3)/min | Note |
|----------------------------------|---------------|-------------|------|--|---|
| Min. | Max. | No Pipes | Dia. | | |
| | 19 (48.26) | 1 | 5 | 610 | |
| Over 19 (48.26)... | 25 (63.5) | 1 | 6 | 880 | When width "W" permits, exhaust ducts should be as near heaviest grinding as possible. |
| Over 25 (63.5)... | 30 | 1 | 7 | 1,200 | |

| | | | | |
|---------------------|----------------|---|---|-------|
| Over 30 (76.2)... | (76.2) 53 | 2 | 6 | 1,770 |
| Over 53 (134.62)... | (134.62) 72 | 4 | 8 | 6,280 |
| | (182.88) | | | |

Entry loss = 0.45 velocity pressure for tapered takeoff.

Figure D-57.8 -- A Typical Hood for a Belt Operation

Entry loss = 0.45 velocity pressure for tapered takeoff.

| Belt width W. inches (centimeters) | Exhaust Volume ft. ³ /min |
|------------------------------------|---|
| Up to 3 (7.62)..... | 220 |
| 3 to 5 (7.62 to 12.7)..... | 300 |
| 5 to 7 (12.7 to 17.78)..... | 390 |
| 7 to 9 (17.78 to 22.86)..... | 500 |
| 9 to 11 (22.86 to 27.94)..... | 610 |
| 11 to 13 (27.94 to 33.02)..... | 740 |

Minimum duct velocity = 4,500 ft/min branch, 3,500 ft/min main.

Entry loss = 0.45 velocity pressure for tapered takeoff; 0.65 velocity pressure for straight takeoff.

(6) Scope. This paragraph (b), prescribes the use of exhaust hood enclosures and systems in removing dust, dirt, fumes, and gases generated through the grinding, polishing, or buffing of ferrous and nonferrous metals.

(h) Spray finishing operations

(1) Definitions applicable to this paragraph

(i) Spray-finishing operations. Spray-finishing operations are employment of methods wherein organic or inorganic materials are utilized in dispersed form for deposit on surfaces to be coated, treated, or cleaned. Such methods of deposit may involve either automatic, manual, or electrostatic deposition but do not include metal spraying or metallizing, dipping, flow coating, roller coating, tumbling, centrifuging, or spray washing and degreasing as conducted in self-contained washing and degreasing machines or systems.

(ii) Spray booth. Spray booths are defined and described in 1926.66(a). (See sections 103, 104, and 105 of the Standard for Spray Finishing Using Flammable and Combustible Materials, NFPA No. 33-1969).

(iii) Spray room. A spray room is a room in which spray-finishing operations not conducted in a spray booth are performed separately from other areas.

(iv) Minimum maintained velocity. Minimum maintained velocity is the velocity of air movement which must be maintained in order to meet minimum specified requirements for health and safety.

(2) Location and application. Spray booths or spray rooms are to be used to enclose or confine all operations. Spray-finishing operations shall be located as provided in sections 201 through 206 of the Standard for Spray Finishing Using Flammable and Combustible Materials, NFPA No. 33-1969. STEP

(3) Design and construction of spray booths.

(i) Spray booths shall be designed and constructed in accordance with 1926.66(b)(1) through (4) and (6) through (10) (see sections 301-304 and 306-310 of the Standard for Spray Finishing Using Flammable and Combustible Materials, NFPA No. 33-1969), for general construction specifications. For a more detailed discussion of fundamentals relating to this subject, see ANSI Z9.2-1960

(a) Lights, motors, electrical equipment, and other sources of ignition shall conform to the requirements of 1926.66 (b)(10) and (c). (See section 310 and chapter 4 of the Standard for Spray Finishing Using Flammable and Combustible Materials NFPA No. 33-1969.)

(b) In no case shall combustible material be used in the construction of a spray booth and supply or exhaust duct connected to it. STEP

(ii) Unobstructed walkways shall not be less than 6 1/2 feet high and shall be maintained clear of obstruction from any work location in the booth to a booth exit or open booth front. In booths where the open front is the only exit, such exits shall be not less than 3 feet wide. In booths having multiple exits, such exits shall not be less than 2 feet wide, provided that the maximum distance from the work location to the exit is 25 feet or less. Where booth exits are provided with doors, such doors shall open outward from the booth.

(iii) Baffles, distribution plates, and dry-type overspray collectors shall conform to the requirements of 1926.66(b) (4) and (5). (See sections 304 and 305 of the Standard for Spray Finishing Using Flammable and Combustible Materials, NFPA No. 33-1969.)

(a) Overspray filters shall be installed and maintained in accordance with the requirements of 1926.66 (b)(5), (see section 305 of the Standard for Spray Finishing Using Flammable and Combustible Materials, NFPA No. 33-1969), and shall only be in a location easily accessible for inspection, cleaning, or replacement.

(b) Where effective means, independent of the overspray filters, are installed which will result in design air distribution across the booth cross section, it is permissible to operate the booth without the filters in place.

(iv)

(a) For wet or water-wash spray booths, the water-chamber enclosure,

within which intimate contact of contaminated air and cleaning water or other cleaning medium is maintained, if made of steel, shall be 18 gage or heavier and adequately protected against corrosion.

(b) Chambers may include scrubber spray nozzles, headers, troughs, or other devices. Chambers shall be provided with adequate means for creating and maintaining scrubbing action for removal of particulate matter from the exhaust air stream.

(v) Collecting tanks shall be of welded steel construction or other suitable non-combustible material. If pits are used as collecting tanks, they shall be concrete, masonry, or other material having similar properties.

(a) Tanks shall be provided with weirs, skimmer plates, or screens to prevent sludge and floating paint from entering the pump suction box. Means for automatically maintaining the proper water level shall also be provided. Fresh water inlets shall not be submerged. They shall terminate at least one pipe diameter above the safety overflow level of the tank.

(b) Tanks shall be so constructed as to discourage accumulation of hazardous deposits.

(vi) Pump manifolds, risers, and headers shall be adequately sized to insure sufficient water flow to provide efficient operation of the water chamber.

(4) Design and construction of spray rooms.

(i) Spray rooms, including floors, shall be constructed of masonry, concrete, or other noncombustible material.

STEP

(ii) Spray rooms shall have noncombustible fire doors and shutters.

(iii) Spray rooms shall be adequately ventilated so that the atmosphere in the breathing zone of the operator shall be maintained in accordance with the requirements of subparagraph (6)(ii) of this paragraph.

(iv) Spray rooms used for production spray-finishing operations shall conform to the requirements for spray booths.

(5) Ventilation.

(i) Ventilation shall be provided in accordance with provisions of 1926.66(d) (see chapter 5 of the Standard for Spray Finishing Using Flammable or Combustible Materials, NFPA No. 33-1969), and in accordance with the following:

(a) Where a fan plenum is used to equalize or control the distribution of exhaust air movement through the booth, it shall be of sufficient strength or rigidity to withstand the differential air pressure or other superficially imposed loads for which the equipment is designed and also to facilitate cleaning. Construction specifications shall be at least equivalent to those of subdivision (iii) of this subparagraph.

(ii) Inlet or supply ductwork used to transport makeup air to spray booths or surrounding areas shall be constructed of noncombustible materials.

(a) If negative pressure exists within inlet ductwork, all seams and joints shall be sealed if there is a possibility of infiltration of harmful quantities of noxious gases, fumes, or mists from areas through which ductwork passes.

(b) Inlet ductwork shall be sized in accordance with volume flow requirements and provide design air requirements at the spray booth.

(c) Inlet ductwork shall be adequately supported throughout its length to sustain at least its own weight plus any negative pressure which is exerted upon it under normal operating conditions.

(iii) [Reserved]

(a) Exhaust ductwork shall be adequately supported throughout its length to sustain its weight plus any normal accumulation in interior during normal operating conditions and any negative pressure exerted upon it.

(b) Exhaust ductwork shall be sized in accordance with good design practice which shall include consideration of fan capacity, length of duct, number of turns and elbows, variation in size, volume, and character of materials being exhausted. See American National Standard Z9.2-1960 for further details and explanation concerning elements of design.

(c) Longitudinal joints in sheet steel ductwork shall be either lock-seamed, riveted, or welded. For other than steel construction, equivalent securing of joints shall be provided.

(d) Circumferential joints in ductwork shall be substantially fastened together and lapped in the direction of airflow. At least every fourth joint shall be provided with connecting flanges, bolted together, or of equivalent fastening security.

(e) Inspection or clean-out doors shall be provided for every 9 to 12 feet of running length for ducts up to 12 inches in diameter, but the distance between cleanout doors may be greater for larger pipes. (See 8.3.21 of American National Standard Z9.1-1951.) A clean-out door or doors shall be provided for servicing the fan, and where necessary, a drain shall be provided.

(f) Where ductwork passes through a combustible roof or wall, the roof or wall shall be protected at the point of penetration by open space or fire-resistive material between the duct and the roof or wall. When ducts pass through firewalls, they shall be provided with automatic fire dampers on both sides of the wall, except that three-eighth-inch steel plates may be used in lieu of automatic fire dampers for ducts not exceeding 18 inches in diameter.

(g) Ductwork used for ventilating any process covered in this standard shall not be connected to ducts ventilating any other process or any chimney or flue used for conveying any products of combustion.

(6) Velocity and air flow requirements. STEP

(i) Except where a spray booth has an adequate air replacement system, the velocity of air into all openings of a spray booth shall be not less than that specified in Table D-57.7 for the operating conditions specified. An adequate air replacement system is one which introduces replacement air upstream or above the object being sprayed and is so designed that the velocity of air in the booth cross section is not less than that specified in Table D-57.7 when measured upstream or above the object being sprayed. STEP

TABLE D-57.7 - MINIMUM MAINTAINED VELOCITIES INTO SPRAY BOOTHS

| Operating conditions for objects completely inside booth | Crossdraft, f.p.m. | Airflow velocities, f.p.m. | |
|--|--------------------|----------------------------|---------|
| | | Design | Range |
| Electrostatic and automatic airless operation contained in booth without operator. | Negligible..... | 50 large booth... | 50-75 |
| | | 100 small booth.. | 75-125 |
| Air-operated guns, manual or automatic | Up to 50 | 100 large booth.. | 75-125 |
| | | 150 small booth.. | 125-175 |
| Air-operated guns, manual or automatic | Up to 100..... | 150 large booth.. | 125-175 |
| | | 200 small booth.. | 150-250 |

Footnote(1) Attention is invited to the fact that the effectiveness of the spray booth is dependent upon the relationship of the depth of the booth to its height and width.

Footnote(2) Crossdrafts can be eliminated through proper design and such design should be sought. Crossdrafts in excess of 100fpm (feet per minute) should not be permitted.

Footnote(3) Excessive air pressures result in loss of both efficiency and material waste in addition to creating a backlash that may carry overspray and fumes into adjacent work areas.

Footnote(4) Booths should be designed with velocities shown in the column headed "Design." However, booths operating with velocities shown in the column headed "Range" are in compliance with this standard.

(ii) In addition to the requirements in subdivision (i) of this subparagraph the total air volume exhausted through a spray booth shall be such as to dilute solvent vapor to at least 25 percent of the lower explosive limit of the solvent being sprayed. An example of the

method of calculating this volume is given below.

Example: To determine the lower explosive limits of the most common solvents used in spray finishing, see Table D-57.8. Column 1 gives the number of cubic feet of vapor per gallon of solvent and column 2 gives the lower explosive limit (LEL) in percentage by volume of air. Note that the quantity of solvent will be diminished by the quantity of solids and nonflammables contained in the finish.

To determine the volume of air in cubic feet necessary to dilute the vapor from 1 gallon of solvent to 25 percent of the lower explosive limit, apply the following formula:

Dilution volume required per gallon of solvent = 4 (100 - LEL) (cubic feet of vapor per gallon) divided by LEL

Using toluene as the solvent.

1. LEL of toluene from Table D-57.8, column 2, is 1.4 percent.
2. Cubic feet of vapor per gallon from Table D-57.8, column 1, is 30.4 cubic feet per gallon.
3. Dilution volume required = 4 (100 - 1.4) 30.4 divided by 1.4 = 8,564 cubic feet.
4. To convert to cubic feet per minute of required ventilation, multiply the dilution volume required per gallon of solvent by the number of gallons of solvent evaporated per minute.

TABLE D-57.8 - LOWER EXPLOSIVE LIMIT OF SOME COMMONLY USED SOLVENTS

| Solvent | Cubic feet per gallon of vapor of liquid at 70 deg. F (21.11 deg. C). | Lower explosive limit in percent by volume of air at 70 deg. F (21.11 deg. C) |
|--------------------------|---|---|
| | Column 1 | Column 2 |
| Acetone | 44.0 | 2.6 |
| Amyl Acetate (iso) | 21.6 | (1) 1.0 |
| Amyl Alcohol (n) | 29.6 | 1.2 |
| Amyl Alcohol (iso) | 29.6 | 1.2 |
| Benzene | 36.8 | (1) 1.4 |
| Butyl Acetate (n) | 24.8 | 1.7 |
| Butyl Alcohol (n) | 35.2 | 1.4 |

| | | |
|----------------------------|------|---------|
| Butyl Cellosolve | 24.8 | 1.1 |
| Cellosolve | 33.6 | 1.8 |
| Cellosolve Acetate | 23.2 | 1.7 |
| Cyclohexnone | 31.2 | (1) 1.1 |
| 1,1 Dichloroethylene | 42.4 | 5.9 |
| 1,2 Dichloroethylene | 42.4 | 9.7 |
| Ethyl Acetate | 32.8 | 2.5 |
| Ethyl Alcohol | 55.2 | 4.3 |
| Ethyl Lactate | 28.0 | (1) 1.5 |
| Methyl Acetate | 40.0 | 3.1 |
| Methyl Alcohol | 80.8 | 7.3 |
| Methyl Cellosolve | 40.8 | 2.5 |
| Methyl Ethyl Ketone | 36.0 | 1.8 |
| Methyl n-Propyl Ketone ... | 30.4 | 1.5 |
| Naphtha (VM&P) | | |
| (76 deg. Naphtha)..... | 22.4 | 0.9 |
| Naphtha (100 deg. Flash) | | |
| Safety Solvent - | | |
| Stoddard Solvent | 23.2 | 1.0 |
| Propyl Acetate (n) | 27.2 | 2.8 |
| Propyl Acetate (iso) | 28.0 | 1.1 |
| Propyl Alcohol (n) | 44.8 | 2.1 |
| Propyl Alcohol (iso) | 44.0 | 2.0 |
| Toluene | 30.4 | 1.4 |
| Turpentine | 20.8 | 0.8 |
| Xylene (o) | 26.4 | 1.0 |

Footnote(1) At 212 deg. F (100 deg. C)

(iii)

(a) When an operator is in a booth downstream of the object being sprayed, an air-supplied respirator or other type of respirator approved by NIOSH under 42 CFR Part 84 for the material being sprayed should be used by the operator.

(b) Where downdraft booths are provided with doors, such doors shall be closed when spray painting.

(7) Make-up air.

(i) Clean fresh air, free of contamination from adjacent industrial exhaust systems, chimneys, stacks, or vents, shall be supplied to a spray booth or room in quantities equal to the volume of air exhausted through the spray booth.

(ii) Where a spray booth or room receives make-up air through self-closing doors, dampers, or louvers, they shall be fully open at all times when the booth or room is in use for spraying. The velocity of air through such doors, dampers, or louvers shall not exceed 200 feet per minute. If the fan characteristics are such that the required air flow through the booth will be provided, higher velocities through the doors, dampers, or louvers may be used.

(iii)

(a) Where the air supply to a spray booth or room is filtered, the fan static pressure shall be calculated on the assumption that the filters are dirty to the extent that they require cleaning or replacement.

(b) The rating of filters shall be governed by test data supplied by the manufacturer of the filter. A pressure gage shall be installed to show the pressure drop across the filters. This gage shall be marked to show the pressure drop at which the filters require cleaning or replacement. Filters shall be replaced or cleaned whenever the pressure drop across them becomes excessive or whenever the air flow through the face of the booth falls below that specified in Table G-10.

STEP

(iv)

(a) Means for heating make-up air to any spray booth or room, before or at the time spraying is normally performed, shall be provided in all places where the outdoor temperature may be expected to remain below 55 deg. F. for appreciable periods of time during the operation of the booth except where adequate and safe means of radiant heating for all operating personnel affected is provided. The replacement air during the heating seasons shall be maintained at not less than 65 deg. F. at the point of entry into the spray booth or spray room. When otherwise unheated make-up air would be at a temperature of more than 10 deg. F. below room temperature, its temperature shall be regulated as provided in section 3.6.3 of ANSI Z9.2-1960.

(b) As an alternative to an air replacement system complying with the preceding section, general heating of the building in which the spray room or booth is located may be employed provided that all occupied parts of the building are maintained at not less than 65 deg. F. when the exhaust system is in operation or the general heating system supplemented by other sources of heat may be employed to meet this requirement.

(c) No means of heating make-up air shall be located in a spray booth.

(d) Where make-up air is heated by coal or oil, the products of combustion shall not be allowed to mix with the make-up air, and the products of combustion shall be conducted outside the building through a flue terminating at a point remote from all points where make-up air enters the building.

(e) Where make-up air is heated by gas, and the products of combustion are not mixed with the make-up air but are conducted through an independent flue to a point outside the building remote from all points where make-up air enters the building, it is not necessary to comply with paragraph (f) of this subdivision.

(f) Where make-up air to any manually operated spray booth or room is heated by gas and the products of combustion are allowed to mix with the supply air, the following precautions must be taken:

(1) The gas must have a distinctive and strong enough odor to warn workmen in a spray booth or room of its presence if in an unburned state in the make-up air.

(2) The maximum rate of gas supply to the make-up air heater burners must not exceed that which would yield in excess of 200 p.p.m. (parts per million) of carbon monoxide or 2,000 p.p.m. of total combustible gases in the mixture if the unburned gas upon the occurrence of flame failure were mixed with all of the make-up air supplied.

(3) A fan must be provided to deliver the mixture of heated air and products of combustion from the plenum chamber housing the gas burners to the spray booth or room.

(8) Scope. Spray booths or spray rooms are to be used to enclose or confine all spray finishing operations covered by this paragraph (c). This paragraph does not apply to the spraying of the exteriors of buildings, fixed tanks, or similar structures, nor to small portable spraying apparatus not used repeatedly in the same location. STEP

(i) Open surface tanks

(1) General.

(i) This paragraph applies to all operations involving the immersion of materials in liquids, or in the vapors of such liquids, for the purpose of cleaning or altering the surface or adding to or imparting a finish thereto or changing the character of the materials, and their subsequent removal from the liquid or vapor, draining, and drying. These operations include washing, electroplating, anodizing, pickling, quenching, dyeing, dipping, tanning, dressing, bleaching, degreasing, alkaline cleaning, stripping, rinsing, digesting, and other similar operations.

(ii) Except where specific construction specifications are prescribed in this section, hoods, ducts, elbows, fans, blowers, and all other exhaust system parts, components, and supports thereof shall be so constructed as to meet conditions of service and to facilitate maintenance and shall conform in construction to the specifications contained in American National Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, Z9.2-1960.

(2) Classification of open-surface tank operations.

(i) Open-surface tank operations shall be classified into 16 classes, numbered A-1 to D-4, inclusive.

(ii) Determination of class. Class is determined by two factors, hazard potential designated by a letter from A to D, inclusive, and rate of gas, vapor, or mist evolution designated by a number from 1 to 4, inclusive (for example, B.3).

(iii) Hazard potential is an index, on a scale of from A to D, inclusive, of the severity of the hazard associated with the substance contained in the tank because of the toxic, flammable, or explosive nature of the vapor, gas, or mist produced therefrom. The toxic hazard is determined from the concentration, measured in parts by volume of a gas or vapor, per million parts by volume of contaminated air (p.p.m.), or in milligrams of mist per cubic meter of air (mg./meter (3)), below which ill effects are unlikely to occur to the exposed worker. The concentrations shall be those in 1926.55 or other pertinent sections of this part.

(iv) The relative fire or explosion hazard is measured in degrees Fahrenheit in terms of the closed-cup flash point of the substance in the tank. Detailed information on the prevention of fire hazards in dip tanks may be found in Dip Tanks Containing Flammable or Combustible Liquids, NFPA No. 34-1966, National Fire Protection Association. Where the tank contains a mixture of liquids, other than organic solvents, whose effects are additive, the hygienic standard of the most toxic component (for example, the one having the lowest p.p.m. or mg./meter (3) shall be used, except where such substance constitutes an insignificantly small fraction of the mixture. For mixtures of organic solvents, their combined effect, rather than that of either individually, shall determine the hazard potential. In the absence of information to the contrary, the effects shall be considered as additive. If the sum of the ratios of the airborne concentration of each contaminant to the toxic concentration of that contaminant exceeds unity, the toxic concentration shall be considered to have been exceeded. (See Note A to subdivision (v) of this subparagraph.)

(v) Hazard potential shall be determined from Table D-57.9, with the value indicating greater hazard being used. When the hazardous material may be either a vapor with a threshold limit value (TLV) in p.p.m. or a mist with a TLV in mg./meter (3), the TLV indicating the greater hazard shall be used (for example, A takes precedence over B or C; B over C; C over D).

Note A:

$$(c(1)+TLV(1))+(c(2)+TLV(2))+(c(3)+TLV(3))+;\dots (c(N)+TLV(N))1$$

where:

c = Concentration measured at the operation in p.p.m.

TABLE D-57.9 - DETERMINATION OF HAZARD POTENTIAL

| Hazard potential | Toxicity group | | |
|------------------|-----------------------|-----------------|--------------------------------|
| | Gas or vapor (p.p.m.) | Mist (mg./m(3)) | Flash point in degrees F. (C.) |
| A..... | 0-10 | 0-0.1 | |
| B..... | 11-100 | 0.11-1.0 | Under 100 (37.77) |
| C..... | 101-500 | 1.1-10 | 100 200 (37.77-93.33) |
| D..... | Over 500 | Over 10 | Over 200 (93.33) |

(vi) Rate of gas, vapor, or mist evolution is a numerical index, on a scale of from 1 to 4, inclusive, both of the relative capacity of the tank to produce gas, vapor, or mist and of the relative energy with which it is projected or carried upwards from the tank. Rate is evaluated in terms of

(a) The temperature of the liquid in the tank in degrees Fahrenheit;

(b) The number of degrees Fahrenheit that this temperature is below the boiling point of the liquid in degrees Fahrenheit;

(c) The relative evaporation of the liquid in still air at room temperature in an arbitrary scale-fast, medium, slow, or nil; and

(d) The extent that the tank gasses or produces mist in an arbitrary scale-high, medium, low, and nil. (See Table D-57.10, Note 2.) Gassing depends upon electrochemical or mechanical processes, the effects of which have to be individually evaluated for each installation (see Table D-57.10, Note 3).

(vii) Rate of evolution shall be determined from Table D-57.10. When evaporation and gassing yield different rates, the lowest numerical value shall be used.

TABLE D-57.10 - DETERMINATION OF RATE OF GAS, VAPOR, OR MIST EVOLUTION(1)

| Rate | Liquid temperature, deg. F (C) | Degrees below boiling point | Relative evaporation(2) | Gassing(3) |
|------|--------------------------------|-----------------------------|-------------------------|------------|
| 1... | Over 200 (93.33) | 0-20 | Fast..... | High. |
| 2... | 150-200 (65.55-93.33) | 21-50 | Medium..... | Medium. |
| 3... | 94-149 (34.44-65) | 51-100 | Slow..... | Low. |
| 4... | Under 94 (34.44) | Over 100 | Nil..... | Nil. |

Footnote(1) In certain classes of equipment, specifically vapor degreasers, an internal condenser or vapor level thermostat is used to prevent the vapor from leaving the tank during normal operation. In such cases, rate of vapor evolution from the tank into the workroom is not dependent upon the factors listed in the table, but rather upon abnormalities of operating procedure, such as carryout of vapors from excessively fast action, dragout of liquid by entrainment in parts, contamination of solvent by water and other materials, or improper heat balance. When operating procedure is excellent, effective rate of evolution may be taken as 4. When operating procedure is average, the effective rate of evolution may be taken as 3.

Footnote(2) Relative evaporation rate is determined according to the methods described by A. K. Doolittle in Industrial and Engineering Chemistry, vol. 27 p. 1169, (3) where time for 100-percent evaporation is as follows: Fast: 0-3 hours; Medium: 3-12

hours; Slow: 12-50 hours; Nil: more than 50 hours.

Footnote(3) Gassing means the formation by chemical or electrochemical action of minute bubbles of gas under the surface of the liquid in the tank and is generally limited to aqueous solutions.

(3) Ventilation. Where ventilation is used to control potential exposures to workers as defined in subparagraph (2)(iii) of this paragraph, it shall be adequate to reduce the concentration of the air contaminant to the degree that a hazard to the worker does not exist. Methods of ventilation are discussed in American National Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, Z9.2-1960.

(4) Control requirements.

(i) Control velocities shall conform to Table D-57.11 in all cases where the flow of air past the breathing or working zone of the operator and into the hoods is undisturbed by local environmental conditions, such as open windows, wall fans, unit heaters, or moving machinery.

(ii) All tanks exhausted by means of hoods which

(a) Project over the entire tank;

(b) Are fixed in position in such a location that the head of the workman, in all his normal operating positions while working at the tank, is in front of all hood openings; and

(c) Are completely enclosed on at least two sides, shall be considered to be exhausted through an enclosing hood.

(d) The quantity of air in cubic feet per minute necessary to be exhausted through an enclosing hood shall be not less than the product of the control velocity times the net area of all openings in the enclosure through which air can flow into the hood.

TABLE D-57.11 - CONTROL VELOCITIES IN FEET PER MINUTE (F.P.M.)
FOR UNDISTURBED LOCATIONS

| Class | Enclosing hood | | Lateral exhaust[1] | Canopy hood[2] | |
|--|----------------|----------------|--------------------|------------------|-----------------|
| | One open side | Two open sides | | Three open sides | Four open sides |
| B-1 and A-2 | 100 | 150 | 150 | Do not use | Do not use |
| A-3[2], B-1, B-2, and C-1 | 75 | 100 | 100 | 125 | 175 |
| A-3, C-2, and D-1[3] | 65 | 90 | 75 | 100 | 150 |
| B-4[2], C-3, and | | | | | |

| | | | | | |
|-------------------------------------|-------|-------|-------|-------|-------|
| D-2[3] | 50 | 75 | 50 | 75 | 125 |
| A-4, C-4, D-3[3], and D-4[4] ... | | | | | |

Footnote(1) See Table D-57.12 for computation of ventilation rate.
Footnote(2) Do not use canopy hood for Hazard Potential A processes.
Footnote(3) Where complete control of hot water is desired, design as next highest class.
Footnote(4) General room ventilation required.

(iii) All tanks exhausted by means of hoods which do not project over the entire tank, and in which the direction of air movement into the hood or hoods is substantially horizontal, shall be considered to be laterally exhausted. The quantity of air in cubic feet per minute necessary to be laterally exhausted per square foot of tank area in order to maintain the required control velocity shall be determined from Table D-57.12 for all variations in ratio of tank width (W) to tank length (L). The total quantity of air in cubic feet per minute required to be exhausted per tank shall be not less than the product of the area of tank surface times the cubic feet per minute per square foot of tank area, determined from Table D-57.12.

(a) For lateral exhaust hoods over 42 inches wide, or where it is desirable to reduce the amount of air removed from the workroom, air supply slots or orifices shall be provided along the side or the center of the tank opposite from the exhaust slots. The design of such systems shall meet the following criteria:

(1) The supply air volume plus the entrained air shall not exceed 50 percent of the exhaust volume.

(2) The velocity of the supply airstream as it reaches the effective control area of the exhaust slot shall be less than the effective velocity over the exhaust slot area.

TABLE D-57.12 - MINIMUM VENTILATION RATE IN CUBIC FEET OF AIR PER MINUTE PER SQUARE FOOT OF TANK AREA FOR LATERAL EXHAUST

| | | | | | |
|--|---|----------|-----------|----------|---------|
| Required minimum control velocity, f.p.m. (from Table D-57.11) | C.f.m. per sq. ft. to maintain required minimum velocities at following ratios (tank width (W)/ tank length (L))(1),(2) | | | | |
| | 0.0-0.09 | 0.1-0.24 | 0.25-0.49 | 0.5-0.99 | 1.0-2.0 |

Hood along one side or two parallel sides of tank when one hood is against a wall or baffle(2).
Also for a manifold along tank centerline(3).

| | | | | | |
|----------|-----|-----|-----|-----|-----|
| 50..... | 50 | 60 | 75 | 90 | 100 |
| 75..... | 75 | 90 | 110 | 130 | 150 |
| 100..... | 100 | 125 | 150 | 175 | 200 |
| 150..... | 150 | 190 | 225 | 260 | 300 |

Hood along one side or two parallel sides of free standing tank not against wall or baffle.

| | | | | | |
|----------|-----|-----|-----|-----|-----|
| 50..... | 75 | 90 | 100 | 110 | 125 |
| 75..... | 110 | 130 | 150 | 170 | 190 |
| 100..... | 150 | 175 | 200 | 225 | 250 |
| 150..... | 225 | 260 | 300 | 340 | 375 |

Footnote(1) It is not practicable to ventilate across the long dimension of a tank whose ratio W/L exceeds 2.0.

It is undesirable to do so when W/L exceeds 1.0. For circular tanks with lateral exhaust along up to 1/2 the circumference, use W/L=1.0; for over one-half the circumference use W/L=0.5.

Footnote(2) Baffle is a vertical plate the same length as the tank, and with the top of the plate as high as the tank is wide. If the exhaust hood is on the side of a tank against a building wall or close to it, it is perfectly baffled.

Footnote(3) Use W/2 as tank width in computing when manifold is along centerline, or when hoods are used on two parallel sides of a tank.

Tank Width (W) means the effective width over which the hood must pull air to operate (for example, where the hood face is set back from the edge of the tank, this set back must be added in measuring tank width). The surface area of tanks can frequently be reduced and better control obtained (particularly on conveyORIZED systems) by using covers extending from the upper edges of the slots toward the center of the tank.

(3) The vertical height of the receiving exhaust hood, including any baffle, shall not be less than one-quarter the width of the tank.

(4) The supply airstream shall not be allowed to impinge on obstructions between it and the exhaust slot in such a manner as to significantly interfere with the performance of the exhaust hood.

(5) Since most failure of push-pull systems result from excessive supply air volumes and pressures, methods of measuring and adjusting the supply air shall be provided. When satisfactory control has been achieved, the adjustable features of the hood shall be fixed so that they will not be altered.

(iv) All tanks exhausted by means of hoods which project over the entire tank, and which do not conform to the definition of enclosing hoods, shall be considered to be overhead canopy hoods. The quantity of air in cubic feet per minute necessary to be exhausted through a canopy hood shall be not less than the product of the control velocity times the net area

of all openings between the bottom edges of the hood and the top edges of the tank.

(v) The rate of vapor evolution (including steam or products of combustion) from the process shall be estimated. If the rate of vapor evolution is equal to or greater than 10 percent of the calculated exhaust volume required, the exhaust volume shall be increased in equal amount.

(5) Spray cleaning and degreasing. Wherever spraying or other mechanical means are used to disperse a liquid above an open-surface tank, control must be provided for the airborne spray. Such operations shall be enclosed as completely as possible. The inward air velocity into the enclosure shall be sufficient to prevent the discharge of spray into the workroom. Mechanical baffles may be used to help prevent the discharge of spray. Spray painting operations are covered by paragraph (c) of this section.

(6) Control means other than ventilation. Tank covers, foams, beads, chips, or other materials floating on the tank surface so as to confine gases, mists, or vapors to the area under the cover or to the foam, bead, or chip layer; or surface tension depressive agents added to the liquid in the tank to minimize mist formation, or any combination thereof, may all be used as gas, mist, or vapor control means for open-surface tank operations, provided that they effectively reduce the concentrations of hazardous materials in the vicinity of the worker below the limits set in accordance with subparagraph (2) of this paragraph.

(7) System design.

(i) The equipment for exhausting air shall have sufficient capacity to produce the flow of air required in each of the hoods and openings of the system.

(ii) The capacity required in subdivision (i) of this subparagraph shall be obtained when the airflow producing equipment is operating against the following pressure losses, the sum of which is the static pressure:

- (a) Entrance losses into the hood.
- (b) Resistance to airflow in branch pipe including bends and transformations.
- (c) Entrance loss into the main pipe.
- (d) Resistance to airflow in main pipe including bends and transformations.
- (e) Resistance of mechanical equipment; that is, filters, washers, condensers, absorbers, etc., plus their entrance and exit losses.
- (f) Resistance in outlet duct and discharge stack.

(iii) Two or more operations shall not be connected to the same exhaust system where either one or the combination of the substances removed may constitute a fire, explosion, or chemical reaction hazard in the duct system. Traps or other devices shall be provided to insure that condensate in ducts does not drain back into any tank.

(iv) The exhaust system, consisting of hoods, ducts, air mover, and discharge outlet, shall be designed in accordance with American National Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, Z9.2-1960, or the manual, Industrial Ventilation, published by the American Conference of Governmental Industrial Hygienists 1970. Airflow and pressure loss data provided by the manufacturer of any air cleaning device shall be included in the design calculations. STEP

(8) Operation.

(i) The required airflow shall be maintained at all times during which gas, mist, or vapor is emitted from the tank, and at all times the tank, the draining, or the drying area is in operation or use. When the system is first installed, the airflow from each hood shall be measured by means of a pitot traverse in the exhaust duct and corrective action taken if the flow is less than that required. When the proper flow is obtained, the hood static pressure shall be measured and recorded. At intervals of not more than 3 months operation, or after a prolonged shutdown period, the hoods and duct system shall be inspected for evidence of corrosion or damage. In any case where the airflow is found to be less than required, it shall be increased to the required value. (Information on airflow and static pressure measurement and calculations may be found in American National Standard Fundamental Governing the Design and Operation of Local Exhaust Systems, Z9.2-1960, or in the manual, Industrial Ventilation, published by the American Conference of Governmental Industrial Hygienists.) STEP

(ii) The exhaust system shall discharge to the outer air in such a manner that the possibility of its effluent entering any building is at a minimum. Recirculation shall only be through a device for contaminant removal which will prevent the creation of a health hazard in the room or area to which the air is recirculated.

(iii) A volume of outside air in the range of 90 percent to 110 percent of the exhaust volume shall be provided to each room having exhaust hoods. The outside air supply shall enter the workroom in such a manner as not to be detrimental to any exhaust hood. The airflow of the makeup air system shall be measured on installation. Corrective action shall be taken when the airflow is below that required. The makeup air shall be uncontaminated.

(9) Personal protection.

(i) All employees working in and around open-surface tank operations must be instructed as to the hazards of their respective jobs, and in the personal protection and first aid procedures applicable to these hazards. STEP

(ii) All persons required to work in such a manner that their feet may become wet shall be provided with rubber or other impervious boots or shoes, rubbers, or wooden-soled shoes sufficient to keep feet dry.

(iii) All persons required to handle work wet with a liquid other than water shall be provided with gloves impervious to such a liquid and of a length sufficient to prevent entrance of liquid into the tops of the gloves. The interior of gloves shall be kept free from corrosive or irritating contaminants. STEP

(iv) All persons required to work in such a manner that their clothing may

become wet shall be provided with such aprons, coats, jackets, sleeves, or other garments made of rubber, or of other materials impervious to liquids other than water, as are required to keep their clothing dry. Aprons shall extend well below the top of boots to prevent liquid splashing into the boots. Provision of dry, clean, cotton clothing along with rubber shoes or short boots and an apron impervious to liquids other than water shall be considered a satisfactory substitute where small parts are cleaned, plated, or acid dipped in open tanks and rapid work is required. STEP

(v) Whenever there is a danger of splashing, for example, when additions are made manually to the tanks, or when acids and chemicals are removed from the tanks, the employees so engaged shall be required to wear either tight-fitting chemical goggles or an effective face shield. See 1926.102. STEP

(vi) When, during emergencies specified in paragraph (i)(11)(v) of this section, employees must be in areas where concentrations of air contaminants are greater than the limit set by paragraph (i)(2)(iii) of this section, or oxygen concentrations are less than 19.5 percent, they must use respirators that reduce their exposure to a level below these limits or that provide adequate oxygen. Such respirators must also be provided in marked, quickly-accessible storage compartments built for this purpose, when the possibility exists of accidental release of hazardous concentrations of air contaminants. Respirators must be approved by NIOSH under 42 CFR part 84, selected by a competent industrial hygienist or other technically-qualified source, and used in accordance with 29 CFR 1926.103. Respirators shall be used in accordance with 1926.103, and persons who may require them shall be trained in their use.

(vii) Near each tank containing a liquid which may burn, irritate, or otherwise be harmful to the skin if splashed upon the worker's body, there shall be a supply of clean cold water. The water pipe (carrying a pressure not exceeding 25 pounds) shall be provided with a quick opening valve and at least 48 inches of hose not smaller than three-fourths inch, so that no time may be lost in washing off liquids from the skin or clothing. Alternatively, deluge showers and eye flushes shall be provided in cases where harmful chemicals may be splashed on parts of the body. STEP

(viii) Operators with sores, burns, or other skin lesions requiring medical treatment shall not be allowed to work at their regular operations until so authorized by a physician. Any small skin abrasions, cuts, rash, or open sores which are found or reported shall be treated by a properly designated person so that chances of exposures to the chemicals are removed. Workers exposed to chromic acids shall have a periodic examination made of the nostrils and other parts of the body, to detect incipient ulceration. STEP

(ix) Sufficient washing facilities, including soap, individual towels, and hot water, shall be provided for all persons required to use or handle any liquids which may burn, irritate, or otherwise be harmful to the skin, on the basis of at least one basin (or its equivalent) with a hot water faucet for every 10 employees. See 1926.51(f).

(x) Locker space or equivalent clothing storage facilities shall be provided to prevent contamination of street clothing.

(xi) First aid facilities specific to the hazards of the operations conducted shall be readily available.

(10) Special precautions for cyanide. Dikes or other arrangements shall be provided to prevent the possibility of intermixing of cyanide and acid in the event of tank rupture. STEP

(11) Inspection, maintenance, and installation.

(i) Floors and platforms around tanks shall be prevented from becoming slippery both by original type of construction and by frequent flushing. They shall be firm, sound, and of the design and construction to minimize the possibility of tripping.

(ii) Before cleaning the interior of any tank, the contents shall be drained off, and the cleanout doors shall be opened where provided. All pockets in tanks or pits, where it is possible for hazardous vapors to collect, shall be ventilated and cleared of such vapors.

(iii) Tanks which have been drained to permit employees to enter for the purposes of cleaning, inspection, or maintenance may contain atmospheres which are hazardous to life or health, through the presence of flammable or toxic air contaminants, or through the absence of sufficient oxygen. Before employees shall be permitted to enter any such tank, appropriate tests of the atmosphere shall be made to determine if the limits set by paragraph (d)(2)(iii) of this section are exceeded, or if the oxygen concentration is less than 19.5 percent.

(iv) If the tests made in accordance with paragraph(d)(11)(iii) of this section indicate that the atmosphere in the tank is unsafe, before any employee is permitted to enter the tank, the tank shall be ventilated until the hazardous atmosphere is removed, and ventilation shall be continued so as to prevent the occurrence of a hazardous atmosphere as long as an employee is in the tank.

(v) If, in emergencies, such as rescue work, it is necessary to enter a tank which may contain a hazardous atmosphere, suitable respirators, such as self-contained breathing apparatus; hose mask with blower, if there is a possibility of oxygen deficiency; or a gas mask, selected and operated in accordance with paragraph (d)(9)(vi) of this section, shall be used. If a contaminant in the tank can cause dermatitis, or be absorbed through the skin, the employee entering the tank shall also wear protective clothing. At least one trained standby employee, with suitable respirator, shall be present in the nearest uncontaminated area. The standby employee must be able to communicate with the employee in the tank and be able to haul him out of the tank with a lifeline if necessary.

(vi) Maintenance work requiring welding or open flame, where toxic metal fumes such as cadmium, chromium, or lead may be evolved, shall be done only with sufficient local exhaust ventilation to prevent the creation of a health hazard, or be done with respirators selected and used in accordance with paragraph (d)(9)(vi) of this section. Welding, or the use of open flames near any solvent cleaning equipment shall be permitted only after such equipment has first been thoroughly cleared of solvents and vapors.

(12) Vapor degreasing tanks.

(i) In any vapor degreasing tank equipped with a condenser or vapor level thermostat, the condenser or thermostat shall keep the level of vapors below the top edge of the tank by a distance at least equal to one-half the tank width, or at least 36 inches, whichever is shorter.

(ii) Where gas is used as a fuel for heating vapor degreasing tanks, the

combustion chamber shall be of tight construction, except for such openings as the exhaust flue, and those that are necessary for supplying air for combustion. Flues shall be of corrosion-resistant construction and shall extend to the outer air. If mechanical exhaust is used on this flue, a draft diverter shall be used. Special precautions must be taken to prevent solvent fumes from entering the combustion air of this or any other heater when chlorinated or fluorinated hydrocarbon solvents (for example, trichloroethylene, Freon) are used.

(iii) Heating elements shall be so designed and maintained that their surface temperature will not cause the solvent or mixture to decompose, break down, or be converted into an excessive quantity of vapor.

(iv) Tanks or machines of more than 4 square feet of vapor area, used for solvent cleaning or vapor degreasing, shall be equipped with suitable cleanout or sludge doors located near the bottom of each tank or still. These doors shall be so designed and gasketed that there will be no leakage of solvent when they are closed.

(13) Scope.

(i) This paragraph (d) applies to all operations involving the immersion of materials in liquids, or in the vapors of such liquids, for the purpose of cleaning or altering their surfaces, or adding or imparting a finish thereto, or changing the character of the materials, and their subsequent removal from the liquids or vapors, draining, and drying. Such operations include washing, electroplating, anodizing, pickling, quenching, dyeing, dipping, tanning, dressing, bleaching, degreasing, alkaline cleaning, stripping, rinsing, digesting, and other similar operations, but do not include molten materials handling operations, or surface coating operations.

(ii) "Molten materials handling operations" means all operations, other than welding, burning, and soldering operations, involving the use, melting, smelting, or pouring of metals, alloys, salts, or other similar substances in the molten state. Such operations also include heat treating baths, descaling baths, die casting stereotyping, galvanizing, tinning, and similar operations.

(iii) "Surface coating operations" means all operations involving the application of protective, decorative, adhesive, or strengthening coating or impregnation to one or more surfaces, or into the interstices of any object or material, by means of spraying, spreading, flowing, brushing, roll coating, pouring, cementing, or similar means; and any subsequent draining or drying operations, excluding open-tank operations.

1926.58 [Reserved]

1926.59 Hazard communication.

Note: The requirements applicable to construction work under this section are identical to those set forth at [1910.1200](#) of this chapter.

1926.60 Methylenedianiline.

(a) Scope and application.

(1) This section applies to all construction work as defined in 29 CFR 1910.12(b), in which there is exposure to MDA, including but not limited to the following:

(i) Construction, alteration, repair, maintenance, or renovation of structures, substrates, or portions thereof, that contain MDA;

(ii) Installation or the finishing of surfaces with products containing MDA;

(iii) MDA spill/emergency cleanup at construction sites; and

(iv) Transportation, disposal, storage, or containment of MDA or products containing MDA on the site or location at which construction activities are performed.

(2) Except as provided in paragraphs (a)(7) and (f)(5) of this section, this section does not apply to the processing, use, and handling of products containing MDA where initial monitoring indicates that the product is not capable of releasing MDA in excess of the action level under the expected conditions of processing, use, and handling which will cause the greatest possible release; and where no "dermal exposure to MDA" can occur.

(3) Except as provided in paragraph (a)(7) of this section, this section does not apply to the processing, use, and handling of products containing MDA where objective data are reasonably relied upon which demonstrate the product is not capable of releasing MDA under the expected conditions of processing, use, and handling which will cause the greatest possible release; and where no "dermal exposure to MDA" can occur.

(4) Except as provided in paragraph (a)(7) of this section, this section does not apply to the storage, transportation, distribution or sale of MDA in intact containers sealed in such a manner as to contain the MDA dusts, vapors, or liquids, except for the provisions of 29 CFR 1910.1200 and paragraph (e) of this section.

(5) Except as provided in paragraph (a)(7) of this section, this section does not apply to materials in any form which contain less than 0.1% MDA by weight or volume.

(6) Except as provided in paragraph (a)(7) of this section, this section does not apply to "finished articles containing MDA."

(7) Where products containing MDA are exempted under paragraphs (a)(2) through (a)(6) of this section, the employer shall maintain records of the initial monitoring results or objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in the recordkeeping provision of paragraph (o) of this section.

(b) Definitions. For the purpose of this section, the following definitions shall apply:

Action level means a concentration of airborne MDA of 5 ppb as an eight (8)-hour time-weighted average.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically authorized by the employer whose duties

require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (p) of this section, or any other person authorized by the Act or regulations issued under the Act.

Container means any barrel, bottle, can, cylinder, drum, reaction vessel, storage tank, commercial packaging or the like, but does not include piping systems.

Decontamination area means an area outside of but as near as practical to the regulated area, consisting of an equipment storage area, wash area, and clean change area, which is used for the decontamination of workers, materials, and equipment contaminated with MDA.

Dermal exposure to MDA occurs where employees are engaged in the handling, application or use of mixtures or materials containing MDA, with any of the following non-airborne forms of MDA:

(i) Liquid, powdered, granular, or flaked mixtures containing MDA in concentrations greater than 0.1% by weight or volume; and

(ii) Materials other than "finished articles" containing MDA in concentrations greater than 0.1% by weight or volume.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which results in an unexpected and potentially hazardous release of MDA.

Employee exposure means exposure to MDA which would occur if the employee were not using respirators or protective work clothing and equipment.

Finished article containing MDA is defined as a manufactured item:

(i) Which is formed to a specific shape or design during manufacture;

(ii) Which has end use function(s) dependent in whole or part upon its shape or design during end use; and

(iii) Where applicable, is an item which is fully cured by virtue of having been subjected to the conditions (temperature, time) necessary to complete the desired chemical reaction.

Historical monitoring data means monitoring data for construction jobs that meet the following conditions:

(i) The data upon which judgments are based are scientifically sound and were collected using methods that are sufficiently accurate and precise;

(ii) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for

which initial monitoring will not be performed;

(iii) The characteristics of the MDA-containing material being handled when the historical monitoring data were obtained are the same as those on the job for which initial monitoring will not be performed;

(iv) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which initial monitoring will not be performed; and

(v) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception are substantially similar. The data must be scientifically sound, the characteristics of the MDA containing material must be similar and the environmental conditions comparable.

4,4 Methylene-dianiline or MDA means the chemical; 4,4-diaminodiphenylmethane, Chemical Abstract Service Registry number 101-77-9, in the form of a vapor, liquid, or solid. The definition also includes the salts of MDA.

Regulated Areas means areas where airborne concentrations of MDA exceed or can reasonably be expected to exceed, the permissible exposure limits, or where "dermal exposure to MDA" can occur.

STEL means short term exposure limit as determined by any 15-minute sample period.

(c) Permissible exposure limits. The employer shall assure that no employee is exposed to an airborne concentration of MDA in excess of ten parts per billion (10 ppb) as an 8-hour time-weighted average and a STEL of one hundred parts per billion (100 ppb).

(d) Communication among employers. On multi-employer worksites, an employer performing work involving the application of MDA or materials containing MDA for which establishment of one or more regulated areas is required shall inform other employers on the site of the nature of the employer's work with MDA and of the existence of, and requirements pertaining to, regulated areas.

(e) Emergency situations

(1) Written plan.

(i) A written plan for emergency situations shall be developed for each construction operation where there is a possibility of an emergency. The plan shall include procedures where the employer identifies emergency escape routes for his employees at each construction site before the construction operation begins. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with the appropriate personal protective equipment and clothing as required in paragraphs (i) and (j) of this section until the emergency is abated.

(iii) The plan shall specifically include provisions for alerting and evacuating affected employees as well as the applicable elements prescribed in 29 CFR 1910.38,

“Employee emergency plans and fire prevention plans.”

(2) Alerting employees. Where there is the possibility of employee exposure to MDA due to an emergency, means shall be developed to promptly alert employees who have the potential to be directly exposed. Affected employees not engaged in correcting emergency conditions shall be evacuated immediately in the event that an emergency occurs. Means shall also be developed for alerting other employees who may be exposed as a result of the emergency.

(f) Exposure monitoring

(1) General.

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of each employee's exposure to airborne MDA over an eight (8) hour period. Determination of employee exposure to the STEL shall be made from breathing zone air samples collected over a 15 minute sampling period.

(ii) Representative employee exposure shall be determined on the basis of one or more samples representing full shift exposure for each shift for each job classification in each work area where exposure to MDA may occur.

(iii) Where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer shall only be required to determine representative employee exposure for that operation during one shift.

(2) Initial monitoring. Each employer who has a workplace or work operation covered by this standard shall perform initial monitoring to determine accurately the airborne concentrations of MDA to which employees may be exposed unless:

(i) The employer can demonstrate, on the basis of objective data, that the MDA-containing product or material being handled cannot cause exposures above the standard's action level, even under worst-case release conditions; or

(ii) The employer has historical monitoring or other data demonstrating that exposures on a particular job will be below the action level.

(3) Periodic monitoring and monitoring frequency.

(i) If the monitoring required by paragraph (f)(2) of this section reveals employee exposure at or above the action level, but at or below the PELs, the employer shall repeat such monitoring for each such employee at least every six (6) months.

(ii) If the monitoring required by paragraph (f)(2) of this section reveals employee exposure above the PELs, the employer shall repeat such monitoring for each such employee at least every three (3) months.

(iii) Employers who are conducting MDA operations within a regulated area can forego periodic monitoring if the employees are all wearing supplied-air respirators while working in the regulated area.

(iv) The employer may alter the monitoring schedule from every three months to every six months for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee exposure has decreased to below the PELs but above the action level.

(4) Termination of monitoring.

(i) If the initial monitoring required by paragraph (f)(2) of this section reveals employee exposure to be below the action level, the employer may discontinue the monitoring for that employee, except as otherwise required by paragraph (f)(5) of this section.

(ii) If the periodic monitoring required by paragraph (f)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level the employer may discontinue the monitoring for that employee, except as otherwise required by paragraph (f)(5) of this section.

(5) Additional monitoring. The employer shall institute the exposure monitoring required under paragraphs (f)(2) and (f)(3) of this section when there has been a change in production process, chemicals present, control equipment, personnel, or work practices which may result in new or additional exposures to MDA, or when the employer has any reason to suspect a change which may result in new or additional exposures.

(6) Accuracy of monitoring. Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of MDA.

(7) Employee notification of monitoring results.

(i) The employer must, as soon as possible but no later than 5 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) The written notification required by paragraph (f)(7)(i) of this section shall contain the corrective action being taken by the employer or any other protective measures which have been implemented to reduce the employee exposure to or below the PELs, wherever the PELs are exceeded.

(8) Visual monitoring. The employer shall make routine inspections of employee hands, face and forearms potentially exposed to MDA. Other potential dermal exposures reported by the employee must be referred to the appropriate medical personnel for observation. If the employer determines that the employee has been exposed to MDA the employer shall:

(i) Determine the source of exposure;

(ii) Implement protective measures to correct the hazard; and

(iii) Maintain records of the corrective actions in accordance with paragraph (o) of this section.

(g) Regulated areas

(1) Establishment.

(i) Airborne exposures. The employer shall establish regulated areas where airborne concentrations of MDA exceed or can reasonably be expected to exceed, the permissible exposure limits.

(ii) Dermal exposures. Where employees are subject to "dermal exposure to MDA" the employer shall establish those work areas as regulated areas.

(2) Demarcation. Regulated areas shall be demarcated from the rest of the workplace in a manner that minimizes the number of persons potentially exposed.

(3) Access. Access to regulated areas shall be limited to authorized persons.

(4) Personal protective equipment and clothing. Each person entering a regulated area shall be supplied with, and required to use, the appropriate personal protective clothing and equipment in accordance with paragraphs (i) and (j) of this section.

(5) Prohibited activities. The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

(h) Methods of compliance

(1) Engineering controls and work practices and respirators.

(i) The employer shall use one or any combination of the following control methods to achieve compliance with the permissible exposure limits prescribed by paragraph (c) of this section:

(A) Local exhaust ventilation equipped with HEPA filter dust collection systems;

(B) General ventilation systems;

(C) Use of workpractices; or

(D) Other engineering controls such as isolation and enclosure that the Assistant Secretary can show to be feasible.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the PELs, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protective devices which comply with the requirements of paragraph (i) of this section.

(2) Special Provisions. For workers engaged in spray application methods, respiratory protection must be used in addition to feasible engineering controls and work practices to reduce employee exposure to or below the PELs.

(3) Prohibitions. Compressed air shall not be used to remove MDA, unless the compressed air is used in conjunction with an enclosed ventilation system designed to capture the dust cloud created by the compressed air.

(4) Employee rotation. The employer shall not use employee rotation as a means of compliance with the exposure limits prescribed in paragraph (c) of this section.

(5) Compliance program.

(i) The employer shall establish and implement a written program to reduce employee exposure to or below the PELs by means of engineering and work practice controls, as required by paragraph (h)(1) of this section, and by use of respiratory protection where permitted under this section.

(ii) Upon request this written program shall be furnished for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. The employer shall review and, as necessary, update such plans at least once every 12 months to make certain they reflect the current status of the program.

(i) Respiratory protection

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work practice controls.

(ii) Work operations, such as maintenance and repair activities and spray-application processes, for which engineering and work practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the PELs.

(iv) Emergencies.

(2) Respirator program. The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d)(except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(3) Respirator selection.

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide HEPA filters for powered and non-powered air-purifying respirators.

(C) For escape, provide employees with one of the following respirator options: Any self-contained breathing apparatus with a full facepiece or hood operated in the positive-pressure or continuous-flow mode; or a full facepiece air-purifying respirator.

(D) Provide a combination HEPA filter and organic vapor canister or cartridge with air-purifying respirators when MDA is in liquid form or used as part of a process requiring heat.

(ii) An employee who cannot use a negative-pressure respirator must be given the option of using a positive-pressure respirator, or a supplied-air respirator operated in the continuous-flow or pressure-demand mode.

(4) Respirator use.

(i) Where air-purifying respirators (cartridge or canister) are used, the employer shall replace the air purifying element as needed to maintain the effectiveness of the respirator. The employer shall ensure that each cartridge is dated at the beginning of use.

(ii) Employees who wear respirators shall be allowed to leave the regulated area to readjust the face piece or to wash their faces and to wipe clean the face pieces on their respirators in order to minimize potential skin irritation associated with respirator use.

(5) Respirator fit testing.

(i) The employer shall perform and record the results of either quantitative or qualitative fit tests at the time of initial fitting and at least annually thereafter for each employee wearing a negative pressure respirator. The test shall be used to select a respirator facepiece which provides the required protection as prescribed in Table 1.

(ii) The employer shall follow the test protocols outlined in Appendix E of this standard for whichever type of fit testing the employer chooses.

(j) Protective work clothing and equipment

(1) Provision and use. Where employees are subject to dermal exposure to MDA, where liquids containing MDA can be splashed into the eyes, or where airborne concentrations of MDA are in excess of the PEL, the employer shall provide, at no cost to the employee, and ensure that the employee uses, appropriate protective work clothing and equipment which prevent contact with MDA such as, but not limited to:

(i) Aprons, coveralls or other full-body work clothing;

(ii) Gloves, head coverings, and foot coverings; and

(iii) Face shields, chemical goggles; or

(iv) Other appropriate protective equipment which comply with 29 CFR

1910.133.

(2) Removal and storage.

(i) The employer shall ensure that, at the end of their work shift, employees remove MDA-contaminated protective work clothing and equipment that is not routinely removed throughout the day in change areas provided in accordance with the provisions in paragraph (k) of this section.

(ii) The employer shall ensure that, during their work shift, employees remove all other MDA-contaminated protective work clothing or equipment before leaving a regulated area.

(iii) The employer shall ensure that no employee takes MDA-contaminated work clothing or equipment out of the decontamination areas, except those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(iv) MDA-contaminated work clothing or equipment shall be placed and stored and transported in sealed, impermeable bags, or other closed impermeable containers.

(v) Containers of MDA-contaminated protective work clothing or equipment which are to be taken out of decontamination areas or the workplace for cleaning, maintenance, or disposal, shall bear labels warning of the hazards of MDA.

(3) Cleaning and replacement.

(i) The employer shall provide the employee with clean protective clothing and equipment. The employer shall ensure that protective work clothing or equipment required by this paragraph is cleaned, laundered, repaired, or replaced at intervals appropriate to maintain its effectiveness.

(ii) The employer shall prohibit the removal of MDA from protective work clothing or equipment by blowing, shaking, or any methods which allow MDA to re-enter the workplace.

(iii) The employer shall ensure that laundering of MDA-contaminated clothing shall be done so as to prevent the release of MDA in the workplace.

(iv) Any employer who gives MDA-contaminated clothing to another person for laundering shall inform such person of the requirement to prevent the release of MDA.

(v) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with MDA of the potentially harmful effects of exposure.

(4) Visual Examination.

(i) The employer shall ensure that employees' work clothing is examined periodically for rips or tears that may occur during performance of work.

(ii) When rips or tears are detected, the protective equipment or clothing shall be repaired and replaced immediately.

(k) Hygiene facilities and practices

(1) General.

(i) The employer shall provide decontamination areas for employees required to work in regulated areas or required by paragraph (j)(1) of this section to wear protective clothing. Exception: In lieu of the decontamination area requirement specified in paragraph (k)(1)(i) of this section, the employer may permit employees engaged in small scale, short duration operations, to clean their protective clothing or dispose of the protective clothing before such employees leave the area where the work was performed.

(ii) Change areas. The employer shall ensure that change areas are equipped with separate storage facilities for protective clothing and street clothing, in accordance with 29 CFR 1910.141(e).

(iii) Equipment area. The equipment area shall be supplied with impermeable, labeled bags and containers for the containment and disposal of contaminated protective clothing and equipment.

(2) Shower area.

(i) Where feasible, shower facilities shall be provided which comply with 29 CFR 1910.141(d)(3) wherever the possibility of employee exposure to airborne levels of MDA in excess of the permissible exposure limit exists.

(ii) Where dermal exposure to MDA occurs, the employer shall ensure that materials spilled or deposited on the skin are removed as soon as possible by methods which do not facilitate the dermal absorption of MDA.

(3) Lunch Areas.

(i) Whenever food or beverages are consumed at the worksite and employees are exposed to MDA the employer shall provide clean lunch areas where MDA levels are below the action level and where no dermal exposure to MDA can occur.

(ii) The employer shall ensure that employees wash their hands and faces with soap and water prior to eating, drinking, smoking, or applying cosmetics.

(iii) The employer shall ensure that employees do not enter lunch facilities with contaminated protective work clothing or equipment.

(l) Communication of hazards to employees

(1) ~~Signs and labels.~~

~~_____ (i) The employer shall post and maintain legible signs demarcating regulated areas and entrances or accessways to regulated areas that bear the following legend:~~

~~DANGER
MDA~~

~~MAY CAUSE CANCER
LIVER TOXIN
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN
THIS AREA~~

~~_____ (ii) The employer shall ensure that labels or other appropriate forms of warning are provided for containers of MDA within the workplace. The labels shall comply with the requirements of 29 CFR 1910.1200(f) and shall include one of the following legends:~~

~~_____ (A) For pure MDA~~

~~DANGER
CONTAINS MDA
MAY CAUSE CANCER
LIVER TOXIN~~

~~_____ (B) For mixtures containing MDA~~

~~DANGER
CONTAINS MDA
CONTAINS MATERIALS WHICH MAY CAUSE CANCER
LIVER TOXIN~~

Hazard communication. The employer shall include Methylenedianiline (MDA) in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of MDA and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (1)(3) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; liver effects; and skin sensitization.

~~(2) Material safety data sheets (MSDS). Employers shall obtain or develop, and shall provide access to their employees, to a material safety data sheet (MSDS) for MDA. Signs and labels—~~

~~(i) Signs.~~

~~_____ (A) The employer shall post and maintain legible signs demarcating regulated areas and entrances or access-ways to regulated areas that bear the following legend:~~

~~DANGER
MDA
MAY CAUSE CANCER
CAUSES DAMAGE TO THE LIVER
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN
THIS AREA
AUTHORIZED PERSONNEL ONLY~~

~~_____ (B) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (1)(2)(i)(A) of this section:~~

DANGER
MDA
MAY CAUSE CANCER
LIVER TOXIN
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN

(ii) Labels.

(A) The employer shall ensure that labels or other appropriate forms of warning are provided for containers of MDA within the workplace. The labels shall comply with the requirements of § 1910.1200(f) and shall include at least the following information for pure MDA and mixtures containing MDA:

DANGER
CONTAINS MDA
MAY CAUSE CANCER
CAUSES DAMAGE TO THE LIVER

(B) Prior to June 1, 2015, employers may include the following information workplace labels in lieu of the labeling requirements in paragraph (1)(2)(ii)(A) of this section:

(1) For Pure MDA:

DANGER
CONTAINS MDA
MAY CAUSE CANCER
LIVER TOXIN

(2) For mixtures containing MDA:

DANGER
CONTAINS MDA
CONTAINS MATERIALS WHICH MAY CAUSE CANCER
LIVER TOXIN

(3) Information and training.

(i) The employer shall provide employees with information and training on MDA, in accordance with 29 CFR 1910.1200(h), at the time of initial assignment and at least annually thereafter.

(ii) In addition to the information required under 29 CFR 1910.1200, the employer shall:

(A) Provide an explanation of the contents of this section, including appendices A and B of this section, and indicate to employees where a copy of the standard is available;

(B) Describe the medical surveillance program required under paragraph (n) of this section, and explain the information contained in appendix C of this section; and

(C) Describe the medical removal provision required under paragraph (n) of this section.

(4) Access to training materials.

(i) The employer shall make readily available to all affected employees, without cost, all written materials relating to the employee training program, including a copy of this regulation.

(ii) The employer shall provide to the Assistant Secretary and the Director, upon request, all information and training materials relating to the employee information and training program.

(m) Housekeeping.

(1) All surfaces shall be maintained as free as practicable of visible accumulations of MDA.

(2) The employer shall institute a program for detecting MDA leaks, spills, and discharges, including regular visual inspections of operations involving liquid or solid MDA.

(3) All leaks shall be repaired and liquid or dust spills cleaned up promptly.

(4) Surfaces contaminated with MDA may not be cleaned by the use of compressed air.

(5) Shoveling, dry sweeping, and other methods of dry clean-up of MDA may be used where HEPA filtered vacuuming and/or wet cleaning are not feasible or practical.

(6) Waste, scrap, debris, bags, containers, equipment, and clothing contaminated with MDA shall be collected and disposed of in a manner to prevent the re-entry of MDA into the workplace.

(n) Medical surveillance

(1) General.

(2) Initial examinations.

(i) Within 150 days of the effective date of this standard, or before the time of initial assignment, the employer shall provide each employee covered by paragraph (n)(1)(i) of this section with a medical examination including the following elements:

(A) A detailed history which includes:

(1) Past work exposure to MDA or any other toxic substances;

(2) A history of drugs, alcohol, tobacco, and medication routinely taken (duration and quantity); and

(3) A history of dermatitis, chemical skin sensitization, or previous hepatic disease.

(B) A physical examination which includes all routine physical examination parameters, skin examination, and examination for signs of liver disease.

(C) Laboratory tests including:

(1) Liver function tests and

(2) Urinalysis.

(D) Additional tests as necessary in the opinion of the physician.

(ii) No initial medical examination is required if adequate records show that the employee has been examined in accordance with the requirements of this section within the previous six months prior to the effective date of this standard or prior to the date of initial assignment.

(3) Periodic examinations.

(i) The employer shall provide each employee covered by this section with a medical examination at least annually following the initial examination. These periodic examinations shall include at least the following elements:

(A) A brief history regarding any new exposure to potential liver toxins, changes in drug, tobacco, and alcohol intake, and the appearance of physical signs relating to the liver, and the skin;

(B) The appropriate tests and examinations including liver function tests and skin examinations; and

(C) Appropriate additional tests or examinations as deemed necessary by the physician.

(ii) If in the physician's opinion the results of liver function tests indicate an abnormality, the employee shall be removed from further MDA exposure in accordance with paragraph (n)(9) of this section. Repeat liver function tests shall be conducted on advice of the physician.

(4) Emergency examinations. If the employer determines that the employee has been exposed to a potentially hazardous amount of MDA in an emergency situation under paragraph (e) of this section, the employer shall provide medical examinations in accordance with paragraphs (n)(3) (i) and (ii) of this section. If the results of liver function testing indicate an abnormality, the employee shall be removed in accordance with paragraph (n)(9) of this section. Repeat liver function tests shall be conducted on the advice of the physician. If the results of the tests are normal, tests must be repeated two to three weeks from the initial testing. If the results of the second set of tests are normal and on the advice of the physician, no additional testing is required.

(5) Additional examinations. Where the employee develops signs and symptoms

associated with exposure to MDA, the employer shall provide the employee with an additional medical examination including liver function tests. Repeat liver function tests shall be conducted on the advice of the physician. If the results of the tests are normal, tests must be repeated two to three weeks from the initial testing. If the results of the second set of tests are normal and on the advice of the physician, no additional testing is required.

(6) Multiple physician review mechanism.

(i) If the employer selects the initial physician who conducts any medical examination or consultation provided to an employee under this section, and the employee has signs or symptoms of occupational exposure to MDA (which could include an abnormal liver function test), and the employee disagrees with the opinion of the examining physician, and this opinion could affect the employee's job status, the employee may designate an appropriate and mutually acceptable second physician:

(A) To review any findings, determinations or recommendations of the initial physician; and

(B) To conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

(ii) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation pursuant to this section. The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the foregoing notification, or receipt of the initial physician's written opinion, whichever is later:

(A) The employee informing the employer that he or she intends to seek a second medical opinion, and

(B) The employee initiating steps to make an appointment with a second physician.

(iii) If the findings, determinations, or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve any disagreement.

(iv) If the two physicians have been unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician:

(A) To review any findings, determinations, or recommendations of the prior physicians; and

(B) To conduct such examinations, consultations, laboratory tests, and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(v) The employer shall act consistent with the findings, determinations, and

recommendations of the second physician, unless the employer and the employee reach a mutually acceptable agreement.

(7) Information provided to the examining physician.

(i) The employer shall provide the following information to the examining physician:

- (A) A copy of this regulation and its appendices;
- (B) A description of the affected employee's duties as they relate to the employee's potential exposure to MDA;
- (C) The employee's current actual or representative MDA exposure level;
- (D) A description of any personal protective equipment used or to be used; and
- (E) Information from previous employment related medical examinations of the affected employee.

(ii) The employer shall provide the foregoing information to a second physician under this section upon request either by the second physician, or by the employee.

(8) Physician's written opinion.

(i) For each examination under this section, the employer shall obtain, and provide the employee with a copy of, the examining physician's written opinion within 15 days of its receipt. The written opinion shall include the following:

- (A) The occupationally pertinent results of the medical examination and tests;
- (B) The physician's opinion concerning whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of health from exposure to MDA;
- (C) The physician's recommended limitations upon the employee's exposure to MDA or upon the employee's use of protective clothing or equipment and respirators; and
- (D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from MDA exposure which require further explanation or treatment.

(ii) The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposures.

(9) Medical removal

(i) Temporary medical removal of an employee

(A) Temporary removal resulting from occupational exposure. The employee shall be removed from work environments in which exposure to MDA is at or above the action level or where dermal exposure to MDA may occur, following an initial examination (paragraph (n)(2) of this section), periodic examinations (paragraph (n)(3) of this section), an emergency situation (paragraph (n)(4) of this section), or an additional examination (paragraph (n)(5) of this section) in the following circumstances:

(1) When the employee exhibits signs and/or symptoms indicative of acute exposure to MDA; or

(2) When the examining physician determines that an employee's abnormal liver function tests are not associated with MDA exposure but that the abnormalities may be exacerbated as a result of occupational exposure to MDA.

(B) Temporary removal due to a final medical determination.

(1) The employer shall remove an employee from work having an exposure to MDA at or above the action level or where the potential for dermal exposure exists on each occasion that a final medical determination results in a medical finding, determination, or opinion that the employee has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to MDA.

(2) For the purposes of this section, the phrase "final medical determination" shall mean the outcome of the physician review mechanism used pursuant to the medical surveillance provisions of this section.

(3) Where a final medical determination results in any recommended special protective measures for an employee, or limitations on an employee's exposure to MDA, the employer shall implement and act consistent with the recommendation.

(ii) Return of the employee to former job status.

(A) The employer shall return an employee to his or her former job status:

(1) When the employee no longer shows signs or symptoms of exposure to MDA, or upon the advice of the physician.

(2) When a subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to MDA.

(B) For the purposes of this section, the requirement that an employer return an employee to his or her former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

(iii) Removal of other employee special protective measure or limitations. The employer shall remove any limitations placed on an employee or end any special protective

measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

(iv) Employer options pending a final medical determination. Where the physician review mechanism used pursuant to the medical surveillance provisions of this section, has not yet resulted in a final medical determination with respect to an employee, the employer shall act as follows:

(A) Removal. The employer may remove the employee from exposure to MDA, provide special protective measures to the employee, or place limitations upon the employee, consistent with the medical findings, determinations, or recommendations of the physician who has reviewed the employee's health status.

(B) Return. The employer may return the employee to his or her former job status, and end any special protective measures provided to the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions:

(1) If the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician; or

(2) The employee has been on removal status for the preceding six months as a result of exposure to MDA, then the employer shall await a final medical determination.

(v) Medical removal protection benefits

(A) Provisions of medical removal protection benefits. The employer shall provide to an employee up to six (6) months of medical removal protection benefits on each occasion that an employee is removed from exposure to MDA or otherwise limited pursuant to this section.

(B) Definition of medical removal protection benefits. For the purposes of this section, the requirement that an employer provide medical removal protection benefits means that the employer shall maintain the earnings, seniority, and other employment rights and benefits of an employee as though the employee had not been removed from normal exposure to MDA or otherwise limited.

(C) Follow-up medical surveillance during the period of employee removal or limitations. During the period of time that an employee is removed from normal exposure to MDA or otherwise limited, the employer may condition the provision of medical removal protection benefits upon the employee's participation in follow-up medical surveillance made available pursuant to this section.

(D) Workers' compensation claims. If a removed employee files a claim for workers' compensation payments for a MDA-related disability, then the employer shall continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation shall be reduced by such amount. The

employer shall receive no credit for workers' compensation payments received by the employee for treatment-related expenses.

(E) Other credits. The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from employment with any employer made possible by virtue of the employee's removal.

(F) Employees who do not recover within the 6 months of removal. The employer shall take the following measures with respect to any employee removed from exposure to MDA:

(1) The employer shall make available to the employee a medical examination pursuant to this section to obtain a final medical determination with respect to the employee;

(2) The employer shall assure that the final medical determination obtained indicates whether or not the employee may be returned to his or her former job status, and, if not, what steps should be taken to protect the employee's health;

(3) Where the final medical determination has not yet been obtained, or once obtained indicates that the employee may not yet be returned to his or her former job status, the employer shall continue to provide medical removal protection benefits to the employee until either the employee is returned to former job status, or a final medical determination is made that the employee is incapable of ever safely returning to his or her former job status; and

(4) Where the employer acts pursuant to a final medical determination which permits the return of the employee to his or her former job status despite what would otherwise be an unacceptable liver function test, later questions concerning removing the employee again shall be decided by a final medical determination. The employer need not automatically remove such an employee pursuant to the MDA removal criteria provided by this section.

(vi) Voluntary removal or restriction of an employee. Where an employer, although not required by this section to do so, removes an employee from exposure to MDA or otherwise places limitations on an employee due to the effects of MDA exposure on the employee's medical condition, the employer shall provide medical removal protection benefits to the employee equal to that required by paragraph (n)(9)(v) of this section.

(o) Recordkeeping

(1) Objective data for exempted operations.

(i) Where the employer has relied on objective data that demonstrate that products made from or containing MDA are not capable of releasing MDA or do not present a dermal exposure problem under the expected conditions of processing, use, or handling to exempt such operations from the initial monitoring requirements under paragraph (f)(2) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

(ii) The record shall include at least the following information:

- (A) The product qualifying for exemption;
- (B) The source of the objective data;
- (C) The testing protocol, results of testing, and/or analysis of the material for the release of MDA;
- (D) A description of the operation exempted and how the data support the exemption; and
- (E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) Historical monitoring data.

(i) Where the employer has relied on historical monitoring data that demonstrate that exposures on a particular job will be below the action level to exempt such operations from the initial monitoring requirements under paragraph (f)(2) of this section, the employer shall establish and maintain an accurate record of historical monitoring data reasonably relied upon in support of the exception.

(ii) The record shall include information that reflect the following conditions:

(A) The data upon which judgments are based are scientifically sound and were collected using methods that are sufficiently accurate and precise;

(B) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which initial monitoring will not be performed;

(C) The characteristics of the MDA-containing material being handled when the historical monitoring data were obtained are the same as those on the job for which initial monitoring will not be performed;

(D) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which initial monitoring will not be performed; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such historical monitoring data.

(3) The employer may utilize the services of competent organizations such as industry trade associations and employee associations to maintain the records required by this section.

(4) Exposure measurements.

(i) The employer shall keep an accurate record of all measurements taken to monitor employee exposure to MDA.

(ii) This record shall include at least the following information:

- (A) The date of measurement;
- (B) The operation involving exposure to MDA;
- (C) Sampling and analytical methods used and evidence of their accuracy;
- (D) Number, duration, and results of samples taken;
- (E) Type of protective devices worn, if any; and
- (F) Name, social security number, and exposure of the employees whose exposures are represented.

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.33

(5) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (n) of this section, in accordance with 29 CFR 1910.33

(ii) The record shall include at least the following information:

- (A) The name and social security number of the employee;
- (B) A copy of the employee's medical examination results, including the medical history, questionnaire responses, results of any tests, and physician's recommendations.
- (C) Physician's written opinions;
- (D) Any employee medical complaints related to exposure to MDA; and
- (E) A copy of the information provided to the physician as required by paragraph (n) of this section.

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.33

(iv) A copy of the employee's medical removal and return to work status.

(6) Training records. The employer shall maintain all employee training records for one (1) year beyond the last date of employment.

(7) Availability.

(i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying.

(ii) The employer, upon request, shall make any exposure records required by paragraphs (f) and (n) of this section available for examination and copying to affected employees, former employees, designated representatives, and the Assistant Secretary, in accordance with 29 CFR 1910.33(a)-(e) and (g)-(i).

(iii) The employer, upon request, shall make employee medical records required by paragraphs (n) and (o) of this section available for examination and copying to the subject employee, anyone having the specific written consent of the subject employee, and the Assistant Secretary, in accordance with 29 CFR 1910.33

(8) Transfer of records. The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

(p) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees, or their designated representatives, an opportunity to observe the measuring or monitoring of employee exposure to MDA conducted pursuant to paragraph (f) of this section.

(2) Observation procedures. When observation of the measuring or monitoring of employee exposure to MDA requires entry into areas where the use of protective clothing and equipment or respirators is required, the employer shall provide the observer with personal protective clothing and equipment or respirators required to be worn by employees working in the area, assure the use of such clothing and equipment or respirators, and require the observer to comply with all other applicable safety and health procedures.

(q) Appendices. The information contained in appendices A, B, C and D of this section is not intended, by itself, to create any additional obligations not otherwise imposed by this standard nor detract from any existing obligation.

Appendix A to Section 1926.60-Substance Data Sheet, for 4-4'-Methylenedianiline

Note: The requirements applicable to construction work under this Appendix A are identical to those set forth in Appendix A to [1910.1050](#) of this chapter.

Appendix B to Section 1926.60-Substance Technical Guidelines, MDA

Note: The requirements applicable to construction work under this Appendix B are identical to those set forth in Appendix B to [1910.1050](#) of this chapter.

Appendix C to Section 1926.60-Medical Surveillance Guidelines for MDA

Note: The requirements applicable to construction work under this Appendix B are identical to those set forth in Appendix C to [1910.1050](#) of this chapter.

Appendix D Section 1926.60-Sampling and Analytical Methods for MDA Monitoring and Measurement Procedures

Note: The requirements applicable to construction work under this Appendix B are identical to those set forth in Appendix D to [1910.1050](#) of this chapter.

Appendix E to Section 1926.60-Qualitative and Quantitative Fit Testing Procedures [Removed]

1926.61 Retention of DOT markings, placards and labels.

Note: The requirements applicable to construction work under this section are identical to those set forth at [1910.1201](#) of this chapter.

1926.62 Lead

(a) Scope. This section applies to all construction work where an employee may be occupationally exposed to lead. All construction work excluded from coverage in the general industry standard for lead by 29 CFR 1910.1025(a)(2) is covered by this standard. Construction work is defined as work for construction, alteration and/or repair, including painting and decorating. It includes but is not limited to the following:

- (1) Demolition or salvage of structures where lead or materials containing lead are present;
- (2) Removal or encapsulation of materials containing lead;
- (3) New construction, alteration, repair, or renovation of structures, substrates, or portions thereof, that contain lead, or materials containing lead;
- (4) Installation of products containing lead;
- (5) Lead contamination/emergency cleanup;
- (6) Transportation, disposal, storage, or containment of lead or materials containing lead on the site or location at which construction activities are performed, and
- (7) Maintenance operations associated with the construction activities described in this paragraph.

(b) Definitions.

Action level means employee exposure, without regard to the use of respirators, to an

airborne concentration of lead of 30 micrograms per cubic meter of air (30 :g/m³) calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Competent person means one who is capable of identifying existing and predictable lead hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them.

Director means the Director, National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Lead means metallic lead, all inorganic lead compounds, and organic lead soaps. Excluded from this definition are all other organic lead compounds.

This section means this standard.

(c) Permissible exposure limit.

(1) The employer shall assure that no employee is exposed to lead at concentrations greater than fifty micrograms per cubic meter of air (50 :g/m³) averaged over an 8-hour period.

(2) If an employee is exposed to lead for more than 8 hours in any work day the employees' allowable exposure, as a time weighted average (TWA) for that day, shall be reduced according to the following formula:

Allowable employee exposure (in :g/m³)=400 divided by hours worked in the day.

(3) When respirators are used to limit employee exposure as required under paragraph (c) of this section and all the requirements of paragraphs (e)(1) and (f) of this section have been met, employee exposure may be considered to be at the level provided by the protection factor of the respirator for those periods the respirator is worn. Those periods may be averaged with exposure levels during periods when respirators are not worn to determine the employee's daily TWA exposure.

(d) Exposure assessment

(1) General.

(i) Each employer who has a workplace or operation covered by this standard shall initially determine if any employee may be exposed to lead at or above the action level.

(ii) For the purposes of paragraph (d) of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(iii) With the exception of monitoring under paragraph (d)(3), where monitoring is required under this section, the employer shall collect personal samples representative of a full shift including at least one sample for each job classification in each work area either for each shift or for the shift with the highest exposure level.

(iv) Full shift personal samples shall be representative of the monitored employee's regular, daily exposure to lead.

(2) Protection of employees during assessment of exposure.

(i) With respect to the lead related tasks listed in paragraph (d)(2)(i) of this section, where lead is present, until the employer performs an employee exposure assessment as required in paragraph (d) of this section and documents that the employee performing any of the listed tasks is not exposed above the PEL, the employer shall treat the employee as if the employee were exposed above the PEL, and not in excess of ten (10) times the PEL, and shall implement employee protective measures prescribed in paragraph (d)(2)(v) of this section. The tasks covered by this requirement are:

(A) Where lead containing coatings or paint are present: Manual demolition of structures (e.g. dry wall), manual scraping, manual sanding, heat gun applications, and power tool cleaning with dust collection systems;

(B) Spray painting with lead paint

(ii) In addition, with regard to tasks not listed in paragraph (d)(2)(i), where the employee has any reason to believe that an employee performing the task may be exposed to lead in excess of the PEL, until the employer performs an employee exposure assessment as required by paragraph (d) of this section and documents that the employee's lead exposure is not above the PEL the employer shall treat the employee as if the employee were exposed above the PEL and shall implement employee protective measures as prescribed in paragraph (d)(2)(v) of this section.

(iii) With respect to the tasks listed in paragraph (d)(2)(iii) of this section, where lead is present, until the employer performs an employee exposure assessment as required in paragraph (d) of this section, and documents that the employee performing any of the listed tasks is not exposed in excess of 500 :g/m³, the employer shall treat the employee as if the employee were exposed to lead in excess of 500 :g/m³ and shall implement employee protective measures as prescribed in paragraph (d)(2)(v) of this section. Where the employer does establish that the employee is exposed to levels of lead below 500 :g/m³, the employer may provide the exposed employee with the appropriate respirator prescribed for such use at such lower exposures, in accordance with Table 1 of this section. The tasks covered by this requirement are:

(A) Using lead containing mortar; lead burning

(B) Where lead containing coatings or paint are present: rivet busting; power tool cleaning without dust collection systems; cleanup activities where dry expendable abrasives are used; and abrasive blasting enclosure movement and removal.

(iv) With respect to the tasks listed in paragraph (d)(2)(iv) of this section, where lead is present, until the employer performs an employee exposure assessment as required in paragraph (d) of this section and documents that the employee performing any of the listed tasks is not exposed to lead in excess of 2,500 :g/m³ (50PEL), the employer shall treat the employee as if the employee were exposed to lead in excess of 2,500 :g/m³ and shall implement employee protective measures as prescribed in paragraph (d)(2)(v) of this section. Where the employer

does establish that the employee is exposed to levels of lead below 2,500 $\mu\text{g}/\text{m}^3$, the employer may provide the exposed employee with the appropriate respirator prescribed for use at such lower exposures, in accordance with Table I of this section. Interim protection as described in this paragraph is required where lead containing coatings or paint are present on structures when performing:

- (A) Abrasive blasting,
- (B) Welding,
- (C) Cutting, and
- (D) Torch burning.

(v) Until the employer performs an employee exposure assessment as required under paragraph (d) of this section and determines actual employee exposure, the employer shall provide to employees performing the tasks described in paragraphs (d)(2)(i), (d)(2)(ii), (d)(2)(iii), and (d)(2)(iv) of this section with interim protection as follows:

(A) Appropriate respiratory protection in accordance with paragraph (f) of this section.

(B) Appropriate personal protective clothing and equipment in accordance with paragraph (g) of this section.

(C) Change areas in accordance with paragraph (i)(2) of this section.

(D) Hand washing facilities in accordance with paragraph (i)(5) of this section.

(E) Biological monitoring in accordance with paragraph (j)(1)(i) of this section, to consist of blood sampling and analysis for lead and zinc protoporphyrin levels, and

(F) Training as required under paragraph (l)(1)(i) of this section regarding 29 CFR 1926.59, Hazard Communication; training as required under paragraph (1)(2)(iii) of this section, regarding use of respirators; and training in accordance with 29 CFR 1926.21, Safety training and education.

(3) Basis of initial determination.

(i) Except as provided under paragraphs (d)(3)(iii) and (d)(3)(iv) of this section the employer shall monitor employee exposures and shall base initial determinations on the employee exposure monitoring results and any of the following, relevant considerations:

(A) Any information, observations, or calculations which would indicate employee exposure to lead;

(B) Any previous measurements of airborne lead; and

(C) Any employee complaints of symptoms which may be attributable to

exposure to lead.

(ii) Monitoring for the initial determination where performed may be limited to a representative sample of the exposed employees who the employer reasonably believes are exposed to the greatest airborne concentrations of lead in the workplace.

(iii) Where the employer has previously monitored for lead exposures, and the data were obtained within the past 12 months during work operations conducted under workplace conditions closely resembling the processes, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraphs (d)(3)(i) and (d)(6) of this section if the sampling and analytical methods meet the accuracy and confidence levels of paragraph (d)(10) of this section.

(iv) Where the employer has objective data, demonstrating that a particular product or material containing lead or a specific process, operation or activity involving lead cannot result in employee exposure to lead at or above the action level during processing, use, or handling, the employer may rely upon such data instead of implementing initial monitoring.

(A) The employer shall establish and maintain an accurate record documenting the nature and relevancy of objective data as specified in paragraph (n)(4) of this section, where used in assessing employee exposure in lieu of exposure monitoring.

(B) Objective data, as described in paragraph (d)(3)(iv) of this section, is not permitted to be used for exposure assessment in connection with paragraph (d)(2) of this section.

(4) Positive initial determination and initial monitoring.

(i) Where a determination conducted under paragraphs (d)(1), (2) and (3) of this section shows the possibility of any employee exposure at or above the action level the employer shall conduct monitoring which is representative of the exposure for each employee in the workplace who is exposed to lead.

(ii) Where the employer has previously monitored for lead exposure, and the data were obtained within the past 12 months during work operations conducted under workplace conditions closely resembling the processes, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(4)(i) of this section if the sampling and analytical methods meet the accuracy and confidence levels of paragraph (d)(10) of this section.

(5) Negative initial determination. Where a determination, conducted under paragraphs (d)(1), (2), and (3) of this section is made that no employee is exposed to airborne concentrations of lead at or above the action level the employer shall make a written record of such determination. The record shall include at least the information specified in paragraph (d)(3)(i) of this section and shall also include the date of determination, location within the worksite, and the name and social security number of each employee monitored.

(6) Frequency.

(i) If the initial determination reveals employee exposure to be below the action level further exposure determination need not be repeated except as otherwise provided in paragraph (d)(7) of this section.

(ii) If the initial determination or subsequent determination reveals employee exposure to be at or above the action level but at or below the PEL the employer shall perform monitoring in accordance with this paragraph at least every 6 months. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level at which time the employer may discontinue monitoring for that employee except as otherwise provided in paragraph (d)(7) of this section.

(iii) If the initial determination reveals that employee exposure is above the PEL the employer shall perform monitoring quarterly. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are at or below the PEL but at or above the action level at which time the employer shall repeat monitoring for that employee at the frequency specified in paragraph (d)(6)(ii) of this section, except as otherwise provided in paragraph (d)(7) of this section. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level at which time the employer may discontinue monitoring for that employee except as otherwise provided in paragraph (d)(7) of this section.

(7) Additional exposure assessments. Whenever there has been a change of equipment, process, control, personnel or a new task has been initiated that may result in additional employees being exposed to lead at or above the action level or may result in employees already exposed at or above the action level being exposed above the PEL, the employer shall conduct additional monitoring in accordance with this paragraph.

(8) Employee notification.

(i) The employer must, as soon as possible but no later than 5 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) Whenever the results indicate that the representative employee exposure, without regard to respirators, is at or above the PEL the employer shall include in the written notice a statement that the employees exposure was at or above that level and a description of the corrective action taken or to be taken to reduce exposure to below that level.

(9) Accuracy of measurement. The employer shall use a method of monitoring and analysis which has an accuracy (to a confidence level of 95%) of not less than plus or minus 25 percent for airborne concentrations of lead equal to or greater than 30:g/m.

(e) Methods of compliance

(1) Engineering and work practice controls. The employer shall implement engineering and work practice controls, including administrative controls, to reduce and maintain employee exposure to lead to or below the permissible exposure limit to the extent that such controls are feasible. Wherever all feasible engineering and work practices controls that can be instituted are not sufficient to reduce employee exposure to or below the permissible exposure limit prescribed

in paragraph (c) of this section, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (f) of this section.

(2) Compliance program.

(i) Prior to commencement of the job each employer shall establish and implement a written compliance program to achieve compliance with paragraph (c) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each activity in which lead is emitted; e.g. equipment used, material involved, controls in place, crew size, employee job responsibilities, operating procedures and maintenance practices;

(B) A description of the specific means that will be employed to achieve compliance and, where engineering controls are required engineering plans and studies used to determine methods selected for controlling exposure to lead;

(C) A report of the technology considered in meeting the PEL;

(D) Air monitoring data which documents the source of lead emissions;

(E) A detailed schedule for implementation of the program, including documentation such as copies of purchase orders for equipment, construction contracts, etc.;

(F) A work practice program which includes items required under paragraphs (g), (h) and (i) of this section and incorporates other relevant work practices such as those specified in paragraph (e)(5) of this section;

(G) An administrative control schedule required by paragraph (e)(4) of this section, if applicable;

(H) A description of arrangements made among contractors on multi-contractor sites with respect to informing affected employees of potential exposure to lead and with respect to responsibility for compliance with this section as set-forth in 1926.16.

(I) Other relevant information.

(iii) The compliance program shall provide for frequent and regular inspections of job sites, materials, and equipment to be made by a competent person.

(iv) Written programs shall be submitted upon request to any affected employee or authorized employee representatives, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary and the Director.

(v) Written programs must be revised and updated at least annually to reflect the current status of the program.

(3) Mechanical ventilation. When ventilation is used to control lead exposure, the employer shall evaluate the mechanical performance of the system in controlling exposure as necessary to maintain its effectiveness.

(4) Administrative controls. If administrative controls are used as a means of reducing employees TWA exposure to lead, the employer shall establish and implement a job rotation schedule which includes:

(i) Name or identification number of each affected employee;

(ii) Duration and exposure levels at each job or work station where each affected employee is located; and

(iii) Any other information which may be useful in assessing the reliability of administrative controls to reduce exposure to lead.

(5) The employer shall ensure that, to the extent relevant, employees follow good work practices such as described in Appendix B of this section.

(f) Respiratory protection

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:

(i) Periods when an employees's exposure to lead exceeds the PEL;

(ii) Work operations for which engineering controls and work- practices are not sufficient to reduce exposures to or below the PEL;

(iii) Periods when an employee requests a respirator.

(iv) Periods when respirators are required to provide interim protection of employees while they perform the operations specified in paragraph (d)(2) of this section.

(2) Respirator program.

(i) The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) If an employee has breathing difficulty during fit testing or respirator use, the employer must provide the employee with a medical examination in accordance with paragraph (j)(3)(i)(B) of this section to determine whether or not the employee can use a respirator while performing the required duty.

(3) Respirator selection.

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with a full facepiece respirator instead of a half mask respirator for protection against lead aerosols that may cause eye or skin irritation at the use concentrations.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.

(ii) The employer must provide a powered air-purifying respirator when an employee chooses to use such a respirator and it will provide adequate protection to the employee.

(g) Protective work clothing and equipment

(1) Provision and use. Where an employee is exposed to lead above the PEL without regard to the use of respirators, where employees are exposed to lead compounds which may cause skin or eye irritation (e.g. lead arsenate, lead azide), and as interim protection for employees performing tasks as specified in paragraph (d)(2) of this section, the employer shall provide at no cost to the employee and assure that the employee uses appropriate protective work clothing and equipment that prevents contamination of the employee and the employee's garments such as, but not limited to:

(i) Coveralls or similar full-body work clothing;

(ii) Gloves, hats, and shoes or disposable shoe coverlets; and

(iii) Face shields, vented goggles, or other appropriate protective equipment which complies with 1910.133 of this chapter.

(2) Cleaning and replacement.

(i) The employer shall provide the protective clothing required in paragraph (g)(1) of this section in a clean and dry condition at least weekly, and daily to employees whose exposure levels without regard to a respirator are over 200 $\mu\text{g}/\text{m}^3$ of lead as an 8-hour TWA.

(ii) The employer shall provide for the cleaning, laundering, and disposal of protective clothing and equipment required by paragraph (g)(1) of this section.

(iii) The employer shall repair or replace required protective clothing and equipment as needed to maintain their effectiveness.

(iv) The employer shall assure that all protective clothing is removed at the completion of a work shift only in change areas provided for that purpose as prescribed in paragraph (i)(2) of this section.

(v) The employer shall assure that contaminated protective clothing which is to be cleaned, laundered, or disposed of, is placed in a closed container in the change area which prevents dispersion of lead outside the container.

(vi) The employer shall inform in writing any person who cleans or launders protective clothing or equipment of the potentially harmful effects of exposure to lead.

~~(vii) The employer shall assure that the containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) of this section are labelled as follows:~~

~~_____ Caution: Clothing contaminated with lead. Do not remove dust by blowing or shaking. Dispose of lead contaminated wash water in accordance with applicable local, state, or federal regulations. (A) The employer shall ensure that the containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) of this section are labeled as follows:~~

DANGER: CLOTHING AND EQUIPMENT CONTAMINATED WITH LEAD. MAY DAMAGE FERTILITY OR THE UNBORN CHILD. CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM. DO NOT EAT, DRINK OR SMOKE WHEN HANDLING. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

(B) Prior to June 1, 2015, employers may include the following information on bags or containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) in lieu of the labeling requirements in paragraph (g)(2)(vii)(A) of this section:

Caution: Clothing contaminated with lead. Do not remove dust by blowing or shaking. Dispose of lead contaminated wash water in accordance with applicable local, state, or federal regulations.

(viii) The employer shall prohibit the removal of lead from protective clothing or equipment by blowing, shaking, or any other means which disperses lead into the air.

(h) Housekeeping

(1) All surfaces shall be maintained as free as practicable of accumulations of lead.

(2) Clean-up of floors and other surfaces where lead accumulates shall wherever possible, be cleaned by vacuuming or other methods that minimize the likelihood of lead becoming airborne.

(3) Shoveling, dry or wet sweeping, and brushing may be used only where vacuuming or other equally effective methods have been tried and found not to be effective.

(4) Where vacuuming methods are selected, the vacuums shall be equipped with HEPA filters and used and emptied in a manner which minimizes the reentry of lead into the workplace.

(5) Compressed air shall not be used to remove lead from any surface unless the compressed air is used in conjunction with a ventilation system designed to capture the airborne dust created by the compressed air.

(i) Hygiene facilities and practices.

(1) The employer shall assure that in areas where employees are exposed to lead above the PEL without regard to the use of respirators, food or beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied.

(2) Change areas.

(i) The employer shall provide clean change areas for employees whose airborne exposure to lead is above the PEL, and as interim protection for employees performing tasks as specified in paragraph (d)(2) of this section, without regard to the use of respirators.

(ii) The employer shall assure that change areas are equipped with separate storage facilities for protective work clothing and equipment and for street clothes which prevent cross-contamination.

(iii) The employer shall assure that employees do not leave the workplace wearing any protective clothing or equipment that is required to be worn during the work shift.

(3) Showers.

(i) The employer shall provide shower facilities, where feasible, for use by employees whose airborne exposure to lead is above the PEL.

(ii) The employer shall assure, where shower facilities are available, that employees shower at the end of the work shift and shall provide an adequate supply of cleansing agents and towels for use by affected employees.

(4) Eating facilities.

(i) The employer shall provide lunchroom facilities or eating areas for employees whose airborne exposure to lead is above the PEL, without regard to the use of respirators.

(ii) The employer shall assure that lunchroom facilities or eating areas are as free as practicable from lead contamination and are readily accessible to employees.

(iii) The employer shall assure that employees whose airborne exposure to lead is above the PEL, without regard to the use of a respirator, wash their hands and face prior to eating, drinking, smoking or applying cosmetics.

(iv) The employer shall assure that employees do not enter lunchroom facilities

or eating areas with protective work clothing or equipment unless surface lead dust has been removed by vacuuming, downdraft booth, or other cleaning method that limits dispersion of lead dust.

(5) Hand washing facilities.

(i) The employer shall provide adequate handwashing facilities for use by employees exposed to lead in accordance with 29 CFR 1926.51(f).

(ii) Where showers are not provided the employer shall assure that employees wash their hands and face at the end of the work-shift.

(j) Medical surveillance

(1) General.

(i) The employer shall make available initial medical surveillance to employees occupationally exposed on any day to lead at or above the action level. Initial medical surveillance consists of biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin levels.

(ii) The employer shall institute a medical surveillance program in accordance with paragraphs (j)(2) and (j)(3) of this section for all employees who are or may be exposed by the employer at or above the action level for more than 30 days in any consecutive 12 months;

(iii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician.

(iv) The employer shall make available the required medical surveillance including multiple physician review under paragraph (j)(3)(iii) without cost to employees and at a reasonable time and place.

(2) Biological monitoring

(i) Blood lead and ZPP level sampling and analysis. The employer shall make available biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin levels to each employee covered under paragraphs (j)(1)(i) and (ii) of this section on the following schedule:

(A) For each employee covered under paragraph (j)(1)(ii) of this section, at least every 2 months for the first 6 months and every 6 months thereafter;

(B) For each employee covered under paragraphs (j)(1) (i) or (ii) of this section whose last blood sampling and analysis indicated a blood lead level at or above 40 :g/dl, at least every two months. This frequency shall continue until two consecutive blood samples and analyses indicate a blood lead level below 40 :g/dl; and

(C) For each employee who is removed from exposure to lead due to an elevated blood lead level at least monthly during the removal period.

(ii) Follow-up blood sampling tests. Whenever the results of a blood lead level

test indicate that an employee's blood lead level is at or above the numerical criterion for medical removal under paragraph (k)(1)(i) of this section, the employer shall provide a second (follow-up) blood sampling test within two weeks after the employer receives the results of the first blood sampling test.

(iii) Accuracy of blood lead level sampling and analysis. Blood lead level sampling and analysis provided pursuant to this section shall have an accuracy (to a confidence level of 95 percent) within plus or minus 15 percent or 6 :g/dl, whichever is greater, and shall be conducted by a laboratory approved by OSHA.

(iv) Employee notification.

(A) Within five working days after the receipt of biological monitoring results, the employer shall notify each employee in writing of his or her blood lead level; and

(B) the employer shall notify each employee whose blood lead level is at or above 40 :g/dl that the standard requires temporary medical removal with Medical Removal Protection benefits when an employee's blood lead level exceeds the numerical criterion for medical removal under paragraph (k)(1)(i) of this section.

(3) Medical examinations and consultations

(i) Frequency. The employer shall make available medical examinations and consultations to each employee covered under paragraph (j)(1)(ii) of this section on the following schedule:

(A) At least annually for each employee for whom a blood sampling test conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 :g/dl;

(B) As soon as possible, upon notification by an employee either that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice concerning the effects of current or past exposure to lead on the employee's ability to procreate a healthy child, that the employee is pregnant, or that the employee has demonstrated difficulty in breathing during a respirator fitting test or during use; and

(C) As medically appropriate for each employee either removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited pursuant to a final medical determination.

(ii) Content. The content of medical examinations made available pursuant to paragraph (j)(3)(i)(B)-(C) of this section shall be determined by an examining physician and, if requested by an employee, shall include pregnancy testing or laboratory evaluation of male fertility. Medical examinations made available pursuant to paragraph (j)(3)(i)(A) of this section shall include the following elements:

(A) A detailed work history and a medical history, with particular attention to past lead exposure (occupational and non-occupational), personal habits (smoking, hygiene), and past gastrointestinal, hematologic, renal, cardiovascular, reproductive and

neurological problems;

(B) A thorough physical examination, with particular attention to teeth, gums, hematologic, gastrointestinal, renal, cardiovascular, and neurological systems. Pulmonary status should be evaluated if respiratory protection will be used;

(C) A blood pressure measurement;

(D) A blood sample and analysis which determines:

(1) Blood lead level;

(2) Hemoglobin and hematocrit determinations, red cell indices, and examination of peripheral smear morphology;

(3) Zinc protoporphyrin;

(4) Blood urea nitrogen; and,

(5) Serum creatinine;

(E) A routine urinalysis with microscopic examination; and

(F) Any laboratory or other test relevant to lead exposure which the examining physician deems necessary by sound medical practice.

(iii) Multiple physician review mechanism.

(A) If the employer selects the initial physician who conducts any medical examination or consultation provided to an employee under this section, the employee may designate a second physician:

(1) To review any findings, determinations or recommendations of the initial physician; and

(2) To conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

(B) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation pursuant to this section. The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the foregoing notification, or receipt of the initial physician's written opinion, whichever is later:

(1) The employee informing the employer that he or she intends to seek a second medical opinion, and

(2) The employee initiating steps to make an appointment with a second physician.

(C) If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve any disagreement.

(D) If the two physicians have been unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician:

(1) To review any findings, determinations or recommendations of the prior physicians;
and

(2) To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(E) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(iv) Information provided to examining and consulting physicians.

(A) The employer shall provide an initial physician conducting a medical examination or consultation under this section with the following information:

(1) A copy of this regulation for lead including all Appendices;

(2) A description of the affected employee's duties as they relate to the employee's exposure;

(3) The employee's exposure level or anticipated exposure level to lead and to any other toxic substance (if applicable);

(4) A description of any personal protective equipment used or to be used;

(5) Prior blood lead determinations; and

(6) All prior written medical opinions concerning the employee in the employer's possession or control.

(B) The employer shall provide the foregoing information to a second or third physician conducting a medical examination or consultation under this section upon request either by the second or third physician, or by the employee.

(v) Written medical opinions.

(A) The employer shall obtain and furnish the employee with a copy of a written medical opinion from each examining or consulting physician which contains only the following information:

(1) The physician's opinion as to whether the employee has any detected medical

condition which would place the employee at increased risk of material impairment of the employee's health from exposure to lead;

(2) Any recommended special protective measures to be provided to the employee, or limitations to be placed upon the employee's exposure to lead;

(3) Any recommended limitation upon the employee's use of respirators, including a determination of whether the employee can wear a powered air purifying respirator if a physician determines that the employee cannot wear a negative pressure respirator; and

(4) The results of the blood lead determinations.

(B) The employer shall instruct each examining and consulting physician to:

(1) Not reveal either in the written opinion or orally, or in any other means of communication with the employer, findings, including laboratory results, or diagnoses unrelated to an employee's occupational exposure to lead; and

(2) Advise the employee of any medical condition, occupational or nonoccupational, which dictates further medical examination or treatment.

(vi) Alternate physician determination mechanisms. The employer and an employee or authorized employee representative may agree upon the use of any alternate physician determination mechanism in lieu of the multiple physician review mechanism provided by paragraph (j)(3)(iii) of this section so long as the alternate mechanism is as expeditious and protective as the requirements contained in this paragraph.

(4) Chelation.

(i) The employer shall assure that any person whom he retains, employs, supervises or controls does not engage in prophylactic chelation of any employee at any time.

(ii) If therapeutic or diagnostic chelation is to be performed by any person in paragraph (j)(4)(i) of this section, the employer shall assure that it be done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring and that the employee is notified in writing prior to its occurrence.

(k) Medical removal protection

(1) Temporary medical removal and return of an employee

(i) Temporary removal due to elevated blood lead level. The employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 50 :g/dl; and,

(ii) Temporary removal due to a final medical determination.

(A) The employer shall remove an employee from work having an

exposure to lead at or above the action level on each occasion that a final medical determination results in a medical finding, determination, or opinion that the employee has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead.

(B) For the purposes of this section, the phrase "final medical determination" means the written medical opinion on the employees' health status by the examining physician or, where relevant, the outcome of the multiple physician review mechanism or alternate medical determination mechanism used pursuant to the medical surveillance provisions of this section.

(C) Where a final medical determination results in any recommended special protective measures for an employee, or limitations on an employee's exposure to lead, the employer shall implement and act consistent with the recommendation.

(iii) Return of the employee to former job status.

(A) The employer shall return an employee to his or her former job status:

(1) For an employee removed due to a blood lead level at or above 50 :g/dl when two consecutive blood sampling tests indicate that the employee's blood lead level is below 40 :g/dl;

(2) For an employee removed due to a final medical determination, when a subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead.

(B) For the purposes of this section, the requirement that an employer return an employee to his or her former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

(iv) Removal of other employee special protective measure or limitations. The employer shall remove any limitations placed on an employee or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

(v) Employer options pending a final medical determination. Where the multiple physician review mechanism, or alternate medical determination mechanism used pursuant to the medical surveillance provisions of this section, has not yet resulted in a final medical determination with respect to an employee, the employer shall act as follows:

(A) Removal. The employer may remove the employee from exposure to lead, provide special protective measures to the employee, or place limitations upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status.

(B) Return. The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions.

(1) If the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician or;

(2) If the employee has been on removal status for the preceding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(2) Medical removal protection benefits

(i) Provision of medical removal protection benefits. The employer shall provide an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

(ii) Definition of medical removal protection benefits. For the purposes of this section, the requirement that an employer provide medical removal protection benefits means that, as long as the job the employee was removed from continues, the employer shall maintain the total normal earnings, seniority and other employment rights and benefits of an employee, including the employee's right to his or her former job status as though the employee had not been medically removed from the employee's job or otherwise medically limited.

(iii) Follow-up medical surveillance during the period of employee removal or limitation. During the period of time that an employee is medically removed from his or her job or otherwise medically limited, the employer may condition the provision of medical removal protection benefits upon the employee's participation in follow-up medical surveillance made available pursuant to this section.

(iv) Workers' compensation claims. If a removed employee files a claim for workers' compensation payments for a lead-related disability, then the employer shall continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation shall be reduced by such amount. The employer shall receive no credit for workers' compensation payments received by the employee for treatment-related expenses.

(v) Other credits. The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from employment with another employer made possible by virtue of the employee's removal.

(vi) Voluntary removal or restriction of an employee. Where an employer, although not required by this section to do so, removes an employee from exposure to lead or otherwise places limitations on an employee due to the effects of lead exposure on the employee's medical condition, the employer shall provide medical removal protection benefits to

the employee equal to that required by paragraph (k)(2)(i) and (ii) of this section.

(1) ~~Employee information and training~~ Communication of hazards—

(1) General.

(i) ~~The employer shall communicate information concerning lead hazards according to the requirements of OSHA's Hazard Communication Standard for the construction industry, 29 CFR 1926.59, including but not limited to the requirements concerning warning signs and labels, material safety data sheets (MSDS), and employee information and training. In addition, employers shall comply with the following requirements: *Hazard communication*. The employer shall include lead in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of lead and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (1) of this section. The employer shall ensure that at least the following hazards are addressed:~~

(A) Reproductive/developmental toxicity;

(B) Central nervous system effects;

(C) Kidney effects;

(D) Blood effects; and

(E) Acute toxicity effects.

(ii) For all employees who are subject to exposure to lead at or above the action level on any day or who are subject to exposure to lead compounds which may cause skin or eye irritation (e.g. lead arsenate, lead azide), the employer shall provide a training program in accordance with paragraph (1)(2) of this section and assure employee participation.

(iii) The employer shall provide the training program as initial training prior to the time of job assignment or prior to the start up date for this requirement, whichever comes last.

(iv) The employer shall also provide the training program at least annually for each employee who is subject to lead exposure at or above the action level on any day.

(2) Training program. The employer shall assure that each employee is trained in the following:

(i) The content of this standard and its appendices;

(ii) The specific nature of the operations which could result in exposure to lead above the action level;

(iii) The purpose, proper selection, fitting, use, and limitations of respirators;

(iv) The purpose and a description of the medical surveillance program, and the

medical removal protection program including information concerning the adverse health effects associated with excessive exposure to lead (with particular attention to the adverse reproductive effects on both males and females and hazards to the fetus and additional precautions for employees who are pregnant);

(v) The engineering controls and work practices associated with the employee's job assignment including training of employees to follow relevant good work practices described in Appendix B of this section;

(vi) The contents of any compliance plan in effect;

(vii) Instructions to employees that chelating agents should not routinely be used to remove lead from their bodies and should not be used at all except under the direction of a licensed physician; and

(viii) The employee's right of access to records under 29 CFR 1910.20.

(3) Access to information and training materials.

(i) The employer shall make readily available to all affected employees a copy of this standard and its appendices.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to affected employees and their designated representatives, and to the Assistant Secretary and the Director.

(m) Signs

(1) General.

~~(i) The employer may use signs required by other statutes, regulations or ordinances in addition to, or in combination with, signs required by this paragraph. The employer shall post the following warning signs in each work area where an employee's exposure to lead is above the PEL.~~

DANGER
LEAD WORK AREA
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM
DO NOT EAT, DRINK OR SMOKE IN THIS AREA

~~(ii) The employer shall assure that no statement appears on or near any sign required by this paragraph which contradicts or detracts from the meaning of the required sign. The employer shall ensure that no statement appears on or near any sign required by this paragraph (m) that contradicts or detracts from the meaning of the required sign.~~

(iii) The employer shall ensure that signs required by this paragraph (m) are illuminated and cleaned as necessary so that the legend is readily visible.

(iv) The employer may use signs required by other statutes, regulations or

ordinances in addition to, or in combination with, signs required by this paragraph (m).

(v) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (m)(1)(i) of this section:

WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING

~~(2) Signs.~~

~~_____ (i) The employer shall post the following warning signs in each work area where an employees exposure to lead is above the PEL.~~

~~_____ WARNING
_____ LEAD WORK AREA
_____ POISON
_____ NO SMOKING OR EATING~~

~~_____ (ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.~~

(n) Recordkeeping

(1) Exposure assessment.

(i) The employer shall establish and maintain an accurate record of all monitoring and other data used in conducting employee exposure assessments as required in paragraph (d) of this section.

(ii) Exposure monitoring records shall include:

(A) The date(s), number, duration, location and results of each of the samples taken if any, including a description of the sampling procedure used to determine representative employee exposure where applicable;

(B) A description of the sampling and analytical methods used and evidence of their accuracy;

(C) The type of respiratory protective devices worn, if any;

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent; and

(E) The environmental variables that could affect the measurement of employee exposure.

(iii) The employer shall maintain monitoring and other exposure assessment records in accordance with the provisions of 29 CFR 1910.20.

(2) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (j) of this section.

(ii) This record shall include:

(A) The name, social security number, and description of the duties of the employee;

(B) A copy of the physician's written opinions;

(C) Results of any airborne exposure monitoring done on or for that employee and provided to the physician; and

(D) Any employee medical complaints related to exposure to lead.

(iii) The employer shall keep, or assure that the examining physician keeps, the following medical records:

(A) A copy of the medical examination results including medical and work history required under paragraph (j) of this section;

(B) A description of the laboratory procedures and a copy of any standards or guidelines used to interpret the test results or references to that information;

(C) A copy of the results of biological monitoring.

(iv) The employer shall maintain or assure that the physician maintains medical records in accordance with the provisions of 29 CFR 1910.20.

(3) Medical removals.

(i) The employer shall establish and maintain an accurate record for each employee removed from current exposure to lead pursuant to paragraph (k) of this section.

(ii) Each record shall include:

(A) The name and social security number of the employee;

(B) The date of each occasion that the employee was removed from current exposure to lead as well as the corresponding date on which the employee was returned to his or her former job status;

(C) A brief explanation of how each removal was or is being accomplished; and

(D) A statement with respect to each removal indicating whether or not the reason for the removal was an elevated blood lead level.

(iii) The employer shall maintain each medical removal record for at least the duration of an employee's employment.

(4) Objective data for exemption from requirement for initial monitoring.

(i) For purposes of this section, objective data are information demonstrating that a particular product or material containing lead or a specific process, operation, or activity involving lead cannot release dust or fumes in concentrations at or above the action level under any expected conditions of use. Objective data can be obtained from an industry-wide study or from laboratory product test results from manufacturers of lead containing products or materials. The data the employer uses from an industry-wide survey must be obtained under workplace conditions closely resembling the processes, types of material, control methods, work practices and environmental conditions in the employer's current operations.

(ii) The employer shall maintain the record of the objective data relied upon for at least 30 years.

(5) Availability. The employer shall make available upon request all records required to be maintained by paragraph (n) of this section to affected employees, former employees, and their designated representatives, and to the Assistant Secretary and the Director for examination and copying.

(6) Transfer of records.

(i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (n) of this section.

(ii) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(o) Observation of monitoring.

(1) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to lead conducted pursuant to paragraph (d) of this section.

(2) Observation procedures.

(i) Whenever observation of the monitoring of employee exposure to lead requires entry into an area where the use of respirators, protective clothing or equipment is required, the employer shall provide the observer with and assure the use of such respirators, clothing and equipment, and shall require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the monitoring of lead performed at the place of exposure; and

(C) Record the results obtained or receive copies of the results when returned by the laboratory.

(p) Appendices. The information contained in the appendices to this section is not intended by itself, to create any additional obligations not otherwise imposed by this standard nor detract from any existing obligation.

Appendix A to 1926.62 - Substance Data Sheet for Occupational Exposure to Lead

I. Substance Identification

A. Substance: Pure lead (Pb) is a heavy metal at room temperature and pressure and is a basic chemical element. It can combine with various other substances to form numerous lead compounds.

B. Compounds covered by the standard: The word "lead" when used in this interim final standard means elemental lead, all inorganic lead compounds and a class of organic lead compounds called lead soaps. This standard does not apply to other organic lead compounds.

C. Uses: Exposure to lead occurs in several different occupations in the construction industry, including demolition or salvage of structures where lead or lead-containing materials are present; removal or encapsulation of lead-containing materials, new construction, alteration, repair, or renovation of structures that contain lead or materials containing lead; installation of products containing lead. In addition, there are construction related activities where exposure to lead may occur, including transportation, disposal, storage, or containment of lead or materials containing lead on construction sites, and maintenance operations associated with construction activities.

D. Permissible exposure: The permissible exposure limit (PEL) set by the standard is 50 micrograms of lead per cubic meter of air (50 $\mu\text{g}/\text{m}^3$), averaged over an 8-hour workday.

E. Action level: The interim final standard establishes an action level of 30 micrograms of lead per cubic meter of air (30 $\mu\text{g}/\text{m}^3$), averaged over an 8-hour workday. The action level triggers several ancillary provisions of the standard such as exposure monitoring, medical surveillance, and training.

II. Health Hazard Data

A. Ways in which lead enters your body. When absorbed into your body in certain doses, lead is a toxic substance. The object of the lead standard is to prevent absorption of harmful quantities of lead. The standard is intended to protect you not only from the immediate toxic effects of lead, but also from the serious toxic effects that may not become apparent until years of exposure have passed. Lead can be absorbed into your body by inhalation (breathing) and ingestion (eating). Lead (except for certain organic lead compounds not covered by the standard, such as tetraethyl lead) is not absorbed through your skin. When lead is scattered in the air as a dust, fume respiratory tract. Inhalation of airborne lead is generally the most important source of occupational lead absorption. You can also absorb lead through your digestive system if lead gets into your mouth and is swallowed. If you handle food, cigarettes, chewing tobacco,

or make-up which have lead on them or handle them with hands contaminated with lead, this will contribute to ingestion. A significant portion of the lead that you inhale or ingest gets into your blood stream. Once in your blood stream, lead is circulated throughout your body and stored in various organs and body tissues. Some of this lead is quickly filtered out of your body and excreted, but some remains in the blood and other tissues. As exposure to lead continues, the amount stored in your body will increase if you are absorbing more lead than your body is excreting. Even though you may not be aware of any immediate symptoms of disease, this lead stored in your tissues can be slowly causing irreversible damage, first to individual cells, then to your organs and whole body systems.

B. Effects of overexposure to lead

(1) Short term (acute) overexposure. Lead is a potent, systemic poison that serves no known useful function once absorbed by your body. Taken in large enough doses, lead can kill you in a matter of days. A condition affecting the brain called acute encephalopathy may arise which develops quickly to seizures, coma, and death from cardiorespiratory arrest. A short term dose of lead can lead to acute encephalopathy. Short term occupational exposures of this magnitude are highly unusual, but not impossible. Similar forms of encephalopathy may, however, arise from extended, chronic exposure to lower doses of lead. There is no sharp dividing line between rapidly developing acute effects of lead, and chronic effects which take longer to acquire. Lead adversely affects numerous body systems, and causes forms of health impairment and disease which arise after periods of exposure as short as days or as long as several years.

(2) Long-term (chronic) overexposure. Chronic overexposure to lead may result in severe damage to your blood-forming, nervous, urinary and reproductive systems. Some common symptoms of chronic overexposure include loss of appetite, metallic taste in the mouth, anxiety, constipation, nausea, pallor, excessive tiredness, weakness, insomnia, headache, nervous irritability, muscle and joint pain or soreness, fine tremors, numbness, dizziness, hyperactivity and colic. In lead colic there may be severe abdominal pain. Damage to the central nervous system in general and the brain (encephalopathy) in particular is one of the most severe forms of lead poisoning. The most severe, often fatal, form of encephalopathy may be preceded by vomiting, a feeling of dullness progressing to drowsiness and stupor, poor memory, restlessness, irritability, tremor, and convulsions. It may arise suddenly with the onset of seizures, followed by coma, and death. There is a tendency for muscular weakness to develop at the same time. This weakness may progress to paralysis often observed as a characteristic "wrist drop" or "foot drop" and is a manifestation of a disease to the nervous system called peripheral neuropathy. Chronic overexposure to lead also results in kidney disease with few, if any, symptoms appearing until extensive and most likely permanent kidney damage has occurred. Routine laboratory tests reveal the presence of this kidney disease only after about two-thirds of kidney function is lost. When overt symptoms of urinary dysfunction arise, it is often too late to correct or prevent worsening conditions, and progression to kidney dialysis or death is possible. Chronic overexposure to lead impairs the reproductive systems of both men and women. Overexposure to lead may result in decreased sex drive, impotence and sterility in men. Lead can alter the structure of sperm cells raising the risk of birth defects. There is evidence of miscarriage and stillbirth in women whose husbands were exposed to lead or who were exposed to lead themselves. Lead exposure also may result in decreased fertility, and abnormal menstrual cycles in women. The course of pregnancy may be adversely affected by exposure to lead since lead crosses the placental barrier and poses risks to developing fetuses. Children born of parents either one of whom were exposed to excess lead levels are more likely to have birth defects,

mental retardation, behavioral disorders or die during the first year of childhood. Overexposure to lead also disrupts the blood-forming system resulting in decreased hemoglobin (the substance in the blood that carries oxygen to the cells) and ultimately anemia. Anemia is characterized by weakness, pallor and fatigability as a result of decreased oxygen carrying capacity in the blood.

(3) Health protection goals of the standard. Prevention of adverse health effects for most workers from exposure to lead throughout a working lifetime requires that a worker's blood lead level (BLL, also expressed as PbB) be maintained at or below forty micrograms per deciliter of whole blood (40 :g/dl). The blood lead levels of workers (both male and female workers) who intend to have children should be maintained below 30 :g/dl to minimize adverse reproductive health effects to the parents and to the developing fetus. The measurement of your blood lead level (BLL) is the most useful indicator of the amount of lead being absorbed by your body. Blood lead levels are most often reported in units of milligrams (mg) or micrograms (:g) of lead (1 mg=1000 :g) per 100 grams (100g), 100 milliliters (100 ml) or deciliter (dl) of blood. These three units are essentially the same. Sometime BLLs are expressed in the form of mg% or :g%. This is a shorthand notation for 100g, 100 ml, or dl. (References to BLL measurements in this standard are expressed in the form of :g/dl.)

BLL measurements show the amount of lead circulating in your blood stream, but do not give any information about the amount of lead stored in your various tissues. BLL measurements merely show current absorption of lead, not the effect that lead is having on your body or the effects that past lead exposure may have already caused. Past research into lead-related diseases, however, has focused heavily on associations between BLLs and various diseases. As a result, your BLL is an important indicator of the likelihood that you will gradually acquire a lead-related health impairment or disease.

Once your blood lead level climbs above 40 :g/dl, your risk of disease increases. There is a wide variability of individual response to lead, thus it is difficult to say that a particular BLL in a given person will cause a particular effect. Studies have associated fatal encephalopathy with BLLs as low as 150 :g/dl. Other studies have shown other forms of diseases in some workers with BLLs well below 80 :g/dl. Your BLL is a crucial indicator of the risks to your health, but one other factor is also extremely important. This factor is the length of time you have had elevated BLLs. The longer you have an elevated BLL, the greater the risk that large quantities of lead are being gradually stored in your organs and tissues (body burden). The greater your overall body burden, the greater the chances of substantial permanent damage. The best way to prevent all forms of lead-related impairments and diseases - both short term and long term - is to maintain your BLL below 40 :g/dl. The provisions of the standard are designed with this end in mind.

Your employer has prime responsibility to assure that the provisions of the standard are complied with both by the company and by individual workers. You, as a worker, however, also have a responsibility to assist your employer in complying with the standard. You can play a key role in protecting your own health by learning about the lead hazards and their control, learning what the standard requires, following the standard where it governs your own actions, and seeing that your employer complies with provisions governing his or her actions.

(4) Reporting signs and symptoms of health problems. You should immediately notify your employer if you develop signs or symptoms associated with lead poisoning or if you desire medical advice concerning the effects of current or past exposure to lead or your ability to have a healthy child. You should also notify your employer if you have difficulty breathing

during a respirator fit test or while wearing a respirator. In each of these cases, your employer must make available to you appropriate medical examinations or consultations. These must be provided at no cost to you and at a reasonable time and place. The standard contains a procedure whereby you can obtain a second opinion by a physician of your choice if your employer selected the initial physician.

Appendix B to 1926.62 - Employee Standard Summary

This appendix summarizes key provisions of the interim final standard for lead in construction that you as a worker should become familiar with.

I. Permissible Exposure Limit (PEL) - Paragraph (C)

The standard sets a permissible exposure limit (PEL) of 50 micrograms of lead per cubic meter of air (50 $\mu\text{g}/\text{m}^3$), averaged over an 8-hour workday which is referred to as a time-weighted average (TWA). This is the highest level of lead in air to which you may be permissibly exposed over an 8-hour workday. However, since this is an 8-hour average, short exposures above the PEL are permitted so long as for each 8-hour work day your average exposure does not exceed this level. This interim final standard, however, takes into account the fact that your daily exposure to lead can extend beyond a typical 8-hour workday as the result of overtime or other alterations in your work schedule. To deal with this situation, the standard contains a formula which reduces your permissible exposure when you are exposed more than 8 hours. For example, if you are exposed to lead for 10 hours a day, the maximum permitted average exposure would be 40 $\mu\text{g}/\text{m}^3$.

II. Exposure Assessment - Paragraph (D)

If lead is present in your workplace in any quantity, your employer is required to make an initial determination of whether any employee's exposure to lead exceeds the action level (30 $\mu\text{g}/\text{m}^3$ averaged over an 8-hour day). Employee exposure is that exposure which would occur if the employee were not using a respirator. This initial determination requires your employer to monitor workers' exposures unless he or she has objective data which can demonstrate conclusively that no employee will be exposed to lead in excess of the action level. Where objective data is used in lieu of actual monitoring the employer must establish and maintain an accurate record, documenting its relevancy in assessing exposure levels for current job conditions. If such objective data is available, the employer need proceed no further on employee exposure assessment until such time that conditions have changed and the determination is no longer valid.

Objective data may be compiled from various sources, e.g., insurance companies and trade associations and information from suppliers or exposure data collected from similar operations. Objective data may also comprise previously-collected sampling data including area monitoring. If it cannot be determined through using objective data that worker exposure is less than the action level, your employer must conduct monitoring or must rely on relevant previous personal sampling, if available. Where monitoring is required for the initial determination, it may be limited to a representative number of employees who are reasonably expected to have the highest exposure levels. If your employer has conducted appropriate air sampling for lead in the past 12 months, he or she may use these results, provided they are applicable to the same employee tasks and exposure conditions and meet the requirements for accuracy as specified in the standard. As with objective data, if such results are relied upon for the initial determination,

your employer must establish and maintain a record as to the relevancy of such data to current job conditions.

If there have been any employee complaints of symptoms which may be attributable to exposure to lead or if there is any other information or observations which would indicate employee exposure to lead, this must also be considered as part of the initial determination.

If this initial determination shows that a reasonable possibility exists that any employee may be exposed, without regard to respirators, over the action level, your employer must set up an air monitoring program to determine the exposure level representative of each employee exposed to lead at your workplace. In carrying out this air monitoring program, your employer is not required to monitor the exposure of every employee, but he or she must monitor a representative number of employees and job types. Enough sampling must be done to enable each employee's exposure level to be reasonably represent full shift exposure. In addition, these air samples must be taken under conditions which represent each employee's regular, daily exposure to lead. Sampling performed in the past 12 months may be used to determine exposures above the action level if such sampling was conducted during work activities essentially similar to present work conditions.

The standard lists certain tasks which may likely result in exposures to lead in excess of the PEL and, in some cases, exposures in excess of 50 times the PEL. If you are performing any of these tasks, your employer must provide you with appropriate respiratory protection, protective clothing and equipment, change areas, hand washing facilities, biological monitoring, and training until such time that an exposure assessment is conducted which demonstrates that your exposure level is below the PEL.

If you are exposed to lead and air sampling is performed, your employer is required to notify you in writing within 5 working days of the air monitoring results which represent your exposure. If the results indicate that your exposure exceeds the PEL (without regard to your use of a respirator), then your employer must also notify you of this in writing, and provide you with a description of the corrective action that has been taken or will be taken to reduce your exposure.

Your exposure must be rechecked by monitoring, at least every six months if your exposure is at or over the action level but below the PEL. Your employer may discontinue monitoring for you if 2 consecutive measurements, taken at least 7 days apart, are at or below the action level. Air monitoring must be repeated every 3 months if you are exposed over the PEL. Your employer must continue monitoring for you at this frequency until 2 consecutive measurements, taken at least 7 days apart, are below the PEL but above the action level, at which time your employer must repeat monitoring of your exposure every six months and may discontinue monitoring only after your exposure drops to or below the action level. However, whenever there is a change of equipment, process, control, or personnel or a new type of job is added at your workplace which may result in new or additional exposure to lead, your employer must perform additional monitoring.

III. Methods of Compliance - Paragraph (E)

Your employer is required to assure that no employee is exposed to lead in excess of the PEL as an 8-hour TWA. The interim final standard for lead in construction requires employers to institute engineering and work practice controls including administrative controls to the extent

feasible to reduce employee exposure to lead. Where such controls are feasible but not adequate to reduce exposures below the PEL they must be used nonetheless to reduce exposures to the lowest level that can be accomplished by these means and then supplemented with appropriate respiratory protection.

Your employer is required to develop and implement a written compliance program prior to the commencement of any job where employee exposures may reach the PEL as an 8-hour TWA. The interim final standard identifies the various elements that must be included in the plan. For example, employers are required to include a description of operations in which lead is emitted, detailing other relevant information about the operation such as the type of equipment used, the type of material involved, employee job responsibilities, operating procedures and maintenance practices. In addition, your employer's compliance plan must specify the means that will be used to achieve compliance and, where engineering controls are required, include any engineering plans or studies that have been used to select the control methods. If administrative controls involving job rotation are used to reduce employee exposure to lead, the job rotation schedule must be included in the compliance plan. The plan must also detail the type of protective clothing and equipment, including respirators, housekeeping and hygiene practices that will be used to protect you from the adverse effects of exposure to lead.

The written compliance program must be made available, upon request, to affected employees and their designated representatives, the Assistant Secretary and the Director.

Finally, the plan must be reviewed and updated at least every 6 months to assure it reflects the current status in exposure control.

IV. Respiratory Protection - Paragraph (f)

Your employer is required to select respirators from the types listed in Table I of the Respiratory Protection section of the standard (Sec. 1926.62 (f)). Any respirator chosen must be approved by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 42 CFR part 84. This respirator selection table will enable your employer to choose a type of respirator that will give you a proper amount of protection based on your airborne lead exposure. Your employer may select a type of respirator that provides greater protection than that required by the standard; that is, one recommended for a higher concentration of lead than is present in your workplace. For example, a powered air-purifying respirator (PAPR) is much more protective than a typical negative pressure respirator, and may also be more comfortable to wear. A PAPR has a filter, cartridge, or canister to clean the air, and a power source that continually blows filtered air into your breathing zone. Your employer might make a PAPR available to you to ease the burden of having to wear a respirator for long periods of time. The standard provides that you can obtain a PAPR upon request.

Your employer is required to select respirators from the types listed in Table I of the Respiratory Protection section of the standard. Any respirator chosen must be approved by the Mine Safety and Health Administration (MSHA) or the National Institute for Occupational Safety and Health (NIOSH). This respirator selection table will enable your employer to choose a type of respirator which will give you a proper amount of protection based on your airborne lead exposure. Your employer may select a type of respirator that provides greater protection than that required by the standard; that is, one recommended for a higher concentration of lead than is present in your workplace. For example, a powered air purifying respirator (PAPR) is much more protective than a typical negative pressure respirator, and may also be more comfortable to wear. A PAPR has a filter, cartridge or canister to clean the air, and a power

source which continuously blows filtered air into your breathing zone. Your employer might make a PAPR available to you to ease the burden of having to wear a respirator for long periods of time. The standard provides that you can obtain a PAPR upon request.

Your employer must also start a Respiratory Protection Program. This program must include written procedures for the proper selection, use, cleaning, storage, and maintenance of respirators.

Your employer must ensure that your respirator facepiece fits properly. Proper fit of a respirator facepiece is critical to your protection from airborne lead. Obtaining a proper fit on each employee may require your employer to make available two or several different types of respirator masks. To ensure that your respirator fits properly and that facepiece leakage is minimal, your employer must give you either a qualitative or quantitative fit test as specified in Appendix A of the Respiratory Protection standard located at 29 CFR 1910.134.

You must also receive from your employer proper training in the use of respirators. Your employer is required to teach you how to wear a respirator, to know why it is needed, and to understand its limitations.

Your employer must test the effectiveness of your negative pressure respirator initially and at least every six months thereafter with a "qualitative fit test." In this test, the fit of the facepiece is checked by seeing if you can smell a substance placed outside the respirator. If you can, there is appreciable leakage where the facepiece meets your face.

The standard provides that if your respirator uses filter elements, you must be given an opportunity to change the filter elements whenever an increase in breathing resistance is detected. You also must be permitted to periodically leave your work area to wash your face and respirator facepiece whenever necessary to prevent skin irritation. If you ever have difficulty in breathing during a fit test or while using a respirator, your employer must make a medical examination available to you to determine whether you can safely wear a respirator. The result of this examination may be to give you a positive pressure respirator (which reduces breathing resistance) or to provide alternative means of protection.

V. Protective Work Clothing and Equipment - Paragraph (G)

If you are exposed to lead above the PEL as an 8-hour TWA, without regard to your use of a respirator, or if you are exposed to lead compounds such as lead arsenate or lead azide which can cause skin and eye irritation, your employer must provide you with protective work clothing and equipment appropriate for the hazard. If work clothing is provided, it must be provided in a clean and dry condition at least weekly, and daily if your airborne exposure to lead is greater than 200 $\mu\text{g}/\text{m}^3$. Appropriate protective work clothing and equipment can include coveralls or similar full-body work clothing, gloves, hats, shoes or disposable shoe coverlets, and face shields or vented goggles. Your employer is required to provide all such equipment at no cost to you. In addition, your employer is responsible for providing repairs and replacement as necessary, and also is responsible for the cleaning, laundering or disposal of protective clothing and equipment.

The interim final standard requires that your employer assure that you follow good work practices when you are working in areas where your exposure to lead may exceed the PEL. With respect to protective clothing and equipment, where appropriate, the following procedures should

be observed prior to beginning work:

1. Change into work clothing and shoe covers in the clean section of the designated changing areas;
2. Use work garments of appropriate protective gear, including respirators before entering the work area; and
3. Store any clothing not worn under protective clothing in the designated changing area.

Workers should follow these procedures upon leaving the work area:

1. HEPA vacuum heavily contaminated protective work clothing while it is still being worn. At no time may lead be removed from protective clothing by any means which result in uncontrolled dispersal of lead into the air;
2. Remove shoe covers and leave them in the work area;
3. Remove protective clothing and gear in the dirty area of the designated changing area. Remove protective coveralls by carefully rolling down the garment to reduce exposure to dust.
4. Remove respirators last; and
5. Wash hands and face.

Workers should follow these procedures upon finishing work for the day (in addition to procedures described above):

1. Where applicable, place disposal coveralls and shoe covers with the abatement waste;
2. Contaminated clothing which is to be cleaned, laundered or disposed of must be placed in closed containers in the change room.
3. Clean protective gear, including respirators, according to standard procedures;
4. Wash hands and face again. If showers are available, take a shower and wash hair. If shower facilities are not available at the work site, shower immediately at home and wash hair.

VI. Housekeeping - Paragraph (H)

Your employer must establish a housekeeping program sufficient to maintain all surfaces as free as practicable of accumulations of lead dust. Vacuuming is the preferred method of meeting this requirement, and the use of compressed air to clean floors and other surfaces is generally prohibited unless removal with compressed air is done in conjunction with ventilation systems designed to contain dispersal of the lead dust. Dry or wet sweeping, shoveling, or brushing may not be used except where vacuuming or other equally effective methods have been tried and do not work. Vacuums must be used equipped with a special filter called a high-efficiency particulate air (HEPA) filter and emptied in a manner which minimizes the reentry of lead into the workplace.

VII. Hygiene Facilities and Practices - Paragraph (I)

The standard requires that hand washing facilities be provided where occupational exposure to lead occurs. In addition, change areas, showers (where feasible), and lunchrooms or eating areas are to be made available to workers exposed to lead above the PEL. Your employer must assure that except in these facilities, food and beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied, where airborne exposures are above the PEL. Change rooms provided by your employer must be equipped with separate storage facilities for your protective clothing and equipment and street clothes to avoid cross-contamination. After showering, no required protective clothing or equipment worn during the shift may be worn home. It is important that contaminated clothing or equipment be removed in change areas and not be worn home or you will extend your exposure and expose your family since lead from your clothing can accumulate in your house, car, etc.

Lunchrooms or eating areas may not be entered with protective clothing or equipment unless surface dust has been removed by vacuuming, downdraft booth, or other cleaning method. Finally, workers exposed above the PEL must wash both their hands and faces prior to eating, drinking, smoking or applying cosmetics.

All of the facilities and hygiene practices just discussed are essential to minimize additional sources of lead absorption from inhalation or ingestion of lead that may accumulate on you, your clothes, or your possessions. Strict compliance with these provisions can virtually eliminate several sources of lead exposure which significantly contribute to excessive lead absorption.

VIII. Medical Surveillance - Paragraph (J)

The medical surveillance program is part of the standard's comprehensive approach to the prevention of lead-related disease. Its purpose is to supplement the main thrust of the standard which is aimed at minimizing airborne concentrations of lead and sources of ingestion. Only medical surveillance can determine if the other provisions of the standard have affectively protected you as an individual. Compliance with the standard's provision will protect most workers from the adverse effects of lead exposure, but may not be satisfactory to protect individual workers (1) who have high body burdens of lead acquired over past years, (2) who have additional uncontrolled sources of non-occupational lead exposure, (3) who exhibit unusual variations in lead absorption rates, or (4) who have specific non-work related medical conditions which could be aggravated by lead exposure (e.g., renal disease, anemia). In addition, control systems may fail, or hygiene and respirator programs may be inadequate. Periodic medical surveillance of individual workers will help detect those failures. Medical surveillance will also be important to protect your reproductive ability-regardless of whether you are a man or woman.

All medical surveillance required by the interim final standard must be performed by or under the supervision of a licensed physician. The employer must provide required medical surveillance without cost to employees and at a reasonable time and place. The standard's medical surveillance program has two parts - periodic biological monitoring and medical examinations. Your employer's obligation to offer you medical surveillance is triggered by the results of the air monitoring program. Full medical surveillance must be made available to all employees who are or may be exposed to lead in excess of the action level for more than 30 days a year and whose blood lead level exceeds 40 ug/dl. Initial medical surveillance consisting of

blood sampling and analysis for lead and zinc protoporphyrin must be provided to all employees exposed at any time (1 day) above the action level.

Biological monitoring under the standard must be provided at least every 2 months for the first 6 months and every 6 months thereafter until your blood lead level is below 40 µg/dl. A zinc protoporphyrin (ZPP) test is a very useful blood test which measures an adverse metabolic effect of lead on your body and is therefore an indicator of lead toxicity.

If your BLL exceeds 40 µg/dl the monitoring frequency must be increased from every 6 months to at least every 2 months and not reduced until two consecutive BLLs indicate a blood lead level below 40 µg/dl. Each time your BLL is determined to be over 40 µg/dl, your employer must notify you of this in writing within five working days of his or her receipt of the test results. The employer must also inform you that the standard requires temporary medical removal with economic protection when your BLL exceeds 50 µg/dl. (See Discussion of Medical Removal Protection-Paragraph (k).) Anytime your BLL exceeds 50 µg/dl your employer must make available to you within two weeks of receipt of these test results a second follow-up BLL test to confirm your BLL. If the two tests both exceed 50 µg/dl, and you are temporarily removed, then your employer must make successive BLL tests available to you on a monthly basis during the period of your removal.

Medical examinations beyond the initial one must be made available on an annual basis if your blood lead level exceeds 40 µg/dl at any time during the preceding year and you are being exposed above the airborne action level of 30 µg/m³ for 30 or more days per year. The initial examination will provide information to establish a baseline to which subsequent data can be compared.

An initial medical examination to consist of blood sampling and analysis for lead and zinc protoporphyrin must also be made available (prior to assignment) for each employee being assigned for the first time to an area where the airborne concentration of lead equals or exceeds the action level at any time. In addition, a medical examination or consultation must be made available as soon as possible if you notify your employer that you are experiencing signs or symptoms commonly associated with lead poisoning or that you have difficulty breathing while wearing a respirator or during a respirator fit test. You must also be provided a medical examination or consultation if you notify your employer that you desire medical advice concerning the effects of current or past exposure to lead on your ability to procreate a healthy child.

Finally, appropriate follow-up medical examinations or consultations may also be provided for employees who have been temporarily removed from exposure under the medical removal protection provisions of the standard. (See Part IX, below.)

The standard specifies the minimum content of pre-assignment and annual medical examinations. The content of other types of medical examinations and consultations is left up to the sound discretion of the examining physician. Pre-assignment and annual medical examinations must include (1) a detailed work history and medical history; (2) a thorough physical examination, including an evaluation of your pulmonary status if you will be required to use a respirator; (3) a blood pressure measurement; and (4) a series of laboratory tests designed to check your blood chemistry and your kidney function. In addition, at any time upon your request, a laboratory evaluation of male fertility will be made (microscopic examination of a sperm sample), or a pregnancy test will be given.

The standard does not require that you participate in any of the medical procedures, tests, etc. which your employer is required to make available to you. Medical surveillance can, however, play a very important role in protecting your health. You are strongly encouraged, therefore, to participate in a meaningful fashion. The standard contains a multiple physician review mechanism which will give you a chance to have a physician of your choice directly participate in the medical surveillance program. If you are dissatisfied with an examination by a physician chosen by your employer, you can select a second physician to conduct an independent analysis. The two doctors would attempt to resolve any differences of opinion, and select a third physician to resolve any firm dispute. Generally your employer will choose the physician who conducts medical surveillance under the lead standard-unless you and your employer can agree on the choice of a physician or physicians. Some companies and unions have agreed in advance, for example, to use certain independent medical laboratories or panels of physicians. Any of these arrangements are acceptable so long as required medical surveillance is made available to workers.

The standard requires your employer to provide certain information to a physician to aid in his or her examination of you. This information includes (1) the standard and its appendices, (2) a description of your duties as they relate to occupational lead exposure, (3) your exposure level or anticipated exposure level, (4) a description of any personal protective equipment you wear, (5) prior blood lead level results, and (6) prior written medical opinions concerning you that the employer has. After a medical examination or consultation the physician must prepare a written report which must contain (1) the physician's opinion as to whether you have any medical condition which places you at increased risk of material impairment to health from exposure to lead, (2) any recommended special protective measures to be provided to you, (3) any blood lead level determinations, and (4) any recommended limitation on your use of respirators. This last element must include a determination of whether you can wear a powered air purifying respirator (PAPR) if you are found unable to wear a negative pressure respirator.

The medical surveillance program of the interim lead standard may at some point in time serve to notify certain workers that they have acquired a disease or other adverse medical condition as a result of occupational lead exposure. If this is true, these workers might have legal rights to compensation from public agencies, their employers, firms that supply hazardous products to their employers, or other persons. Some states have laws, including worker compensation laws, that disallow a worker who learns of a job-related health impairment to sue, unless the worker sues within a short period of time after learning of the impairment. (This period of time may be a matter of months or years.) An attorney can be consulted about these possibilities. It should be stressed that OSHA is in no way trying to either encourage or discourage claims or lawsuits. However, since results of the standard's medical surveillance program can significantly affect the legal remedies of a worker who has acquired a job-related disease or impairment, it is proper for OSHA to make you aware of this.

The medical surveillance section of the standard also contains provisions dealing with chelation. Chelation is the use of certain drugs (administered in pill form or injected into the body) to reduce the amount of lead absorbed in body tissues. Experience accumulated by the medical and scientific communities has largely confirmed the effectiveness of this type of therapy for the treatment of very severe lead poisoning. On the other hand, it has also been established that there can be a long list of extremely harmful side effects associated with the use of chelating agents. The medical community has balanced the advantages and disadvantages resulting from the use of chelating agents in various circumstances and has established when the

use of these agents is acceptable. The standard includes these accepted limitations due to a history of abuse of chelation therapy by some lead companies. The most widely used chelating agents are calcium disodium EDTA, (Ca Na₂ EDTA), Calcium Disodium Versenate (Versenate), and d-penicillamine (pencillamine or Cupramine).

The standard prohibits "prophylactic chelation" of any employee by any person the employer retains, supervises or controls. "Prophylactic chelation" is the routine use of chelating or similarly acting drugs to prevent elevated blood levels in workers who are occupationally exposed to lead, or the use of these drugs to routinely lower blood lead levels to predesignated concentrations believed to be "safe". It should be emphasized that where an employer takes a worker who has no symptoms of lead poisoning and has chelation carried out by a physician (either inside or outside of a hospital) solely to reduce the worker's blood lead level, that will generally be considered prophylactic chelation. The use of a hospital and a physician does not mean that prophylactic chelation is not being performed. Routine chelation to prevent increased or reduce current blood lead levels is unacceptable whatever the setting.

The standard allows the use of "therapeutic" or "diagnostic" chelation if administered under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring. Therapeutic chelation responds to severe lead poisoning where there are marked symptoms. Diagnostic chelation involved giving a patient a dose of the drug then collecting all urine excreted for some period of time as an aid to the diagnosis of lead poisoning.

In cases where the examining physician determines that chelation is appropriate, you must be notified in writing of this fact before such treatment. This will inform you of a potentially harmful treatment, and allow you to obtain a second opinion.

IX. Medical Removal Protection - Paragraph (K)

Excessive lead absorption subjects you to increased risk of disease. Medical removal protection (MRP) is a means of protecting you when, for whatever reasons, other methods, such as engineering controls, work practices, and respirators, have failed to provide the protection you need. MRP involves the temporary removal of a worker from his or her regular job to a place of significantly lower exposure without any loss of earnings, seniority, or other employment rights or benefits. The purpose of this program is to cease further lead absorption and allow your body to naturally excrete lead which has previously been absorbed. Temporary medical removal can result from an elevated blood lead level, or a medical opinion. For up to 18 months, or for as long as the job the employee was removed from lasts, protection is provided as a result of either form of removal. The vast majority of removed workers, however, will return to their former jobs long before this eighteen month period expires.

You may also be removed from exposure even if your blood lead level is below 50 µg/dl if a final medical determination indicates that you temporarily need reduced lead exposure for medical reasons. If the physician who is implementing your employers medical program makes a final written opinion recommending your removal or other special protective measures, your employer must implement the physician's recommendation. If you are removed in this manner, you may only be returned when the doctor indicates that it is safe for you to do so.

The standard does not give specific instructions dealing with what an employer must do with a removed worker. Your job assignment upon removal is a matter for you, your employer and your union (if any) to work out consistent with existing procedures for job assignments.

Each removal must be accomplished in a manner consistent with existing collective bargaining relationships. Your employer is given broad discretion to implement temporary removals so long as no attempt is made to override existing agreements. Similarly, a removed worker is provided no right to veto an employer's choice which satisfies the standard.

In most cases, employers will likely transfer removed employees to other jobs with sufficiently low lead exposure. Alternatively, a worker's hours may be reduced so that the time weighted average exposure is reduced, or he or she may be temporarily laid off if no other alternative is feasible.

In all of these situation, MRP benefits must be provided during the period of removal - i.e., you continue to receive the same earnings, seniority, and other rights and benefits you would have had if you had not been removed. Earnings includes more than just your base wage; it includes overtime, shift differentials, incentives, and other compensation you would have earned if you had not been removed. During the period of removal you must also be provided with appropriate follow-up medical surveillance. If you were removed because your blood lead level was too high, you must be provided with a monthly blood test. If a medical opinion caused your removal, you must be provided medical tests or examinations that the doctor believes to be appropriate. If you do not participate in this follow up medical surveillance, you may lose your eligibility for MRP benefits.

When you are medically eligible to return to your former job, your employer must return you to your "former job status." This means that you are entitled to the position, wages, benefits, etc., you would have had if you had not been removed. If you would still be in your old job if no removal had occurred that is where you go back. If not, you are returned consistent with whatever job assignment discretion your employer would have had if no removal had occurred. MRP only seeks to maintain your rights, not expand them or diminish them.

If you are removed under MRP and you are also eligible for worker compensation or other compensation for lost wages, your employer's MRP benefits obligation is reduced by the amount that you actually receive from these other sources. This is also true if you obtain other employment during the time you are laid off with MRP benefits.

The standard also covers situations where an employer voluntarily removes a worker from exposure to lead due to the effects of lead on the employee's medical condition, even though the standard does not require removal. In these situations MRP benefits must still be provided as though the standard required removal. Finally, it is important to note that in all cases where removal is required, respirators cannot be used as a substitute. Respirators may be used before removal becomes necessary, but not as an alternative to a transfer to a low exposure job, or to a lay-off with MRP benefits.

X. Employee Information and Training - Paragraph (L)

Your employer is required to provide an information and training program for all employees exposed to lead above the action level or who may suffer skin or eye irritation from lead compounds such as lead arsenate or lead azide. The program must train these employees regarding the specific hazards associated with their work environment, protective measures which can be taken, including the contents of any compliance plan in effect, the danger of lead to their bodies (including their reproductive systems), and their rights under the standard. All employees must be trained prior to initial assignment to areas where there is a possibility of

exposure over the action level.

This training program must also be provided at least annually thereafter unless further exposure above the action level will not occur.

XI. Signs - Paragraph (M)

~~The standard requires that the following warning sign be posted in work areas where the exposure to lead exceeds the PEL:~~

~~_____ WARNING
_____ LEAD WORK AREA
_____ POISON
_____ NO SMOKING OR EATING~~

~~_____ These signs are to be posted and maintained in a manner which assures that the legend is readily visible.~~ The standard requires that the following warning sign be posted in work areas when the exposure to lead is above the PEL:

DANGER
LEAD WORK AREA
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM
DO NOT EAT, DRINK OR SMOKE IN THIS AREA

Prior to June 1, 2016, employers may use the following legend in lieu of that specified above:

WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING

XII. Recordkeeping - Paragraph (N)

Your employer is required to keep all records of exposure monitoring for airborne lead. These records must include the name and job classification of employees measured, details of the sampling and analytical techniques, the results of this sampling, and the type of respiratory protection being worn by the person sampled. Such records are to be retained for at least 30 years. Your employer is also required to keep all records of biological monitoring and medical examination results. These records must include the names of the employees, the physician's written opinion, and a copy of the results of the examination. Medical records must be preserved and maintained for the duration of employment plus 30 years. However, if the employee's duration of employment is less than one year, the employer need not retain that employee's medical records beyond the period of employment if they are provided to the employee upon termination of employment.

Recordkeeping is also required if you are temporarily removed from your job under the medical removal protection program. This record must include your name and social security number, the date of your removal and return, how the removal was or is being accomplished, and whether or not the reason for the removal was an elevated blood lead level. Your employer is required to keep each medical removal record only for as long as the duration of an employee's

employment.

The standard requires that if you request to see or copy environmental monitoring, blood lead level monitoring, or medical removal records, they must be made available to you or to a representative that you authorize. Your union also has access to these records. Medical records other than BLL's must also be provided upon request to you, to your physician or to any other person whom you may specifically designate. Your union does not have access to your personal medical records unless you authorize their access.

XIII. Observation of Monitoring - Paragraph (O)

When air monitoring for lead is performed at your workplace as required by this standard, your employer must allow you or someone you designate to act as an observer of the monitoring. Observers are entitled to an explanation of the measurement procedure, and to record the results obtained. Since results will not normally be available at the time of the monitoring, observers are entitled to record or receive the results of the monitoring when returned by the laboratory. Your employer is required to provide the observer with any personal protective devices required to be worn by employees working in the area that is being monitored. The employer must require the observer to wear all such equipment and to comply with all other applicable safety and health procedures.

XIV. For Additional Information

A. A copy of the interim standard for lead in construction can be obtained free of charge by calling or writing the OSHA Office of Publications, room N-3101, United States Department of Labor, Washington, DC 20210: Telephone (202) 219-4667.

B. Additional information about the standard, its enforcement, and your employer's compliance can be obtained from the nearest OSHA Area Office listed in your telephone directory under United States Government/Department of Labor.

Appendix C to 1926.62 - Medical Surveillance Guidelines

Introduction

The primary purpose of the Occupational Safety and Health Act of 1970 is to assure, so far as possible, safe and healthful working conditions for every working man and woman. The interim final occupational health standard for lead in construction is designed to protect workers exposed to inorganic lead including metallic lead, all inorganic lead compounds and organic lead soaps.

Under this interim final standard occupational exposure to inorganic lead is to be limited to 50 $\mu\text{g}/\text{m}^3$ (micrograms per cubic meter) based on an 8 hour time-weighted average (TWA). This permissible exposure limit (PEL) must be achieved through a combination of engineering, work practice and administrative controls to the extent feasible. Where these controls are in place but are found not to reduce employee exposures to or below the PEL, they must be used nonetheless, and supplemented with respirators to meet the 50 $\mu\text{g}/\text{m}^3$ exposure limit.

The standard also provides for a program of biological monitoring for employees exposed to lead above the action level at any time, and additional medical surveillance for all employees

exposed to levels of inorganic lead above 30 :g/m³ (TWA) for more than 30 days per year and whose BLL exceeds 40 :g/dl.

The purpose of this document is to outline the medical surveillance provisions of the interim standard for inorganic lead in construction, and to provide further information to the physician regarding the examination and evaluation of workers exposed to inorganic lead.

Section 1 provides a detailed description of the monitoring procedure including the required frequency of blood testing for exposed workers, provisions for medical removal protection (MRP), the recommended right of the employee to a second medical opinion, and notification and recordkeeping requirements of the employer. A discussion of the requirements for respirator use and respirator monitoring and OSHA's position on prophylactic chelation therapy are also included in this section.

Section 2 discusses the toxic effects and clinical manifestations of lead poisoning and effects of lead intoxication on enzymatic pathways in heme synthesis. The adverse effects on both male and female reproductive capacity and on the fetus are also discussed.

Section 3 outlines the recommended medical evaluation of the worker exposed to inorganic lead, including details of the medical history, physical examination, and recommended laboratory tests, which are based on the toxic effects of lead as discussed in Section 2.

Section 4 provides detailed information concerning the laboratory tests available for the monitoring of exposed workers. Included also is a discussion of the relative value of each test and the limitations and precautions which are necessary in the interpretation of the laboratory results.

I. Medical Surveillance and Monitoring Requirements for Workers Exposed to Inorganic Lead

Under the interim final standard for inorganic lead in the construction industry, initial medical surveillance consisting of biological monitoring to include blood lead and ZPP level determination shall be provided to employees exposed to lead at or above the action level on any one day. In addition, a program of biological monitoring is to be made available to all employees exposed above the action level at any time and additional medical surveillance is to be made available to all employees exposed to lead above 30 :g/m³ TWA for more than 30 days each year and whose BLL exceeds 40 :g/dl. This program consists of periodic blood sampling and medical evaluation to be performed on a schedule which is defined by previous laboratory results, worker complaints or concerns, and the clinical assessment of the examining physician.

Under this program, the blood lead level (BLL) of all employees who are exposed to lead above 30 ug/m³ for more than 30 days per year or whose blood lead is above 40 ug/dl but exposed for no more than 30 days per year is to be determined at least every two months for the first six months of exposure and every six months thereafter. The frequency is increased to every two months for employees whose last blood lead level was 40 ug/dl or above. For employees who are removed from exposure to lead due to an elevated blood lead, a new blood lead level must be measured monthly. A zinc protoporphyrin (ZPP) measurement is strongly recommended on each occasion that a blood lead level measurement is made.

An annual medical examination and consultation performed under the guidelines discussed in Section 3 is to be made available to each employee exposed above 30 ug/m³ for

more than 30 days per year for whom a blood test conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 $\mu\text{g}/\text{dl}$. Also, an examination is to be given to all employees prior to their assignment to an area in which airborne lead concentrations reach or exceed the 30 $\mu\text{g}/\text{m}^3$ for more than 30 days per year. In addition, a medical examination must be provided as soon as possible after notification by an employee that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice regarding lead exposure and the ability to procreate a healthy child, or that the employee has demonstrated difficulty in breathing during a respirator fitting test or during respirator use. An examination is also to be made available to each employee removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited or specially protected pursuant to medical recommendations.

Results of biological monitoring or the recommendations of an examining physician may necessitate removal of an employee from further lead exposure pursuant to the standard's medical removal protection (MRP) program. The object of the MRP program is to provide temporary medical removal to workers either with substantially elevated blood lead levels or otherwise at risk of sustaining material health impairment from continued substantial exposure to lead.

Under the standard's ultimate worker removal criteria, a worker is to be removed from any work having an eight hour TWA exposure to lead of 30 $\mu\text{g}/\text{m}^3$ when his or her blood lead level reaches 50 $\mu\text{g}/\text{dl}$ and is confirmed by a second follow-up blood lead level performed within two weeks after the employer receives the results of the first blood sampling test. Return of the employee to his or her job status depends on a worker's blood lead level declining to 40 $\mu\text{g}/\text{dl}$.

As part of the interim standard, the employer is required to notify in writing each employee whose blood lead level exceeds 40 $\mu\text{g}/\text{dl}$. In addition each such employee is to be informed that the standard requires medical removal with MRP benefits, discussed below, when an employee's blood lead level exceeds the above defined limit.

In addition to the above blood lead level criterion, temporary worker removal may also take place as a result of medical determinations and recommendations. Written medical opinions must be prepared after each examination pursuant to the standard. If the examining physician includes a medical finding, determination or opinion that the employee has a medical condition which places the employee at increased risk of material health impairment from exposure to lead, then the employee must be removed from exposure to lead at or above 30 $\mu\text{g}/\text{m}^3$. Alternatively, if the examining physician recommends special protective measures for an employee (e.g., use of a powered air purifying respirator) or recommends limitations on an employee's exposure to lead, then the employer must implement these recommendations.

Recommendations may be more stringent than the specific provisions of the standard. The examining physician, therefore, is given broad flexibility to tailor special protective procedures to the needs of individual employees. This flexibility extends to the evaluation and management of pregnant workers and male and female workers who are planning to raise children. Based on the history, physical examination, and laboratory studies, the physician might recommend special protective measures or medical removal for an employee who is pregnant or who is planning to conceive a child when, in the physician's judgment, continued exposure to lead at the current job would pose a significant risk. The return of the employee to his or her former job status, or the removal of special protections or limitations, depends upon the examining physician determining that the employee is no longer at increased risk of material

impairment or that special measures are no longer needed.

During the period of any form of special protection or removal, the employer must maintain the worker's earnings, seniority, and other employment rights and benefits (as though the worker had not been removed) for a period of up to 18 months or for as long as the job the employee was removed from lasts if less than 18 months. This economic protection will maximize meaningful worker participation in the medical surveillance program, and is appropriate as part of the employer's overall obligation to provide a safe and healthful workplace. The provisions of MRP benefits during the employee's removal period may, however, be conditioned upon participation in medical surveillance.

The lead standard provides for a multiple physician review in cases where the employee wishes a second opinion concerning potential lead poisoning or toxicity. If an employee wishes a second opinion, he or she can make an appointment with a physician of his or her choice. This second physician will review the findings, recommendations or determinations of the first physician and conduct any examinations, consultations or tests deemed necessary in an attempt to make a final medical determination. If the first and second physicians do not agree in their assessment they must try to resolve their differences. If they cannot reach an agreement then they must designate a third physician to resolve the dispute.

The employer must provide examining and consulting physicians with the following specific information: A copy of the lead regulations and all appendices, a description of the employee's duties as related to exposure, the exposure level or anticipated level to lead and any other toxic substances (if applicable), a description of personal protective equipment used, blood lead levels, and all prior written medical opinions regarding the employee in the employer's possession or control. The employer must also obtain from the physician and provide the employee with a written medical opinion containing blood lead levels, the physicians's opinion as to whether the employee is at risk of material impairment to health, any recommended protective measures for the employee if further exposure is permitted, as well as any recommended limitations upon an employee's use of respirators.

Employers must instruct each physician not to reveal to the employer in writing or in any other way his or her findings, laboratory results, or diagnoses which are felt to be unrelated to occupational lead exposure. They must also instruct each physician to advise the employee of any occupationally or non-occupationally related medical condition requiring further treatment or evaluation.

The standard provides for the use of respirators where engineering and other primary controls are not effective. However, the use of respirator protection shall not be used in lieu of temporary medical removal due to elevated blood lead levels or findings that an employee is at risk of material health impairment. This is based on the numerous inadequacies of respirators including skin rash where the facepiece makes contact with the skin, unacceptable stress to breathing in some workers with underlying cardiopulmonary impairment, difficulty in providing adequate fit, the tendency for respirators to create additional hazards by interfering with vision, hearing, and mobility, and the difficulties of assuring the maximum effectiveness of a complicated work practice program involving respirators. Respirators do, however, serve a useful function where engineering and work practice controls are inadequate by providing supplementary, interim, or short-term protection, provided they are properly selected for the environment in which the employee will be working, properly fitted to the employee, maintained and cleaned periodically, and worn by the employee when required.

In its interim final standard on occupational exposure to inorganic lead in the construction industry, OSHA has prohibited prophylactic chelation. Diagnostic and therapeutic chelation are permitted only under the supervision of a licensed physician with appropriate medical monitoring in an acceptable clinical setting. The decision to initiate chelation therapy must be made on an individual basis and take into account the severity of symptoms felt to be a result of lead toxicity along with blood lead levels, ZPP levels, and other laboratory tests as appropriate. EDTA and penicillamine which are the primary chelating agents used in the therapy of occupational lead poisoning have significant potential side effects and their use must be justified on the basis of expected benefits to the worker. Unless frank and severe symptoms are present, therapeutic chelation is not recommended, given the opportunity to remove a worker from exposure and allow the body to naturally excrete accumulated lead. As a diagnostic aid, the chelation mobilization test using CA-EDTA has limited applicability. According to some investigators, the test can differentiate between lead-induced and other nephropathies. The test may also provide an estimation of the mobile fraction of the total body lead burden.

Employers are required to assure that accurate records are maintained on exposure assessment, including environmental monitoring, medical surveillance, and medical removal for each employee. Exposure assessment records must be kept for at least 30 years. Medical surveillance records must be kept for the duration of employment plus 30 years except in cases where the employment was less than one year. If duration of employment is less than one year, the employer need not retain this record beyond the term of employment if the record is provided to the employee upon termination of employment. Medical removal records also must be maintained for the duration of employment. All records required under the standard must be made available upon request to the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health. Employers must also make environmental and biological monitoring and medical removal records available to affected employees and to former employees or their authorized employee representatives. Employees or their specifically designated representatives have access to their entire medical surveillance records.

In addition, the standard requires that the employer inform all workers exposed to lead at or above 30 $\mu\text{g}/\text{m}^3$ of the provisions of the standard and all its appendices, the purpose and description of medical surveillance and provisions for medical removal protection if temporary removal is required. An understanding of the potential health effects of lead exposure by all exposed employees along with full understanding of their rights under the lead standard is essential for an effective monitoring program.

II. Adverse Health Effects of Inorganic Lead

Although the toxicity of lead has been known for 2,000 years, the knowledge of the complex relationship between lead exposure and human response is still being refined. Significant research into the toxic properties of lead continues throughout the world, and it should be anticipated that our understanding of thresholds of effects and margins of safety will be improved in future years. The provisions of the lead standard are founded on two prime medical judgments: First, the prevention of adverse health effects from exposure to lead throughout a working lifetime requires that worker blood lead levels be maintained at or below 40 $\mu\text{g}/\text{dl}$ and second, the blood lead levels of workers, male or female, who intend to parent in the near future should be maintained below 30 $\mu\text{g}/\text{dl}$ to minimize adverse reproductive health effects to the parents and developing fetus. The adverse effects of lead on reproduction are being

actively researched and OSHA encourages the physician to remain abreast of recent developments in the area to best advise pregnant workers or workers planning to conceive children.

The spectrum of health effects caused by lead exposure can be subdivided into five developmental stages: Normal, physiological changes of uncertain significance, pathophysiological changes, overt symptoms (morbidity), and mortality. Within this process there are no sharp distinctions, but rather a continuum of effects. Boundaries between categories overlap due to the wide variation of individual responses and exposures in the working population. OSHA's development of the lead standard focused on pathophysiological changes as well as later stages of disease.

1. Heme Synthesis Inhibition. The earliest demonstrated effect of lead involves its ability to inhibit at least two enzymes of the heme synthesis pathway at very low blood levels. Inhibition of delta aminolevulinic acid dehydrase (ALA-D) which catalyzes the conversion of delta-aminolevulinic acid (ALA) to protoporphyrin is observed at a blood lead level below 20 $\mu\text{g}/\text{dl}$. At a blood lead level of 40 $\mu\text{g}/\text{dl}$, more than 20% of the population would have 70% inhibition of ALA-D. There is an exponential increase in ALA excretion at blood lead levels greater than 40 $\mu\text{g}/\text{dl}$.

Another enzyme, ferrochelatase, is also inhibited at low blood lead levels. Inhibition of ferrochelatase leads to increased free erythrocyte protoporphyrin (FEP) in the blood which can then bind to zinc to yield zinc protoporphyrin. At a blood lead level of 50 $\mu\text{g}/\text{dl}$ or greater, nearly 100% of the population will have an increase in FEP. There is also an exponential relationship between blood lead levels greater than 40 $\mu\text{g}/\text{dl}$ and the associated ZPP level, which has led to the development of the ZPP screening test for lead exposure.

While the significance of these effects is subject to debate, it is OSHA's position that these enzyme disturbances are early stages of a disease process which may eventually result in the clinical symptoms of lead poisoning. Whether or not the effects do progress to the later stages of clinical disease, disruption of these enzyme processes over a working lifetime is considered to be a material impairment of health.

One of the eventual results of lead-induced inhibition of enzymes in the heme synthesis pathway is anemia which can be asymptomatic if mild but associated with a wide array of symptoms including dizziness, fatigue, and tachycardia when more severe. Studies have indicated that lead levels as low as 50 $\mu\text{g}/\text{dl}$ can be associated with a definite decreased hemoglobin, although most cases of lead-induced anemia, as well as shortened red-cell survival times, occur at lead levels exceeding 80 $\mu\text{g}/\text{dl}$. Inhibited hemoglobin synthesis is more common in chronic cases whereas shortened erythrocyte life span is more common in acute cases.

In lead-induced anemias, there is usually a reticulocytosis along with the presence of basophilic stippling, and ringed sideroblasts, although none of the above are pathognomonic for lead-induced anemia.

2. Neurological Effects. Inorganic lead has been found to have toxic effects on both the central and peripheral nervous systems. The earliest stages of lead-induced central nervous system effects first manifest themselves in the form of behavioral disturbances and central nervous system symptoms including irritability, restlessness, insomnia and other sleep disturbances, fatigue, vertigo, headache, poor memory, tremor, depression, and apathy. With

more severe exposure, symptoms can progress to drowsiness, stupor, hallucinations, delirium, convulsions and coma.

The most severe and acute form of lead poisoning which usually follows ingestion or inhalation of large amounts of lead is acute encephalopathy which may arise precipitously with the onset of intractable seizures, coma, cardiorespiratory arrest, and death within 48 hours.

While there is disagreement about what exposure levels are needed to produce the earliest symptoms, most experts agree that symptoms definitely can occur at blood lead levels of 60 $\mu\text{g}/\text{dl}$ whole blood and therefore recommend a 40 $\mu\text{g}/\text{dl}$ maximum. The central nervous system effects frequently are not reversible following discontinued exposure or chelation therapy and when improvement does occur, it is almost always only partial.

The peripheral neuropathy resulting from lead exposure characteristically involves only motor function with minimal sensory damage and has a marked predilection for the extensor muscles of the most active extremity. The peripheral neuropathy can occur with varying degrees of severity. The earliest and mildest form which can be detected in workers with blood lead levels as low as 50 $\mu\text{g}/\text{dl}$ is manifested by slowing of motor nerve conduction velocity often without clinical symptoms. With progression of the neuropathy there is development of painless extensor muscle weakness usually involving the extensor muscles of the fingers and hand in the most active upper extremity, followed in severe cases by wrist drop or, much less commonly, foot drop.

In addition to slowing of nerve conduction, electromyographical studies in patients with blood lead levels greater than 50 $\mu\text{g}/\text{dl}$ have demonstrated a decrease in the number of acting motor unit potentials, an increase in the duration of motor unit potentials, and spontaneous pathological activity including fibrillations and fasciculations. Whether these effects occur at levels of 40 $\mu\text{g}/\text{dl}$ is undetermined.

While the peripheral neuropathies can occasionally be reversed with therapy, again such recovery is not assured particularly in the more severe neuropathies and often improvement is only partial. The lack of reversibility is felt to be due in part to segmental demyelination.

3. Gastrointestinal. Lead may also affect the gastrointestinal system producing abdominal colic or diffuse abdominal pain, constipation, obstipation, diarrhea, anorexia, nausea and vomiting. Lead colic rarely develops at blood lead levels below 80 $\mu\text{g}/\text{dl}$.

4. Renal. Renal toxicity represents one of the most serious health effects of lead poisoning. In the early stages of disease nuclear inclusion bodies can frequently be identified in proximal renal tubular cells. Renal function remains normal and the changes in this stage are probably reversible. With more advanced disease there is progressive interstitial fibrosis and impaired renal function. Eventually extensive interstitial fibrosis ensues with sclerotic glomeruli and dilated and atrophied proximal tubules; all represent end stage kidney disease. Azotemia can be progressive, eventually resulting in frank uremia necessitating dialysis. There is occasionally associated hypertension and hyperuricemia with or without gout.

Early kidney disease is difficult to detect. The urinalysis is normal in early lead nephropathy and the blood urea nitrogen and serum creatinine increase only when two-thirds of kidney function is lost. Measurement of creatinine clearance can often detect earlier disease as can other methods of measurement of glomerular filtration rate. An abnormal Ca-EDTA

mobilization test has been used to differentiate between lead-induced and other nephropathies, but this procedure is not widely accepted. A form of Fanconi syndrome with aminoaciduria, glycosuria, and hyperphosphaturia indicating severe injury to the proximal renal tubules is occasionally seen in children.

5. Reproductive effects. Exposure to lead can have serious effects on reproductive function in both males and females. In male workers exposed to lead there can be a decrease in sexual drive, impotence, decreased ability to produce healthy sperm, and sterility. Malformed sperm (teratospermia), decreased number of sperm (hypospermia), and sperm with decreased motility (asthenospermia) can all occur. Teratospermia has been noted at mean blood lead levels of 53 $\mu\text{g}/\text{dl}$ and hypospermia and asthenospermia at 41 $\mu\text{g}/\text{dl}$. Furthermore, there appears to be a dose-response relationship for teratospermia in lead exposed workers.

Women exposed to lead may experience menstrual disturbances including dysmenorrhea, menorrhagia and amenorrhea. Following exposure to lead, women have a higher frequency of sterility, premature births, spontaneous miscarriages, and stillbirths.

Germ cells can be affected by lead and cause genetic damage in the egg or sperm cells before conception and result in failure to implant, miscarriage, stillbirth, or birth defects.

Infants of mothers with lead poisoning have a higher mortality during the first year and suffer from lowered birth weights, slower growth, and nervous system disorders.

Lead can pass through the placental barrier and lead levels in the mother's blood are comparable to concentrations of lead in the umbilical cord at birth. Transplacental passage becomes detectable at 12-14 weeks of gestation and increases until birth.

There is little direct data on damage to the fetus from exposure to lead but it is generally assumed that the fetus and newborn would be at least as susceptible to neurological damage as young children. Blood lead levels of 50-60 $\mu\text{g}/\text{dl}$ in children can cause significant neurobehavioral impairments and there is evidence of hyperactivity at blood levels as low as 25 $\mu\text{g}/\text{dl}$. Given the overall body of literature concerning the adverse health effects of lead in children, OSHA feels that the blood lead level in children should be maintained below 30 $\mu\text{g}/\text{dl}$ with a population mean of 15 $\mu\text{g}/\text{dl}$. Blood lead levels in the fetus and newborn likewise should not exceed 30 $\mu\text{g}/\text{dl}$.

Because of lead's ability to pass through the placental barrier and also because of the demonstrated adverse effects of lead on reproductive function in both the male and female as well as the risk of genetic damage of lead on both the ovum and sperm, OSHA recommends a 30 $\mu\text{g}/\text{dl}$ maximum permissible blood lead level in both males and females who wish to bear children.

6. Other toxic effects. Debate and research continue on the effects of lead on the human body. Hypertension has frequently been noted in occupationally exposed individuals although it is difficult to assess whether this is due to lead's adverse effects on the kidney or if some other mechanism is involved. Vascular and electrocardiographic changes have been detected but have not been well characterized. Lead is thought to impair thyroid function and interfere with the pituitary-adrenal axis, but again these effects have not been well defined.

III. Medical Evaluation

The most important principle in evaluating a worker for any occupational disease including lead poisoning is a high index of suspicion on the part of the examining physician. As discussed in Section 2, lead can affect numerous organ systems and produce a wide array of signs and symptoms, most of which are non-specific and subtle in nature at least in the early stages of disease. Unless serious concern for lead toxicity is present, many of the early clues to diagnosis may easily be overlooked.

The crucial initial step in the medical evaluation is recognizing that a worker's employment can result in exposure to lead. The worker will frequently be able to define exposures to lead and lead containing materials but often will not volunteer this information unless specifically asked. In other situations the worker may not know of any exposures to lead but the suspicion might be raised on the part of the physician because of the industry or occupation of the worker. Potential occupational exposure to lead and its compounds occur in many occupations in the construction industry, including demolition and salvaging operations, removal or encapsulation of materials containing lead, construction, alteration, repair or renovation of structures containing lead, transportation, disposal, storage or containment of lead or lead-containing materials on construction sites, and maintenance operations associated with construction activities.

Once the possibility for lead exposure is raised, the focus can then be directed toward eliciting information from the medical history, physical exam, and finally from laboratory data to evaluate the worker for potential lead toxicity.

A complete and detailed work history is important in the initial evaluation. A listing of all previous employment with information on job description, exposure to fumes or dust, known exposures to lead or other toxic substances, a description of any personal protective equipment used, and previous medical surveillance should all be included in the worker's record. Where exposure to lead is suspected, information concerning on-the-job personal hygiene, smoking or eating habits in work areas, laundry procedures, and use of any protective clothing or respiratory protection equipment should be noted. A complete work history is essential in the medical evaluation of a worker with suspected lead toxicity, especially when long term effects such as neurotoxicity and nephrotoxicity are considered.

The medical history is also of fundamental importance and should include a listing of all past and current medical conditions, current medications including proprietary drug intake, previous surgeries and hospitalizations, allergies, smoking history, alcohol consumption, and also non-occupational lead exposures such as hobbies (hunting, riflery). Also known childhood exposures should be elicited. Any previous history of hematological, neurological, gastrointestinal, renal, psychological, gynecological, genetic, or reproductive problems should be specifically noted.

A careful and complete review of systems must be performed to assess both recognized complaints and subtle or slowly acquired symptoms which the worker might not appreciate as being significant. The review of symptoms should include the following:

1. General - weight loss, fatigue, decreased appetite.
2. Head, Eyes, Ears, Nose, Throat (HEENT) - headaches, visual disturbances or decreased visual acuity, hearing deficits or tinnitus, pigmentation of the oral mucosa, or metallic

taste in mouth.

3. Cardio-pulmonary - shortness of breath, cough, chest pains, palpitations, or orthopnea.

4. Gastrointestinal - nausea, vomiting, heartburn, abdominal pain, constipation or diarrhea.

5. Neurologic - irritability, insomnia, weakness (fatigue), dizziness, loss of memory, confusion, hallucinations, incoordination, ataxia, decreased strength in hands or feet, disturbances in gait, difficulty in climbing stairs, or seizures.

6. Hematologic - pallor, easy fatigability, abnormal blood loss, melena.

7. Reproductive (male and female and spouse where relevant) - history of infertility, impotence, loss of libido, abnormal menstrual periods, history of miscarriages, stillbirths, or children with birth defects.

8. Musculo-skeletal - muscle and joint pains.

The physical examination should emphasize the neurological, gastrointestinal, and cardiovascular systems. The worker's weight and blood pressure should be recorded and the oral mucosa checked for pigmentation characteristic of a possible Burtonian or lead line on the gingiva. It should be noted, however, that the lead line may not be present even in severe lead poisoning if good oral hygiene is practiced.

The presence of pallor on skin examination may indicate an anemia which, if severe, might also be associated with a tachycardia. If an anemia is suspected, an active search for blood loss should be undertaken including potential blood loss through the gastrointestinal tract.

A complete neurological examination should include an adequate mental status evaluation including a search for behavioral and psychological disturbances, memory testing, evaluation for irritability, insomnia, hallucinations, and mental clouding. Gait and coordination should be examined along with close observation for tremor. A detailed evaluation of peripheral nerve function including careful sensory and motor function testing is warranted. Strength testing particularly of extensor muscle groups of all extremities is of fundamental importance.

Cranial nerve evaluation should also be included in the routine examination.

The abdominal examination should include auscultation for bowel sounds and abdominal bruits and palpation for organomegaly, masses, and diffuse abdominal tenderness.

Cardiovascular examination should evaluate possible early signs of congestive heart failure. Pulmonary status should be addressed particularly if respirator protection is contemplated.

As part of the medical evaluation, the interim lead standard requires the following laboratory studies:

1. Blood lead level

2. Hemoglobin and hematocrit determinations, red cell indices, and examination of the peripheral blood smear to evaluate red blood cell morphology

3. Blood urea nitrogen

4. Serum creatinine

5. Routine urinalysis with microscopic examination.

6. A zinc protoporphyrin level.

In addition to the above, the physician is authorized to order any further laboratory or other tests which he or she deems necessary in accordance with sound medical practice. The evaluation must also include pregnancy testing or laboratory evaluation of male fertility if requested by the employee. Additional tests which are probably not warranted on a routine basis but may be appropriate when blood lead and ZPP levels are equivocal include delta aminolevulinic acid and coproporphyrin concentrations in the urine, and dark-field illumination for detection of basophilic stippling in red blood cells.

If an anemia is detected further studies including a careful examination of the peripheral smear, reticulocyte count, stool for occult blood, serum iron, total iron binding capacity, bilirubin, and, if appropriate, vitamin B12 and folate may be of value in attempting to identify the cause of the anemia.

If a peripheral neuropathy is suspected, nerve conduction studies are warranted both for diagnosis and as a basis to monitor any therapy.

If renal disease is questioned, a 24 hour urine collection for creatinine clearance, protein, and electrolytes may be indicated. Elevated uric acid levels may result from lead-induced renal disease and a serum uric acid level might be performed.

An electrocardiogram and chest x-ray may be obtained as deemed appropriate.

Sophisticated and highly specialized testing should not be done routinely and where indicated should be under the direction of a specialist.

IV. Laboratory Evaluation

The blood lead level at present remains the single most important test to monitor lead exposure and is the test used in the medical surveillance program under the lead standard to guide employee medical removal. The ZPP has several advantages over the blood lead level. Because of its relatively recent development and the lack of extensive data concerning its interpretation, the ZPP currently remains an ancillary test.

This section will discuss the blood lead level and ZPP in detail and will outline their relative advantages and disadvantages. Other blood tests currently available to evaluate lead exposure will also be reviewed.

The blood lead level is a good index of current or recent lead absorption when there is no anemia present and when the worker has not taken any chelating agents. However, blood lead

levels along with urinary lead levels do not necessarily indicate the total body burden of lead and are not adequate measures of past exposure. One reason for this is that lead has a high affinity for bone and up to 90% of the body's total lead is deposited there. A very important component of the total lead body burden is lead in soft tissue (liver, kidney, and brain). This fraction of the lead body burden, the biologically active lead, is not entirely reflected by blood lead levels since it is a function of the dynamics of lead absorption, distribution, deposition in bone and excretion. Following discontinuation of exposure to lead, the excess body burden is only slowly mobilized from bone and other relatively stable body stores and excreted. Consequently, a high blood lead level may only represent recent heavy exposure to lead without a significant total body excess and likewise a low blood lead level does not exclude an elevated total body burden of lead.

Also due to its correlation with recent exposures, the blood lead level may vary considerably over short time intervals.

To minimize laboratory error and erroneous results due to contamination, blood specimens must be carefully collected after thorough cleaning of the skin with appropriate methods using lead-free blood containers and analyzed by a reliable laboratory. Under the standard, samples must be analyzed in laboratories which are approved by OSHA. Analysis is to be made using atomic absorption spectrophotometry, anodic stripping voltammetry or any method which meets the accuracy requirements set forth by the standard.

The determination of lead in urine is generally considered a less reliable monitoring technique than analysis of whole blood primarily due to individual variability in urinary excretion capacity as well as the technical difficulty of obtaining accurate 24 hour urine collections. In addition, workers with renal insufficiency, whether due to lead or some other cause, may have decreased lead clearance and consequently urine lead levels may underestimate the true lead burden. Therefore, urine lead levels should not be used as a routine test.

The zinc protoporphyrin test, unlike the blood lead determination, measures an adverse metabolic effect of lead and as such is a better indicator of lead toxicity than the level of blood lead itself. The level of ZPP reflects lead absorption over the preceding 3 to 4 months, and therefore is a better indicator of lead body burden. The ZPP requires more time than the blood lead to read significantly elevated levels; the return to normal after discontinuing lead exposure is also slower. Furthermore, the ZPP test is simpler, faster, and less expensive to perform and no contamination is possible. Many investigators believe it is the most reliable means of monitoring chronic lead absorption.

Zinc protoporphyrin results from the inhibition of the enzyme ferrochelatase which catalyzes the insertion of an iron molecule into the protoporphyrin molecule, which then becomes heme. If iron is not inserted into the molecule then zinc, having a greater affinity for protoporphyrin, takes the place of the iron, forming ZPP.

An elevation in the level of circulating ZPP may occur at blood lead levels as low as 20-30 $\mu\text{g}/\text{dl}$ in some workers. Once the blood lead level has reached 40 $\mu\text{g}/\text{dl}$ there is more marked rise in the ZPP value from its normal range of less than 100 $\mu\text{g}/\text{dl}$ per 100 ml. Increases in blood lead levels beyond 40 $\mu\text{g}/100 \text{ g}$ are associated with exponential increases in ZPP.

Whereas blood lead levels fluctuate over short time spans, ZPP levels remain relatively stable. ZPP is measured directly in red blood cells and is present for the cell's entire 120 day life-span. Therefore, the ZPP level in blood reflects the average ZPP production over the previous 3-

4 months and consequently the average lead exposure during that time interval.

It is recommended that a hematocrit be determined whenever a confirmed ZPP of 50 $\mu\text{g}/100$ ml whole blood is obtained to rule out a significant underlying anemia. If the ZPP is in excess of 100 $\mu\text{g}/100$ ml and not associated with abnormal elevations in blood lead levels, the laboratory should be checked to be sure that blood leads were determined using atomic absorption spectrophotometry anodic stripping voltammetry, or any method which meets the accuracy requirements set forth by the standard by an OSHA approved laboratory which is experienced in lead level determinations. Repeat periodic blood lead studies should be obtained in all individuals with elevated ZPP levels to be certain that an associated elevated blood lead level has not been missed due to transient fluctuations in blood leads.

ZPP has a characteristic fluorescence spectrum with a peak at 594 nm which is detectable with a hematofluorimeter. The hematofluorimeter is accurate and portable and can provide on-site, instantaneous results for workers who can be frequently tested via a finger prick.

However, careful attention must be given to calibration and quality control procedures. Limited data on blood lead-ZPP correlations and the ZPP levels which are associated with the adverse health effects discussed in Section 2 are the major limitations of the test. Also it is difficult to correlate ZPP levels with environmental exposure and there is some variation of response with age and sex. Nevertheless, the ZPP promises to be an important diagnostic test for the early detection of lead toxicity and its value will increase as more data is collected regarding its relationship to other manifestations of lead poisoning.

Levels of delta-aminolevulinic acid (ALA) in the urine are also used as a measure of lead exposure. Increasing concentrations of ALA are believed to result from the inhibition of the enzyme delta-aminolevulinic acid dehydrase (ALA-D). Although the test is relatively easy to perform, inexpensive, and rapid, the disadvantages include variability in results, the necessity to collect a complete 24 hour urine sample which has a specific gravity greater than 1.010, and also the fact that ALA decomposes in the presence of light.

The pattern of porphyrin excretion in the urine can also be helpful in identifying lead intoxication. With lead poisoning, the urine concentrations of coproporphyrins I and II, porphobilinogen and uroporphyrin I rise. The most important increase, however, is that of coproporphyrin III; levels may exceed 5,000 $\mu\text{g}/\text{l}$ in the urine in lead poisoned individuals, but its correlation with blood lead levels and ZPP are not as good as those of ALA. Increases in urinary porphyrins are not diagnostic of lead toxicity and may be seen in porphyria, some liver diseases, and in patients with high reticulocyte counts.

Summary. The Occupational Safety and Health Administration's interim standard for inorganic lead in the construction industry places significant emphasis on the medical surveillance of all workers exposed to levels of inorganic lead above 30 $\mu\text{g}/\text{m}^3$ TWA. The physician has a fundamental role in this surveillance program, and in the operation of the medical removal protection program.

Even with adequate worker education on the adverse health effects of lead and appropriate training in work practices, personal hygiene and other control measures, the physician has a primary responsibility for evaluating potential lead toxicity in the worker. It is only through a careful and detailed medical and work history, a complete physical examination and appropriate laboratory testing that an accurate assessment can be made. Many of the adverse

health effects of lead toxicity are either irreversible or only partially reversible and therefore early detection of disease is very important.

This document outlines the medical monitoring program as defined by the occupational safety and health standard for inorganic lead. It reviews the adverse health effects of lead poisoning and describes the important elements of the history and physical examinations as they relate to these adverse effects. Finally, the appropriate laboratory testing for evaluating lead exposure and toxicity is presented.

It is hoped that this review and discussion will give the physician a better understanding of the OSHA standard with the ultimate goal of protecting the health and well-being of the worker exposed to lead under his or her care.

Appendix D to 1926.62 - Qualitative and Quantitative Fit Test Protocols

I. Fit Test Protocols

A. General: The employer shall include the following provisions in the fit test procedures. These provisions apply to both qualitative fit testing (QLFT) and quantitative fit testing (QNFT) permissible for compliance with paragraph (f)(3)(ii) of 1926.62. All testing is to be conducted annually.

1. The test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers. The selection shall include at least three sizes of elastomeric facepieces of the type of respirator that is to be tested, i.e., three sizes of half mask; or three sizes of full facepiece. Respirators of each size must be provided from at least two manufacturers.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted, maintained and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

- (a) position of the mask on the nose;

- (b) room for eye protection;
- (c) room to talk; and
- (d) position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

- (a) chin properly placed;
- (b) adequate strap tension, not overly tightened;
- (c) fit across nose bridge;
- (d) respirator of proper size to span distance from nose to chin;
- (e) tendency of respirator to slip; and
- (f) self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described below or in ANSI Z88.2-1980. Before conducting the negative or positive pressure test, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

(a) Positive pressure check. Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

(b) Negative pressure check. Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or long sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician to determine whether the test subject can wear a respirator while performing her or his duties.

11. If at any time within the first two week of use the respirator becomes uncomfortable, the test subject shall be given the opportunity to select a different facepiece and to be retested.

12. The employer shall maintain a record of the fit test administered to an employee. The record shall contain at least the following information:

- (a) name of employee;
- (b) type of respirator;
- (c) brand, size of respirator;
- (d) date of test;

(e) where QNFT is used: the fit factor, strip chart recording or other recording of the results of the test. The record shall be maintained until the next fit test is administered.

13. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

14. Test Exercises. The test subject shall perform exercises, in the test environment, in the manner described below:

(a) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(b) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage (see below), count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(f) Grimace. The test subject shall grimace by smiling or frowning.

(g) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) Normal breathing. Same as exercise 1.

Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols. 1. General (a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(c) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. Isoamyl Acetate Protocol. (a) Odor threshold screening. The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated but shall not be connected to the same recirculating ventilation system.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled, dried off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): ``The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."`

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl acetate fit test.

(1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the head exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA,

the test has failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test has failed, the subject shall return to the selection room and remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber and again begin the procedure described in (I)(B)(2)(b) (1) through (7) of this appendix. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test. To keep the test area from becoming contaminated, the used towels shall be kept in a self sealing bag so there is no significant IAA concentration build-up in the test chamber during subsequent tests.

3. Saccharin Solution Aerosol Protocol. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a $\frac{3}{4}$ inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her wide open mouth with tongue extended.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer the test conductor shall spray the threshold check solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution consists of 0.83 grams of sodium saccharin USP in 1 cc of warm water. It can be prepared by putting 1 cc of the fit test solution (see (b)(5) below) in 100 cc of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure

(1) The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in I. B. 3. (a) of this appendix.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I. B. 3. (a) of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

(6) As before, the test subject shall breathe through the wide open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the

exercises in section I. A. 14 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

(12) Successful completion of the test protocol shall allow the use of the tested respirator in contaminated atmospheres up to 10 times the PEL. In other words, this protocol may be used for assigned protection factors no higher than 10.

4. Irritant Fume Protocol. (a) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(b) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its characteristic odor.

(c) Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute.

(d) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(e) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(f) The exercises identified in section I. A. 14 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(g) Each test subject passing the smoke test without evidence of a response shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(h) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocol. 1. General. (a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors

properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. Definitions. (a) Quantitative fit test. The test is performed in a test chamber. The normal air-purifying element of the respirator is replaced by a high-efficiency particulate air (HEPA) filter in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(b) Challenge agent means the aerosol, gas or vapor introduced into a test chamber so that its concentration inside and outside the respirator may be measured.

(c) Test subject means the person wearing the respirator for quantitative fit testing.

(d) Normal standing position means standing erect and straight with arms down along the sides and looking straight ahead.

(e) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(f) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(g) "Fit Factor" means the ration of challenge agent concentration outside with respect to the inside of a respirator inlet covering (facepiece or enclosure).

3. Apparatus. (a) Instrumentation. Aerosol generation, dilution, and measurement systems using corn oil or sodium chloride as test aerosols shall be used for quantitative fit testing.

(b) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(c) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter supplied by the same manufacturer.

(d) The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each

inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(e) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process.

(f) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator.

(g) The test chamber and test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(h) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent inside the test chamber constant to within a 10 percent variation for the duration of the test.

(i) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event inside the test chamber and its being recorded.

(j) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(k) The exhaust flow from the test chamber shall pass through a high-efficiency filter before release.

(l) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(m) The limitations of instrument detection shall be taken into account when determining the fit factor.

(n) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

4. Procedural Requirements. (a) When performing the initial positive or negative pressure test the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these tests.

(b) An abbreviated screening isoamyl acetate test or irritant fume test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. When performing a screening isoamyl acetate test, combination high-efficiency organic vapor cartridges/canisters shall be used.

(c) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(d) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(e) A stable challenge concentration shall be obtained prior to the actual start of testing.

(f) Respirator restraining straps shall not be overtightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable comfortable fit typical of normal use.

(g) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested. If two of the three required tests are terminated, the fit shall be deemed inadequate.

(h) In order to successfully complete a QNFT, three successful fit tests are required. The results of each of the three independent fit tests must exceed the minimum fit factor needed for the class of respirator (e.g. half mask respirator, full facepiece respirator).

(i) Calculation of fit factors.

(1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration inside the respirator.

(2) The average test chamber concentration is the arithmetic average of the test chamber concentration at the beginning and of the end of the test.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak concentration

(ii) Maximum peak concentration

(iii) Integration by calculation of the area under the individual peak for each exercise. This includes computerized integration.

(j) Interpretation of test results. The fit factor established by the quantitative fit testing shall be the lowest of the three fit factor values calculated from the three required fit tests.

(k) The test subject shall not be permitted to wear a half mask, or full facepiece respirator unless a minimum fit factor equivalent to at least 10 times the hazardous exposure level is obtained.

(l) Filters used for quantitative fit testing shall be replaced at least weekly, or

whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily (when used) or sooner if there is any indication of breakthrough by a test agent.

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1926.64 Process safety management of highly hazardous chemicals.

Purpose. This section contains requirements for preventing or minimizing the consequences of catastrophic releases of toxic, reactive, flammable, or explosive chemicals. These releases may result in toxic, fire or explosion hazards.

(a) Application.

(1) This section applies to the following:

(i) A process which involves a chemical at or above the specified threshold quantities listed in Appendix A to this section;

~~(ii) A process which involves a flammable liquid or gas (as defined in 1926.59(c) of this part) on site in one location, in a quantity of 10,000 pounds (4535.9 kg) or more except for:~~ A process which involves a Category 1 flammable gas (as defined in § 1910.1200(c)) or flammable liquid with a flashpoint below 100 °F (37.8 °C) on site in one location, in a quantity of 10,000 pounds (4535.9 kg) or more except for:

(A) Hydrocarbon fuels used solely for workplace consumption as a fuel (e.g., propane used for comfort heating, gasoline for vehicle refueling), if such fuels are not a part of a process containing another highly hazardous chemical covered by this standard;

~~(B) Flammable liquids stored in atmospheric tanks or transferred which are kept below their normal boiling point without benefit of chilling or refrigeration.~~ Flammable liquids with a flashpoint below 100 °F (37.8 °C) stored in atmospheric tanks or transferred that are kept below their normal boiling point without benefit of chilling or refrigeration.

(2) This section does not apply to:

- (i) Retail facilities;
- (ii) Oil or gas well drilling or servicing operations; or,
- (iii) Normally unoccupied remote facilities.

(b) Definitions. Atmospheric tank means a storage tank which has been designed to operate at pressures from atmospheric through 0.5 p.s.i.g. (pounds per square inch gauge, 3.45 Kpa).

Boiling point means the boiling point of a liquid at a pressure of 14.7 pounds per square inch absolute (p.s.i.a.) (760 mm.). For the purposes of this section, where an accurate boiling point is unavailable for the material in question, or for mixtures which do not have a constant boiling

point, the 10 percent point of a distillation performed in accordance with the Standard Method of Test for Distillation of Petroleum Products, ASTM D-86-62, may be used as the boiling point of the liquid.

Catastrophic release means a major uncontrolled emission, fire, or explosion, involving one or more highly hazardous chemicals, that presents serious danger to employees in the workplace.

Facility means the buildings, containers or equipment which contain a process.

Highly hazardous chemical means a substance possessing toxic, reactive, flammable, or explosive properties and specified by paragraph (a)(1) of this section.

Hot work means work involving electric or gas welding, cutting, brazing, or similar flame or spark-producing operations.

Normally unoccupied remote facility means a facility which is operated, maintained or serviced by employees who visit the facility only periodically to check its operation and to perform necessary operating or maintenance tasks. No employees are permanently stationed at the facility. Facilities meeting this definition are not contiguous with, and must be geographically remote from all other buildings, processes or persons.

Process means any activity involving a highly hazardous chemical including any use, storage, manufacturing, handling, or the on-site movement of such chemicals, or combination of these activities. For purposes of this definition, any group of vessels which are interconnected and separate vessels which are located such that a highly hazardous chemical could be involved in a potential release shall be considered a single process.

Replacement in kind means a replacement which satisfies the design specification.

Trade secret means any confidential formula, pattern, process, device, information or compilation of information that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it. Appendix D contained in 1926.59 sets out the criteria to be used in evaluating trade secrets.

(c) Employee participation.

(1) Employers shall develop a written plan of action regarding the implementation of the employee participation required by this paragraph.

(2) Employers shall consult with employees and their representatives on the conduct and development of process hazards analyses and on the development of the other elements of process safety management in this standard.

(3) Employers shall provide to employees and their representatives access to process hazard analyses and to all other information required to be developed under this standard.

(d) Process safety information. In accordance with the schedule set forth in paragraph (e)(1) of this section, the employer shall complete a compilation of written process safety information before conducting any process hazard analysis required by the standard. The compilation of written process safety information is to enable the employer and the employees involved in

operating the process to identify and understand the hazards posed by those processes involving highly hazardous chemicals. This process safety information shall include information pertaining to the hazards of the highly hazardous chemicals used or produced by the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

(1) Information pertaining to the hazards of the highly hazardous chemicals in the process. This information shall consist of at least the following:

- (i) Toxicity information;
- (ii) Permissible exposure limits;
- (iii) Physical data;
- (iv) Reactivity data;
- (v) Corrosivity data;
- (vi) Thermal and chemical stability data; and
- (vii) ~~Hazardous effects of inadvertent mixing of different materials that could foreseeably occur.~~

~~Note: Material Safety Data Sheets meeting the requirements of 29 CFR 1926.59(g) may be used to comply with this requirement to the extent they contain the information required by this subparagraph. Hazardous effects of inadvertent mixing of different materials that could foreseeably occur.~~

Note to paragraph (d)(1): Safety data sheets meeting the requirements of § 1910.1200(g) may be used to comply with this requirement to the extent they contain the information required by this paragraph (d)(1).

(2) Information pertaining to the technology of the process.

(i) Information concerning the technology of the process shall include at least the following:

(A) A block flow diagram or simplified process flow diagram (see Appendix B to this section);

(B) Process chemistry;

(C) Maximum intended inventory;

(D) Safe upper and lower limits for such items as temperatures, pressures, flows or compositions; and,

(E) An evaluation of the consequences of deviations, including those affecting the safety and health of employees.

(ii) Where the original technical information no longer exists, such information may be developed in conjunction with the process hazard analysis in sufficient detail to support the analysis.

(3) Information pertaining to the equipment in the process.

(i) Information pertaining to the equipment in the process shall include:

(A) Materials of construction;

(B) Piping and instrument diagrams (P&ID's);

(C) Electrical classification;

(D) Relief system design and design basis;

(E) Ventilation system design;

(F) Design codes and standards employed;

(G) Material and energy balances for processes built after May 26, 1992;

and,

(H) Safety systems (e.g. interlocks, detection or suppression systems).

(ii) The employer shall document that equipment complies with recognized and generally accepted good engineering practices.

(iii) For existing equipment designed and constructed in accordance with codes, standards, or practices that are no longer in general use, the employer shall determine and document that the equipment is designed, maintained, inspected, tested, and operating in a safe manner.

(e) Process hazard analysis.

(1) The employer shall perform an initial process hazard analysis (hazard evaluation) on processes covered by this standard. The process hazard analysis shall be appropriate to the complexity of the process and shall identify, evaluate, and control the hazards involved in the process. Employers shall determine and document the priority order for conducting process hazard analyses based on a rationale which includes such considerations as extent of the process hazards, number of potentially affected employees, age of the process, and operating history of the process. The process hazard analysis shall be conducted as soon as possible, but not later than the following schedule:

(i) No less than 25 percent of the initial process hazards analyses shall be completed by May 26, 1994;

(ii) No less than 50 percent of the initial process hazards analyses shall be completed by May 26, 1995;

(iii) No less than 75 percent of the initial process hazards analyses shall be completed by May 26, 1996;

(iv) All initial process hazards analyses shall be completed by May 26, 1997.

(v) Process hazards analyses completed after May 26, 1997, which meet the requirements of this paragraph are acceptable as initial process hazards analyses. These process hazard analyses shall be updated and revalidated, based on their completion date, in accordance with paragraph (e)(6) of this standard.

(2) The employer shall use one or more of the following methodologies that are appropriate to determine and evaluate the hazards of the process being analyzed.

(i) What-If;

(ii) Checklist;

(iii) What-If/Checklist;

(iv) Hazard and Operability Study (HAZOP);

(v) Failure Mode and Effects Analysis (FMEA);

(vi) Fault Tree Analysis; or

(vii) An appropriate equivalent methodology.

(3) The process hazard analysis shall address:

(i) The hazards of the process;

(ii) The identification of any previous incident which had a likely potential for catastrophic consequences in the workplace;

(iii) Engineering and administrative controls applicable to the hazards and their interrelationships such as appropriate application of detection methodologies to provide early warning of releases. (Acceptable detection methods might include process monitoring and control instrumentation with alarms, and detection hardware such as hydrocarbon sensors.);

(iv) Consequences of failure of engineering and administrative controls;

(v) Facility siting;

(vi) Human factors; and

(vii) A qualitative evaluation of a range of the possible safety and health effects of failure of controls on employees in the workplace.

(4) The process hazard analysis shall be performed by a team with expertise in

engineering and process operations, and the team shall include at least one employee who has experience and knowledge specific to the process being evaluated. Also, one member of the team must be knowledgeable in the specific process hazard analysis methodology being used.

(5) The employer shall establish a system to promptly address the team's findings and recommendations; assure that the recommendations are resolved in a timely manner and that the resolution is documented; document what actions are to be taken; complete actions as soon as possible; develop a written schedule of when these actions are to be completed; communicate the actions to operating, maintenance and other employees whose work assignments are in the process and who may be affected by the recommendations or actions.

(6) At least every five (5) years after the completion of the initial process hazard analysis, the process hazard analysis shall be updated and revalidated by a team meeting the requirements in paragraph (e)(4) of this section, to assure that the process hazard analysis is consistent with the current process.

(7) Employers shall retain process hazards analyses and updates or revalidations for each process covered by this section, as well as the documented resolution of recommendations described in paragraph (e)(5) of this section for the life of the process.

(f) Operating procedures.

(1) The employer shall develop and implement written operating procedures that provide clear instructions for safely conducting activities involved in each covered process consistent with the process safety information and shall address at least the following elements.

(i) Steps for each operating phase:

(A) Initial startup;

(B) Normal operations;

(C) Temporary operations;

(D) Emergency shutdown including the conditions under which emergency shutdown is required, and the assignment of shutdown responsibility to qualified operators to ensure that emergency shutdown is executed in a safe and timely manner.

(E) Emergency Operations;

(F) Normal shutdown; and,

(G) Startup following a turnaround, or after an emergency shutdown.

(ii) Operating limits:

(A) Consequences of deviation; and

(B) Steps required to correct or avoid deviation.

(iii) Safety and health considerations:

(A) Properties of, and hazards presented by, the chemicals used in the process;

(B) Precautions necessary to prevent exposure, including engineering controls, administrative controls, and personal protective equipment;

(C) Control measures to be taken if physical contact or airborne exposure occurs;

(D) Quality control for raw materials and control of hazardous chemical inventory levels; and,

(E) Any special or unique hazards.

(iv) Safety systems and their functions.

(2) Operating procedures shall be readily accessible to employees who work in or maintain a process.

(3) The operating procedures shall be reviewed as often as necessary to assure that they reflect current operating practice, including changes that result from changes in process chemicals, technology, and equipment, and changes to facilities. The employer shall certify annually that these operating procedures are current and accurate.

(4) The employer shall develop and implement safe work practices to provide for the control of hazards during operations such as lockout/tagout; confined space entry; opening process equipment or piping; and control over entrance into a facility by maintenance, contractor, laboratory, or other support personnel. These safe work practices shall apply to employees and contractor employees.

(g) Training.

(1) Initial training.

(i) Each employee presently involved in operating a process, and each employee before being involved in operating a newly assigned process, shall be trained in an overview of the process and in the operating procedures as specified in paragraph (f) of this section. The training shall include emphasis on the specific safety and health hazards, emergency operations including shutdown, and safe work practices applicable to the employee's job tasks.

(ii) In lieu of initial training for those employees already involved in operating a process on May 26, 1992, an employer may certify in writing that the employee has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities as specified in the operating procedures.

(2) Refresher training. Refresher training shall be provided at least every three years, and more often if necessary, to each employee involved in operating a process to assure that the employee understands and adheres to the current operating procedures of the process. The

employer, in consultation with the employees involved in operating the process, shall determine the appropriate frequency of refresher training.

(3) Training documentation. The employer shall ascertain that each employee involved in operating a process has received and understood the training required by this paragraph. The employer shall prepare a record which contains the identity of the employee, the date of training, and the means used to verify that the employee understood the training.

(h) Contractors.

(1) Application. This paragraph applies to contractors performing maintenance or repair, turnaround, major renovation, or specialty work on or adjacent to a covered process. It does not apply to contractors providing incidental services which do not influence process safety, such as janitorial work, food and drink services, laundry, delivery or other supply services.

(2) Employer responsibilities.

(i) The employer, when selecting a contractor, shall obtain and evaluate information regarding the contract employer's safety performance and programs.

(ii) The employer shall inform contract employers of the known potential fire, explosion, or toxic release hazards related to the contractor's work and the process.

(iii) The employer shall explain to contract employers the applicable provisions of the emergency action plan required by paragraph (n) of this section.

(iv) The employer shall develop and implement safe work practices consistent with paragraph (f)(4) of this section, to control the entrance, presence and exit of contract employers and contract employees in covered process areas.

(v) The employer shall periodically evaluate the performance of contract employers in fulfilling their obligations as specified in paragraph (h)(3) of this section.

(vi) The employer shall maintain a contract employee injury and illness log related to the contractor's work in process areas.

(3) Contract employer responsibilities.

(i) The contract employer shall assure that each contract employee is trained in the work practices necessary to safely perform his/her job.

(ii) The contract employer shall assure that each contract employee is instructed in the known potential fire, explosion, or toxic release hazards related to his/her job and the process, and the applicable provisions of the emergency action plan.

(iii) The contract employer shall document that each contract employee has received and understood the training required by this paragraph. The contract employer shall prepare a record which contains the identity of the contract employee, the date of training, and the means used to verify that the employee understood the training.

(iv) The contract employer shall assure that each contract employee follows the safety rules of the facility including the safe work practices required by paragraph (f)(4) of this section.

(v) The contract employer shall advise the employer of any unique hazards presented by the contract employer's work, or of any hazards found by the contract employer's work.

(i) Pre-startup safety review.

(1) The employer shall perform a pre-startup safety review for new facilities and for modified facilities when the modification is significant enough to require a change in the process safety information.

(2) The pre-startup safety review shall confirm that prior to the introduction of highly hazardous chemicals to a process:

(i) Construction and equipment is in accordance with design specifications;

(ii) Safety, operating, maintenance, and emergency procedures are in place and are adequate;

(iii) For new facilities, a process hazard analysis has been performed and recommendations have been resolved or implemented before startup; and modified facilities meet the requirements contained in management of change, paragraph (l) of this section.

(iv) Training of each employee involved in operating a process has been completed.

(j) Mechanical integrity.

(1) Application. Paragraphs (j)(2) through (j)(6) of this section apply to the following process equipment:

(i) Pressure vessels and storage tanks;

(ii) Piping systems (including piping components such as valves);

(iii) Relief and vent systems and devices;

(iv) Emergency shutdown systems;

(v) Controls (including monitoring devices and sensors, alarms, and interlocks) and,

(vi) Pumps.

(2) Written procedures. The employer shall establish and implement written procedures to maintain the on-going integrity of process equipment.

(3) Training for process maintenance activities. The employer shall train each employee involved in maintaining the on-going integrity of process equipment in an overview of that process and its hazards and in the procedures applicable to the employee's job tasks to assure that the employee can perform the job tasks in a safe manner.

(4) Inspection and testing.

(i) Inspections and tests shall be performed on process equipment.

(ii) Inspection and testing procedures shall follow recognized and generally accepted good engineering practices.

(iii) The frequency of inspections and tests of process equipment shall be consistent with applicable manufacturers' recommendations and good engineering practices, and more frequently if determined to be necessary by prior operating experience.

(iv) The employer shall document each inspection and test that has been performed on process equipment. The documentation shall identify the date of the inspection or test, the name of the person who performed the inspection or test, the serial number or other identifier of the equipment on which the inspection or test was performed, a description of the inspection or test performed, and the results of the inspection or test.

(5) Equipment deficiencies. The employer shall correct deficiencies in equipment that are outside acceptable limits (defined by the process safety information in paragraph (d) of this section) before further use or in a safe and timely manner when necessary means are taken to assure safe operation.

(6) Quality assurance.

(i) In the construction of new plants and equipment, the employer shall assure that equipment as it is fabricated is suitable for the process application for which they will be used.

(ii) Appropriate checks and inspections shall be performed to assure that equipment is installed properly and consistent with design specifications and the manufacturer's instructions.

(iii) The employer shall assure that maintenance materials, spare parts and equipment are suitable for the process application for which they will be used.

(k) Hot work permit.

(1) The employer shall issue a hot work permit for hot work operations conducted on or near a covered process.

(2) The permit shall document that the fire prevention and protection requirements in 29 CFR 1926.352 have been implemented prior to beginning the hot work operations; it shall indicate the date(s) authorized for hot work; and identify the object on which hot work is to be performed. The permit shall be kept on file until completion of the hot work operations.

(l) Management of change.

(1) The employer shall establish and implement written procedures to manage changes (except for "replacements in kind") to process chemicals, technology, equipment, and procedures; and, changes to facilities that affect a covered process.

(2) The procedures shall assure that the following considerations are addressed prior to any change:

- (i) The technical basis for the proposed change;
- (ii) Impact of change on safety and health;
- (iii) Modifications to operating procedures;
- (iv) Necessary time period for the change; and,
- (v) Authorization requirements for the proposed change.

(3) Employees involved in operating a process and maintenance and contract employees whose job tasks will be affected by a change in the process shall be informed of, and trained in, the change prior to start-up of the process or affected part of the process.

(4) If a change covered by this paragraph results in a change in the process safety information required by paragraph (d) of this section, such information shall be updated accordingly.

(5) If a change covered by this paragraph results in a change in the operating procedures or practices required by paragraph (f) of this section, such procedures or practices shall be updated accordingly.

(m) Incident investigation.

(1) The employer shall investigate each incident which resulted in, or could reasonably have resulted in a catastrophic release of highly hazardous chemical in the workplace.

(2) An incident investigation shall be initiated as promptly as possible, but not later than 48 hours following the incident.

(3) An incident investigation team shall be established and consist of at least one person knowledgeable in the process involved, including a contract employee if the incident involved work of the contractor, and other persons with appropriate knowledge and experience to thoroughly investigate and analyze the incident.

(4) A report shall be prepared at the conclusion of the investigation which includes at a minimum:

- (i) Date of incident;
- (ii) Date investigation began;
- (iii) A description of the incident;

(iv) The factors that contributed to the incident; and,

(v) Any recommendations resulting from the investigation.

(5) The employer shall establish a system to promptly address and resolve the incident report findings and recommendations. Resolutions and corrective actions shall be documented.

(6) The report shall be reviewed with all affected personnel whose job tasks are relevant to the incident findings including contract employees where applicable.

(7) Incident investigation reports shall be retained for five years.

(n) Emergency planning and response. The employer shall establish and implement an emergency action plan for the entire plant in accordance with the provisions of 29 CFR 1926.35(a). In addition, the emergency action plan shall include procedures for handling small releases. Employers covered under this standard may also be subject to the hazardous waste and emergency response provisions contained in 29 CFR 1926.65(a), (p) and (q).

(o) Compliance Audits.

(1) Employers shall certify that they have evaluated compliance with the provisions of this section at least every three years to verify that the procedures and practices developed under the standard are adequate and are being followed.

(2) The compliance audit shall be conducted by at least one person knowledgeable in the process.

(3) A report of the findings of the audit shall be developed.

(4) The employer shall promptly determine and document an appropriate response to each of the findings of the compliance audit, and document that deficiencies have been corrected.

(5) Employers shall retain the two (2) most recent compliance audit reports.

(p) Trade secrets.

(1) Employers shall make all information necessary to comply with the section available to those persons responsible for compiling the process safety information (required by paragraph (d) of this section), those assisting in the development of the process hazard analysis (required by paragraph (e) of this section), those responsible for developing the operating procedures (required by paragraph (f) of this section), and those involved in incident investigations (required by paragraph (m) of this section), emergency planning and response (paragraph (n) of this section) and compliance audits (paragraph (o) of this section) without regard to possible trade secret status of such information.

(2) Nothing in this paragraph shall preclude the employer from requiring the persons to whom the information is made available under paragraph (p)(1) of this section to enter into confidentiality agreements not to disclose the information as set forth in 29 CFR 1926.59.

(3) Subject to the rules and procedures set forth in 29 CFR 1926.59(i)(1) through (12), employees and their designated representatives shall have access to trade secret information contained within the process hazard analysis and other documents required to be developed by this standard.

Appendix A to 1926.64--List of Highly Hazardous Chemicals, Toxics and Reactives (Mandatory)

This Appendix contains a listing of toxic and reactive highly hazardous chemicals which present a potential for a catastrophic event at or above the threshold quantity.

| Chemical Name | CAS** | TQ** |
|--|------------|-------|
| Acetaldehyde..... | 75-07-0 | 2500 |
| Acrolein (2-Propenal)..... | 107-02-8 | 150 |
| Acrylyl Chloride..... | 814-68-6 | 250 |
| Allyl Chloride..... | 107-05-1 | 1000 |
| Allylamine..... | 107-11-9 | 1000 |
| Alkylaluminums..... | Varies | 5000 |
| Ammonia, Anhydrous..... | 7664-41-7 | 10000 |
| Ammonia solutions (greater than 44 percent ammonia by weight)..... | 7664-41-7 | 15000 |
| Ammonium Perchlorate..... | 7790-98-9 | 500 |
| Ammonium Permanganate..... | 7787-36-2 | 7500 |
| Arsine (also called Arsenic Hydride).... | 7784-42-1 | 100 |
| Bis(Chloromethyl) Ether..... | 542-88-1 | 100 |
| Boron Trichloride..... | 10294-34-5 | 2500 |
| Boron Trifluoride..... | 7637-07-2 | 250 |
| Bromine..... | 7726-95-6 | 1500 |
| Bromine Chloride..... | 13863-41-7 | 1500 |
| Bromine Pentafluoride..... | 7789-30-2 | 2500 |
| Bromine Trifluoride..... | 7787-71-5 | 15000 |
| 3-Bromopropyne (also called Propargyl Bromide)..... | 106-96-7 | 100 |
| Butyl Hydroperoxide (Tertiary)..... | 75-91-2 | 5000 |
| Butyl Perbenzoate (Tertiary)..... | 614-45-9 | 7500 |
| Carbonyl Chloride (see Phosgene)..... | 75-44-5 | 100 |
| * Carbonyl Fluoride..... | 353-50-4 | 2500 |
| Cellulose Nitrate (concentration greater than 12.6 percent nitrogen).... | 9004-70-0 | 2500 |
| Chlorine..... | 7782-50-5 | 1500 |
| Chlorine Dioxide..... | 10049-04-4 | 1000 |
| Chlorine Pentafluoride..... | 13637-63-3 | 1000 |
| Chlorine Trifluoride..... | 7790-91-2 | 1000 |
| Chlorodiethylaluminum (also called Diethylaluminum Chloride)..... | 96-10-6 | 5000 |
| 1-Chloro-2,4-Dinitrobenzene..... | 97-00-7 | 5000 |
| Chloromethyl Methyl Ether..... | 107-30-2 | 500 |
| Chloropicrin..... | 76-06-2 | 500 |

| | | |
|---|------------|-------|
| Chloropicrin and Methyl Bromide mixture. | None | 1500 |
| Chloropicrin and Methyl Chloride mixture..... | None | 1500 |
| Commune Hydroperoxide..... | 80-15-9 | 5000 |
| Cyanogen..... | 460-19-5 | 2500 |
| Cyanogen Chloride..... | 506-77-4 | 500 |
| Cyanuric Fluoride..... | 675-14-9 | 100 |
| Diastole Peroxide (concentration greater than 70 percent)..... | 110-22-5 | 5000 |
| Diazomethane..... | 334-88-3 | 500 |
| Dibenzoyl Peroxide..... | 94-36-0 | 7500 |
| Diborane..... | 19287-45-7 | 100 |
| Dibutyl Peroxide (Tertiary)..... | 110-05-4 | 5000 |
| Dichloro Acetylene..... | 7572-29-4 | 250 |
| Dichlorosilane..... | 4109-96-0 | 2500 |
| Diethylzinc..... | 557-20-0 | 10000 |
| Diisopropyl Peroxydicarbonate..... | 105-64-6 | 7500 |
| Dilauroyl Peroxide..... | 105-74-8 | 7500 |
| Dimethyldichlorosilane..... | 75-78-5 | 1000 |
| Dimethylhydrazine, 1,1-..... | 57-14-7 | 1000 |
| Dimethylamine, Anhydrous..... | 124-40-3 | 2500 |
| 2,4-Dinitroaniline..... | 97-02-9 | 5000 |
| Ethyl Methyl Ketone Peroxide (also Methyl Ethyl Ketone Peroxide; concentration greater than 60 percent) | 1338-23-4 | 5000 |
| Ethyl Nitrite..... | 109-95-5 | 5000 |
| Ethylamine..... | 75-04-7 | 7500 |
| Ethylene Fluorohydrin..... | 371-62-0 | 100 |
| Ethylene Oxide..... | 75-21-8 | 5000 |
| Ethyleneimine..... | 151-56-4 | 1000 |
| Fluorine..... | 7782-41-4 | 1000 |
| Formaldehyde (Formalin)..... | 50-00-0 | 1000 |
| Furan..... | 110-00-9 | 500 |
| Hexafluoroacetone..... | 684-16-2 | 5000 |
| Hydrochloric Acid, Anhydrous..... | 7647-01-0 | 5000 |
| Hydrofluoric Acid, Anhydrous..... | 7664-39-3 | 1000 |
| Hydrogen Bromide..... | 10035-10-6 | 5000 |
| Hydrogen Chloride..... | 7647-01-0 | 5000 |
| Hydrogen Cyanide, Anhydrous..... | 74-90-8 | 1000 |
| Hydrogen Fluoride..... | 7664-39-3 | 1000 |
| Hydrogen Peroxide (52 percent by weight or greater)..... | 7722-84-1 | 7500 |
| Hydrogen Selenide..... | 7783-07-5 | 150 |
| Hydrogen Sulfide..... | 7783-06-4 | 1500 |
| Hydroxylamine..... | 7803-49-8 | 2500 |
| Iron, Pentacarbonyl..... | 13463-40-6 | 250 |
| Isopropylamine..... | 75-31-0 | 5000 |
| Ketene..... | 463-51-4 | 100 |
| Methacrylaldehyde..... | 78-85-3 | 1000 |
| Methacryloyl Chloride..... | 920-46-7 | 150 |
| Methacryloyloxyethyl Isocyanate..... | 30674-80-7 | 100 |
| Methyl Acrylonitrile..... | 126-98-7 | 250 |

| | | |
|--|------------|-------|
| Methylamine, Anhydrous..... | 74-89-5 | 1000 |
| Methyl Bromide..... | 74-83-9 | 2500 |
| Methyl Chloride..... | 74-87-3 | 15000 |
| Methyl Chloroformate..... | 79-22-1 | 500 |
| Methyl Ethyl Ketone Peroxide (concentration greater than 60 percent)..... | 1338-23-4 | 5000 |
| Methyl Fluoroacetate..... | 453-18-9 | 100 |
| Methyl Fluorosulfate..... | 421-20-5 | 100 |
| Methyl Hydrazine..... | 60-34-4 | 100 |
| Methyl Iodide..... | 74-88-4 | 7500 |
| Methyl Isocyanate..... | 624-83-9 | 250 |
| Methyl Mercaptan..... | 74-93-1 | 5000 |
| Methyl Vinyl Ketone..... | 79-84-4 | 100 |
| Methyltrichlorosilane..... | 75-79-6 | 500 |
| Nickel Carbonyl (Nickel Tetracarbonyl).. | 13463-39-3 | 150 |
| Nitric Acid (94.5 percent by weight or greater)..... | 7697-37-2 | 500 |
| Nitric Oxide..... | 10102-43-9 | 250 |
| Nitroaniline (para Nitroaniline)..... | 100-01-6 | 5000 |
| Nitromethane..... | 75-52-5 | 2500 |
| Nitrogen Dioxide..... | 10102-44-0 | 250 |
| Nitrogen Oxides (NO; NO(2); N2O4; N2O3). | 10102-44-0 | 250 |
| Nitrogen Tetroxide (also called Nitrogen Peroxide)..... | 10544-72-6 | 250 |
| Nitrogen Trifluoride..... | 7783-54-2 | 5000 |
| Nitrogen Trioxide..... | 10544-73-7 | 250 |
| Oleum (65 percent to 80 percent by weight; also called Fuming Sulfuric Acid)..... | 8014-94-7 | 1000 |
| Osmium Tetroxide..... | 20816-12-0 | 100 |
| Oxygen Difluoride (Fluorine Monoxide)... | 7783-41-7 | 100 |
| Ozone..... | 10028-15-6 | 100 |
| Pentaborane..... | 19624-22-7 | 100 |
| Peracetic Acid (concentration greater 60 percent Acetic Acid; also called Peroxyacetic Acid)..... | 79-21-0 | 1000 |
| Perchloric Acid (concentration greater than 60 percent by weight)..... | 7601-90-3 | 5000 |
| Perchloromethyl Mercaptan..... | 594-42-3 | 150 |
| Perchloryl Fluoride..... | 7616-94-6 | 5000 |
| Peroxyacetic Acid (concentration greater than 60 percent Acetic Acid; also called Peracetic Acid)..... | 79-21-0 | 1000 |
| Phosgene (also called Carbonyl Chloride) | 75-44-5 | 100 |
| Phosphine (Hydrogen Phosphide)..... | 7803-51-2 | 100 |
| Phosphorus Oxychloride (also called Phosphoryl Chloride)..... | 10025-87-3 | 1000 |
| Phosphorus Trichloride..... | 7719-12-2 | 1000 |
| Phosphoryl Chloride (also called Phosphorus Oxychloride)..... | 10025-87-3 | 1000 |
| Propargyl Bromide..... | 106-96-7 | 100 |

| | | |
|---|------------|-------|
| Propyl Nitrate..... | 627-3-4 | 2500 |
| Sarin..... | 107-44-8 | 100 |
| Selenium Hexafluoride..... | 7783-79-1 | 1000 |
| Stibine (Antimony Hydride)..... | 7803-52-3 | 500 |
| Sulfur Dioxide (liquid)..... | 7446-09-5 | 1000 |
| Sulfur Pentafluoride..... | 5714-22-7 | 250 |
| Sulfur Tetrafluoride..... | 7783-60-0 | 250 |
| Sulfur Trioxide (also called Sulfuric Anhydride)..... | 7446-11-9 | 1000 |
| Sulfuric Anhydride (also called Sulfur Trioxide)..... | 7446-11-9 | 1000 |
| Tellurium Hexafluoride..... | 7783-80-4 | 250 |
| Tetrafluoroethylene..... | 116-14-3 | 5000 |
| Tetrafluorohydrazine..... | 10036-47-2 | 5000 |
| Tetramethyl Lead..... | 75-74-1 | 1000 |
| Thionyl Chloride..... | 7719-09-7 | 250 |
| Trichloro (Chloromethyl) Silane..... | 1558-25-4 | 100 |
| Trichloro (dichlorophenyl) Silane..... | 27137-85-5 | 2500 |
| Trichlorosilane..... | 10025-78-2 | 5000 |
| Trifluorochloroethylene..... | 79-38-9 | 10000 |
| Trimethoxysilane..... | 2487-90-3 | 1500 |

Footnote(*) Chemical Abstract Service Number

Footnote(**) Threshold Quantity in Pounds (Amount necessary to be covered by this standard.)

Appendix B to 1926.64-Block Flow Diagram and Simplified Process Flow Diagram (Nonmandatory)

Appendix C to 1926.64-Compliance Guidelines and Recommendations for Process Safety Management (Nonmandatory)

This appendix serves as a nonmandatory guideline to assist employers and employees in complying with the requirements of this section, as well as provides other helpful recommendations and information. Examples presented in this appendix are not the only means of achieving the performance goals in the standard. This appendix neither adds nor detracts from the requirements of the standard.

1. Introduction to Process Safety Management. The major objective of process safety management of highly hazardous chemicals is to prevent unwanted releases of hazardous chemicals especially into locations which could expose employees and others to serious hazards. An effective process safety management program requires a systematic approach to evaluating the whole process. Using this approach the process design, process technology, operational and maintenance activities and procedures, nonroutine activities and procedures, emergency preparedness plans and procedures, training programs, and other elements which impact the process are all considered in the evaluation. The various lines of defense that have been incorporated into the design and operation of the process to prevent or mitigate the release of hazardous chemicals need to be evaluated and strengthened to assure their effectiveness at each level. Process safety management is the proactive identification, evaluation and mitigation or prevention of chemical releases that could occur as a result of failures in process, procedures or equipment.

The process safety management standard targets highly hazardous chemicals that have the potential to cause a catastrophic incident. This standard as a whole is to aid employers in their efforts to prevent or mitigate episodic chemical releases that could lead to a catastrophe in the workplace and possibly to the surrounding community. To control these types of hazards, employers need to develop the necessary expertise, experiences, judgement and proactive initiative within their workforce to properly implement and maintain an effective process safety management program as envisioned in the OSHA standard. This OSHA standard is required by the Clean Air Act Amendments as is the Environmental Protection Agency's Risk Management Plan. Employers, who merge the two sets of requirements into their process safety management program, will better assure full compliance with each as well as enhancing their relationship with the local community.

While OSHA believes process safety management will have a positive effect on the safety of employees in workplaces and also offers other potential benefits to employers (increased productivity), smaller businesses which may have limited resources available to them at this time, might consider alternative avenues of decreasing the risks associated with highly hazardous chemicals at their workplaces. One method which might be considered is the reduction in the inventory of the highly hazardous chemical. This reduction in inventory will result in a reduction of the risk or potential for a catastrophic incident. Also, employers including small employers may be able to establish more efficient inventory control by reducing the quantities of highly hazardous chemicals on site below the established threshold quantities. This reduction can be accomplished by ordering smaller shipments and maintaining the minimum inventory necessary for efficient and safe operation. When reduced inventory is not feasible, then the employer might consider dispersing inventory to several locations on site. Dispersing storage into locations where a release in one location will not cause a release in another location is a practical method to also reduce the risk or potential for catastrophic incidents.

2. Employee Involvement in Process Safety Management. Section 304 of the Clean Air Act Amendments states that employers are to consult with their employees and their representatives regarding the employers efforts in the development and implementation of the process safety management program elements and hazard assessments. Section 304 also requires employers to train and educate their employees and to inform affected employees of the findings from incident investigations required by the process safety management program. Many employers, under their safety and health programs, have already established means and methods to keep employees and their representatives informed about relevant safety and health issues and employers may be able to adapt these practices and procedures to meet their obligations under this standard. Employers who have not implemented an occupational safety and health program may wish to form a safety and health committee of employees and management representatives to help the employer meet the obligations specified by this standard. These committees can become a significant ally in helping the employer to implement and maintain an effective process safety management program for all employees.

3. Process Safety Information. Complete and accurate written information concerning process chemicals, process technology, and process equipment is essential to an effective process safety management program and to a process hazards analysis. The compiled information will be a necessary resource to a variety of users including the team that will perform the process hazards analysis as required under paragraph (e); those developing the training programs and the operating procedures; contractors whose employees will be working with the process; those conducting the pre-startup reviews; local emergency preparedness planners; and insurance and

enforcement officials.

The information to be compiled about the chemicals, including process intermediates, needs to be comprehensive enough for an accurate assessment of the fire and explosion characteristics, reactivity hazards, the safety and health hazards to workers, and the corrosion and erosion effects on the process equipment and monitoring tools. Current material safety data sheet (MSDS) information can be used to help meet this requirement which must be supplemented with process chemistry information including runaway reaction and over pressure hazards if applicable.

Process technology information will be a part of the process safety information package and it is expected that it will include diagrams of the type shown in Appendix B of this section as well as employer established criteria for maximum inventory levels for process chemicals; limits beyond which would be considered upset conditions; and a qualitative estimate of the consequences or results of deviation that could occur if operating beyond the established process limits. Employers are encouraged to use diagrams which will help users understand the process.

A block flow diagram is used to show the major process equipment and interconnecting process flow lines and show flow rates, stream composition, temperatures, and pressures when necessary for clarity. The block flow diagram is a simplified diagram.

Process flow diagrams are more complex and will show all main flow streams including valves to enhance the understanding of the process, as well as pressures and temperatures on all feed and product lines within all major vessels, in and out of headers and heat exchangers, and points of pressure and temperature control. Also, materials of construction information, pump capacities and pressure heads, compressor horsepower and vessel design pressures and temperatures are shown when necessary for clarity. In addition, major components of control loops are usually shown along with key utilities on process flow diagrams.

Piping and instrument diagrams (P&IDs) may be the more appropriate type of diagrams to show some of the above details and to display the information for the piping designer and engineering staff. The P&IDs are to be used to describe the relationships between equipment and instrumentation as well as other relevant information that will enhance clarity. Computer software programs which do P&IDs or other diagrams useful to the information package, may be used to help meet this requirement.

The information pertaining to process equipment design must be documented. In other words, what were the codes and standards relied on to establish good engineering practice. These codes and standards are published by such organizations as the American Society of Mechanical Engineers, American Petroleum Institute, American National Standards Institute, National Fire Protection Association, American Society for Testing and Materials, National Board of Boiler and Pressure Vessel Inspectors, National Association of Corrosion Engineers, American Society of Exchange Manufacturers Association, and model building code groups.

In addition, various engineering societies issue technical reports which impact process design. For example, the American Institute of Chemical Engineers has published technical reports on topics such as two phase flow for venting devices. This type of technically recognized report would constitute good engineering practice.

For existing equipment designed and constructed many years ago in accordance with the codes

and standards available at that time and no longer in general use today, the employer must document which codes and standards were used and that the design and construction along with the testing, inspection and operation are still suitable for the intended use. Where the process technology requires a design which departs from the applicable codes and standards, the employer must document that the design and construction is suitable for the intended purpose.

4. Process Hazard Analysis. A process hazard analysis (PHA), sometimes called a process hazard evaluation, is one of the most important elements of the process safety management program. A PHA is an organized and systematic effort to identify and analyze the significance of potential hazards associated with the processing or handling of highly hazardous chemicals. A PHA provides information which will assist employers and employees in making decisions for improving safety and reducing the consequences of unwanted or unplanned releases of hazardous chemicals. A PHA is directed toward analyzing potential causes and consequences of fires, explosions, releases of toxic or flammable chemicals and major spills of hazardous chemicals. The PHA focuses on equipment, instrumentation, utilities, human actions (routine and nonroutine), and external factors that might impact the process. These considerations assist in determining the hazards and potential failure points or failure modes in a process.

The selection of a PHA methodology or technique will be influenced by many factors including the amount of existing knowledge about the process. Is it a process that has been operated for a long period of time with little or no innovation and extensive experience has been generated with its use? Or, is it a new process or one which has been changed frequently by the inclusion of innovative features? Also, the size and complexity of the process will influence the decision as to the appropriate PHA methodology to use. All PHA methodologies are subject to certain limitations. For example, the checklist methodology works well when the process is very stable and no changes are made, but it is not as effective when the process has undergone extensive change. The checklist may miss the most recent changes and consequently the changes would not be evaluated. Another limitation to be considered concerns the assumptions made by the team or analyst. The PHA is dependent on good judgement and the assumptions made during the study need to be documented and understood by the team and reviewer and kept for a future PHA.

The team conducting the PHA need to understand the methodology that is going to be used. A PHA team can vary in size from two people to a number of people with varied operational and technical backgrounds. Some team members may only be a part of the team for a limited time. The team leader needs to be fully knowledgeable in the proper implementation of the PHA methodology that is to be used and should be impartial in the evaluation. The other full or part time team members need to provide the team with expertise in areas such as process technology, process design, operating procedures and practices, including how the work is actually performed, alarms, emergency procedures, instrumentation, maintenance procedures, both routine and nonroutine tasks, including how the tasks are authorized, procurement of parts and supplies, safety and health, and any other relevant subject as the need dictates. At least one team member must be familiar with the process. The ideal team will have an intimate knowledge of the standards, codes, specifications and regulations applicable to the process being studied. The selected team members need to be compatible and the team leader needs to be able to manage the team and the PHA study. The team needs to be able to work together while benefiting from the expertise of others on the team or outside the team, to resolve issues, and to forge a consensus on the findings of the study and the recommendations.

The application of a PHA to a process may involve the use of different methodologies for

various parts of the process. For example, a process involving a series of unit operations of varying sizes, complexities, and ages may use different methodologies and team members for each operation. Then the conclusions can be integrated into one final study and evaluation. A more specific example is the use of a checklist PHA for a standard boiler or heat exchanger and the use of a Hazard and Operability PHA for the overall process. Also, for batch type processes like custom batch operations, a generic PHA of a representative batch may be used where there are only small changes of monomer or other ingredient ratios and the chemistry is documented for the full range and ratio of batch ingredients. Another process that might consider using a generic type of PHA is a gas plant. Often these plants are simply moved from site to site and therefore, a generic PHA may be used for these movable plants. Also, when an employer has several similar size gas plants and no sour gas is being processed at the site, then a generic PHA is feasible as long as the variations of the individual sites are accounted for in the PHA. Finally, when an employer has a large continuous process which has several control rooms for different portions of the process such as for a distillation tower and a blending operation, the employer may wish to do each segment separately and then integrate the final results.

Additionally, small businesses which are covered by this rule, will often have processes that have less storage volume, less capacity, and less complicated than processes at a large facility. Therefore, OSHA would anticipate that the less complex methodologies would be used to meet the process hazard analysis criteria in the standard. These process hazard analyses can be done in less time and with a few people being involved. A less complex process generally means that less data, P&IDs, and process information is needed to perform a process hazard analysis.

Many small businesses have processes that are not unique, such as cold storage lockers or water treatment facilities. Where employer associations have a number of members with such facilities, a generic PHA, evolved from a checklist or what-if questions, could be developed and used by each employer effectively to reflect his/her particular process; this would simplify compliance for them.

When the employer has a number of processes which require a PHA, the employer must set up a priority system of which PHAs to conduct first. A preliminary or gross hazard analysis may be useful in prioritizing the processes that the employer has determined are subject to coverage by the process safety management standard. Consideration should first be given to those processes with the potential of adversely affecting the largest number of employees. This prioritizing should consider the potential severity of a chemical release, the number of potentially affected employees, the operating history of the process such as the frequency of chemical releases, the age of the process and any other relevant factors. These factors would suggest a ranking order and would suggest either using a weighing factor system or a systematic ranking method. The use of a preliminary hazard analysis would assist an employer in determining which process should be of the highest priority and thereby the employer would obtain the greatest improvement in safety at the facility.

Detailed guidance on the content and application of process hazard analysis methodologies is available from the American Institute of Chemical Engineers' Center for Chemical Process Safety (see Appendix D).

5. **Operating Procedures and Practices.** Operating procedures describe tasks to be performed, data to be recorded, operating conditions to be maintained, samples to be collected, and safety and health precautions to be taken. The procedures need to be technically accurate, understandable to employees, and revised periodically to ensure that they reflect current

operations. The process safety information package is to be used as a resource to better assure that the operating procedures and practices are consistent with the known hazards of the chemicals in the process and that the operating parameters are accurate. Operating procedures should be reviewed by engineering staff and operating personnel to ensure that they are accurate and provide practical instructions on how to actually carry out job duties safely.

Operating procedures will include specific instructions or details on what steps are to be taken or followed in carrying out the stated procedures. These operating instructions for each procedure should include the applicable safety precautions and should contain appropriate information on safety implications. For example, the operating procedures addressing operating parameters will contain operating instructions about pressure limits, temperature ranges, flow rates, what to do when an upset condition occurs, what alarms and instruments are pertinent if an upset condition occurs, and other subjects. Another example of using operating instructions to properly implement operating procedures is in starting up or shutting down the process. In these cases, different parameters will be required from those of normal operation. These operating instructions need to clearly indicate the distinctions between startup and normal operations such as the appropriate allowances for heating up a unit to reach the normal operating parameters. Also the operating instructions need to describe the proper method for increasing the temperature of the unit until the normal operating temperature parameters are achieved.

Computerized process control systems add complexity to operating instructions. These operating instructions need to describe the logic of the software as well as the relationship between the equipment and the control system; otherwise, it may not be apparent to the operator.

Operating procedures and instructions are important for training operating personnel. The operating procedures are often viewed as the standard operating practices (SOPs) for operations. Control room personnel and operating staff, in general, need to have a full understanding of operating procedures. If workers are not fluent in English then procedures and instructions need to be prepared in a second language understood by the workers. In addition, operating procedures need to be changed when there is a change in the process as a result of the management of change procedures. The consequences of operating procedure changes need to be fully evaluated and the information conveyed to the personnel. For example, mechanical changes to the process made by the maintenance department (like changing a valve from steel to brass or other subtle changes) need to be evaluated to determine if operating procedures and practices also need to be changed. All management of change actions must be coordinated and integrated with current operating procedures and operating personnel must be oriented to the changes in procedures before the change is made. When the process is shutdown in order to make a change, then the operating procedures must be updated before startup of the process.

Training in how to handle upset conditions must be accomplished as well as what operating personnel are to do in emergencies such as when a pump seal fails or a pipeline ruptures. Communication between operating personnel and workers performing work within the process area, such as nonroutine tasks, also must be maintained. The hazards of the tasks are to be conveyed to operating personnel in accordance with established procedures and to those performing the actual tasks. When the work is completed, operating personnel should be informed to provide closure on the job.

6. Employee Training. All employees, including maintenance and contractor employees, involved with highly hazardous chemicals need to fully understand the safety and health hazards of the chemicals and processes they work with for the protection of themselves, their fellow

employees and the citizens of nearby communities. Training conducted in compliance with 1926.59, the Hazard Communication standard, will help employees to be more knowledgeable about the chemicals they work with as well as familiarize them with reading and understanding MSDS. However, additional training in subjects such as operating procedures and safety work practices, emergency evacuation and response, safety procedures, routine and nonroutine work authorization activities, and other areas pertinent to process safety and health will need to be covered by an employer's training program.

In establishing their training programs, employers must clearly define the employees to be trained and what subjects are to be covered in their training. Employers in setting up their training program will need to clearly establish the goals and objectives they wish to achieve with the training that they provide to their employees. The learning goals or objectives should be written in clear measurable terms before the training begins. These goals and objectives need to be tailored to each of the specific training modules or segments. Employers should describe the important actions and conditions under which the employee will demonstrate competence or knowledge as well as what is acceptable performance.

Hands-on-training where employees are able to use their senses beyond listening, will enhance learning. For example, operating personnel, who will work in a control room or at control panels, would benefit by being trained at a simulated control panel or panels. Upset conditions of various types could be displayed on the simulator, and then the employee could go through the proper operating procedures to bring the simulator panel back to the normal operating parameters. A training environment could be created to help the trainee feel the full reality of the situation but, of course, under controlled conditions. This realistic type of training can be very effective in teaching employees correct procedures while allowing them to also see the consequences of what might happen if they do not follow established operating procedures. Other training techniques using videos or on-the-job training can also be very effective for teaching other job tasks, duties, or other important information. An effective training program will allow the employee to fully participate in the training process and to practice their skill or knowledge.

Employers need to periodically evaluate their training programs to see if the necessary skills, knowledge, and routines are being properly understood and implemented by their trained employees. The means or methods for evaluating the training should be developed along with the training program goals and objectives. Training program evaluation will help employers to determine the amount of training their employees understood, and whether the desired results were obtained. If, after the evaluation, it appears that the trained employees are not at the level of knowledge and skill that was expected, the employer will need to revise the training program, provide retraining, or provide more frequent refresher training sessions until the deficiency is resolved. Those who conducted the training and those who received the training should also be consulted as to how best to improve the training process. If there is a language barrier, the language known to the trainees should be used to reinforce the training messages and information.

Careful consideration must be given to assure that employees including maintenance and contract employees receive current and updated training. For example, if changes are made to a process, impacted employees must be trained in the changes and understand the effects of the changes on their job tasks (e.g., any new operating procedures pertinent to their tasks). Additionally, as already discussed the evaluation of the employee's absorption of training will certainly influence the need for training.

7. Contractors. Employers who use contractors to perform work in and around processes that involve highly hazardous chemicals, will need to establish a screening process so that they hire and use contractors who accomplish the desired job tasks without compromising the safety and health of employees at a facility. For contractors, whose safety performance on the job is not known to the hiring employer, the employer will need to obtain information on injury and illness rates and experience and should obtain contractor references. Additionally, the employer must assure that the contractor has the appropriate job skills, knowledge and certifications (such as for pressure vessel welders). Contractor work methods and experiences should be evaluated. For example, does the contractor conducting demolition work swing loads over operating processes or does the contractor avoid such hazards?

Maintaining a site injury and illness log for contractors is another method employers must use to track and maintain current knowledge of work activities involving contract employees working on or adjacent to covered processes. Injury and illness logs of both the employer's employees and contract employees allow an employer to have full knowledge of process injury and illness experience. This log will also contain information which will be of use to those auditing process safety management compliance and those involved in incident investigations.

Contract employees must perform their work safely. Considering that contractors often perform very specialized and potentially hazardous tasks such as confined space entry activities and nonroutine repair activities it is quite important that their activities be controlled while they are working on or near a covered process. A permit system or work authorization system for these activities would also be helpful to all affected employers. The use of a work authorization system keeps an employer informed of contract employee activities, and as a benefit the employer will have better coordination and more management control over the work being performed in the process area. A well run and well maintained process where employee safety is fully recognized will benefit all of those who work in the facility whether they be contract employees or employees of the owner.

8. Pre-Startup Safety. For new processes, the employer will find a PHA helpful in improving the design and construction of the process from a reliability and quality point of view. The safe operation of the new process will be enhanced by making use of the PHA recommendations before final installations are completed. P&IDs are to be completed along with having the operating procedures in place and the operating staff trained to run the process before startup. The initial startup procedures and normal operating procedures need to be fully evaluated as part of the pre-startup review to assure a safe transfer into the normal operating mode for meeting the process parameters.

For existing processes that have been shutdown for turnaround, or modification, etc., the employer must assure that any changes other than "replacement in kind" made to the process during shutdown go through the management of change procedures. P&IDs will need to be updated as necessary, as well as operating procedures and instructions. If the changes made to the process during shutdown are significant and impact the training program, then operating personnel as well as employees engaged in routine and nonroutine work in the process area may need some refresher or additional training in light of the changes. Any incident investigation recommendations, compliance audits or PHA recommendations need to be reviewed as well to see what impacts they may have on the process before beginning the startup.

9. Mechanical Integrity. Employers will need to review their maintenance programs and schedules to see if there are areas where "breakdown" maintenance is used rather than an on-

going mechanical integrity program. Equipment used to process, store, or handle highly hazardous chemicals needs to be designed, constructed, installed and maintained to minimize the risk of releases of such chemicals. This requires that a mechanical integrity program be in place to assure the continued integrity of process equipment. Elements of a mechanical integrity program include the identification and categorization of equipment and instrumentation, inspections and tests, testing and inspection frequencies, development of maintenance procedures, training of maintenance personnel, the establishment of criteria for acceptable test results, documentation of test and inspection results, and documentation of manufacturer recommendations as to meantime to failure for equipment and instrumentation.

The first line of defense an employer has available is to operate and maintain the process as designed, and to keep the chemicals contained. This line of defense is backed up by the next line of defense which is the controlled release of chemicals through venting to scrubbers or flares, or to surge or overflow tanks which are designed to receive such chemicals, etc. These lines of defense are the primary lines of defense or means to prevent unwanted releases. The secondary lines of defense would include fixed fire protection systems like sprinklers, water spray, or deluge systems, monitor guns, etc., dikes, designed drainage systems, and other systems which would control or mitigate hazardous chemicals once an unwanted release occurs. These primary and secondary lines of defense are what the mechanical integrity program needs to protect and strengthen these primary and secondary lines of defenses where appropriate.

The first step of an effective mechanical integrity program is to compile and categorize a list of process equipment and instrumentation for inclusion in the program. This list would include pressure vessels, storage tanks, process piping, relief and vent systems, fire protection system components, emergency shutdown systems and alarms and interlocks and pumps. For the categorization of instrumentation and the listed equipment the employer would prioritize which pieces of equipment require closer scrutiny than others. Meantime to failure of various instrumentation and equipment parts would be known from the manufacturers data or the employer's experience with the parts, which would then influence the inspection and testing frequency and associated procedures. Also, applicable codes and standards such as the National Board Inspection Code, or those from the American Society for Testing and Material, American Petroleum Institute, National Fire Protection Association, American National Standards Institute, American Society of Mechanical Engineers, and other groups, provide information to help establish an effective testing and inspection frequency, as well as appropriate methodologies.

The applicable codes and standards provide criteria for external inspections for such items as foundation and supports, anchor bolts, concrete or steel supports, guy wires, nozzles and sprinklers, pipe hangers, grounding connections, protective coatings and insulation, and external metal surfaces of piping and vessels, etc. These codes and standards also provide information on methodologies for internal inspection, and a frequency formula based on the corrosion rate of the materials of construction. Also, erosion both internal and external needs to be considered along with corrosion effects for piping and valves. Where the corrosion rate is not known, a maximum inspection frequency is recommended, and methods of developing the corrosion rate are available in the codes. Internal inspections need to cover items such as vessel shell, bottom and head; metallic linings; nonmetallic linings; thickness measurements for vessels and piping; inspection for erosion, corrosion, cracking and bulges; internal equipment like trays, baffles, sensors and screens for erosion, corrosion or cracking and other deficiencies. Some of these inspections may be performed by state or local government inspectors under state and local statutes. However, each employer needs to develop procedures to ensure that tests and inspections are conducted properly and that consistency is maintained even where different

employees may be involved. Appropriate training is to be provided to maintenance personnel to ensure that they understand the preventive maintenance program procedures, safe practices, and the proper use and application of special equipment or unique tools that may be required. This training is part of the overall training program called for in the standard.

A quality assurance system is needed to help ensure that the proper materials of construction are used, that fabrication and inspection procedures are proper, and that installation procedures recognize field installation concerns. The quality assurance program is an essential part of the mechanical integrity program and will help to maintain the primary and secondary lines of defense that have been designed into the process to prevent unwanted chemical releases or those which control or mitigate a release. "As built" drawings, together with certifications of coded vessels and other equipment, and materials of construction need to be verified and retained in the quality assurance documentation. Equipment installation jobs need to be properly inspected in the field for use of proper materials and procedures and to assure that qualified craftsmen are used to do the job. The use of appropriate gaskets, packing, bolts, valves, lubricants and welding rods need to be verified in the field. Also, procedures for installation of safety devices need to be verified, such as the torque on the bolts on ruptured disc installations, uniform torque on flange bolts, proper installation of pump seals, etc. If the quality of parts is a problem, it may be appropriate to conduct audits of the equipment supplier's facilities to better assure proper purchases of required equipment which is suitable for its intended service. Any changes in equipment that may become necessary will need to go through the management of change procedures.

10. Nonroutine Work Authorizations. Nonroutine work which is conducted in process areas needs to be controlled by the employer in a consistent manner. The hazards identified involving the work that is to be accomplished must be communicated to those doing the work, but also to those operating personnel whose work could affect the safety of the process. A work authorization notice or permit must have a procedure that describes the steps the maintenance supervisor, contractor representative or other person needs to follow to obtain the necessary clearance to get the job started. The work authorization procedures need to reference and coordinate, as applicable, lockout/tagout procedures, line breaking procedures, confined space entry procedures and hot work authorizations. This procedure also needs to provide clear steps to follow once the job is completed in order to provide closure for those that need to know the job is now completed and equipment can be returned to normal.

11. Managing Change. To properly manage changes to process chemicals, technology, equipment and facilities, one must define what is meant by change. In this process safety management standard, change includes all modifications to equipment, procedures, raw materials and processing conditions other than "replacement in kind." These changes need to be properly managed by identifying and reviewing them prior to implementation of the change. For example, the operating procedures contain the operating parameters (pressure limits, temperature ranges, flow rates, etc.) and the importance of operating within these limits. While the operator must have the flexibility to maintain safe operation within the established parameters, any operation outside of these parameters requires review and approval by a written management of change procedure.

Management of change covers such as changes in process technology and changes to equipment and instrumentation.

Changes in process technology can result from changes in production rates, raw materials,

experimentation, equipment unavailability, new equipment, new product development, change in catalyst and changes in operating conditions to improve yield or quality. Equipment changes include among others change in materials of construction, equipment specifications, piping pre-arrangements, experimental equipment, computer program revisions and changes in alarms and interlocks. Employers need to establish means and methods to detect both technical changes and mechanical changes.

Temporary changes have caused a number of catastrophes over the years, and employers need to establish ways to detect temporary changes as well as those that are permanent. It is important that a time limit for temporary changes be established and monitored since, without control, these changes may tend to become permanent. Temporary changes are subject to the management of change provisions. In addition, the management of change procedures are used to insure that the equipment and procedures are returned to their original or designed conditions at the end of the temporary change. Proper documentation and review of these changes is invaluable in assuring that the safety and health considerations are being incorporated into the operating procedures and the process.

Employers may wish to develop a form or clearance sheet to facilitate the processing of changes through the management of change procedures. A typical change form may include a description and the purpose of the change, the technical basis for the change, safety and health considerations, documentation of changes for the operating procedures, maintenance procedures, inspection and testing, P&IDs, electrical classification, training and communications, pre-startup inspection, duration if a temporary change, approvals and authorization. Where the impact of the change is minor and well understood, a check list reviewed by an authorized person with proper communication to others who are affected may be sufficient. However, for a more complex or significant design change, a hazard evaluation procedure with approvals by operations, maintenance, and safety departments may be appropriate. Changes in documents such as P&IDs, raw materials, operating procedures, mechanical integrity programs, electrical classifications, etc., need to be noted so that these revisions can be made permanent when the drawings and procedure manuals are updated. Copies of process changes need to be kept in an accessible location to ensure that design changes are available to operating personnel as well as to PHA team members when a PHA is being done or one is being updated.

12. Investigation of Incidents. Incident investigation is the process of identifying the underlying causes of incidents and implementing steps to prevent similar events from occurring. The intent of an incident investigation is for employers to learn from past experiences and thus avoid repeating past mistakes. The incidents for which OSHA expects employers to become aware and to investigate are the types of events which result in or could reasonably have resulted in a catastrophic release. Some of the events are sometimes referred to as "near misses," meaning that a serious consequence did not occur, but could have.

Employers need to develop in-house capability to investigate incidents that occur in their facilities. A team needs to be assembled by the employer and trained in the techniques of investigation including how to conduct interviews of witnesses, needed documentation and report writing. A multi-disciplinary team is better able to gather the facts of the event and to analyze them and develop plausible scenarios as to what happened, and why. Team members should be selected on the basis of their training, knowledge and ability to contribute to a team effort to fully investigate the incident. Employees in the process area where the incident occurred should be consulted, interviewed or made a member of the team. Their knowledge of the events form a significant set of facts about the incident which occurred. The report, its

findings and recommendations are to be shared with those who can benefit from the information. The cooperation of employees is essential to an effective incident investigation. The focus of the investigation should be to obtain facts, and not to place blame. The team and the investigation process should clearly deal with all involved individuals in a fair, open and consistent manner.

13. **Emergency Preparedness.** Each employer must address what actions employees are to take when there is an unwanted release of highly hazardous chemicals. Emergency preparedness or the employer's tertiary (third) lines of defense are those that will be relied on along with the secondary lines of defense when the primary lines of defense which are used to prevent an unwanted release fail to stop the release. Employers will need to decide if they want employees to handle and stop small or minor incidental releases. Whether they wish to mobilize the available resources at the plant and have them brought to bear on a more significant release. Or whether employers want their employees to evacuate the danger area and promptly escape to a preplanned safe zone area, and allow the local community emergency response organizations to handle the release. Or whether the employer wants to use some combination of these actions. Employers will need to select how many different emergency preparedness or tertiary lines of defense they plan to have and then develop the necessary plans and procedures, and appropriately train employees in their emergency duties and responsibilities and then implement these lines of defense.

Employers at a minimum must have an emergency action plan which will facilitate the prompt evacuation of employees when an unwanted release of highly hazardous chemical. This means that the employer will have a plan that will be activated by an alarm system to alert employees when to evacuate and, that employees who are physically impaired, will have the necessary support and assistance to get them to the safe zone as well. The intent of these requirements is to alert and move employees to a safe zone quickly. Delaying alarms or confusing alarms are to be avoided. The use of process control centers or similar process buildings in the process area as safe areas is discouraged. Recent catastrophes have shown that a large life loss has occurred in these structures because of where they have been sited and because they are not necessarily designed to withstand over-pressures from shockwaves resulting from explosions in the process area.

Unwanted incidental releases of highly hazardous chemicals in the process area must be addressed by the employer as to what actions employees are to take. If the employer wants employees to evacuate the area, then the emergency action plan will be activated. For outdoor processes where wind direction is important for selecting the safe route to a refuge area, the employer should place a wind direction indicator such as a wind sock or pennant at the highest point that can be seen throughout the process area. Employees can move in the direction of cross wind to upwind to gain safe access to the refuge area by knowing the wind direction.

If the employer wants specific employees in the release area to control or stop the minor emergency or incidental release, these actions must be planned for in advance and procedures developed and implemented. Preplanning for handling incidental releases for minor emergencies in the process area needs to be done, appropriate equipment for the hazards must be provided, and training conducted for those employees who will perform the emergency work before they respond to handle an actual release. The employer's training program, including the Hazard Communication standard training is to address the training needs for employees who are expected to handle incidental or minor releases.

Preplanning for releases that are more serious than incidental releases is another important line of

defense to be used by the employer. When a serious release of a highly hazardous chemical occurs, the employer through preplanning will have determined in advance what actions employees are to take. The evacuation of the immediate release area and other areas as necessary would be accomplished under the emergency action plan. If the employer wishes to use plant personnel such as a fire brigade, spill control team, a hazardous materials team, or use employees to render aid to those in the immediate release area and control or mitigate the incident, these actions are covered by , the Hazardous Waste Operations and Emergency Response (HAZWOPER) standard. If outside assistance is necessary, such as through mutual aid agreements between employers or local government emergency response organizations, these emergency responders are also covered by HAZWOPER. The safety and health protections required for emergency responders are the responsibility of their employers and of the on-scene incident commander.

Responders may be working under very hazardous conditions and therefore the objective is to have them competently led by an on-scene incident commander and the commander's staff, properly equipped to do their assigned work safely, and fully trained to carry out their duties safely before they respond to an emergency. Drills, training exercises, or simulations with the local community emergency response planners and responder organizations is one means to obtain better preparedness. This close cooperation and coordination between plant and local community emergency preparedness managers will also aid the employer in complying with the Environmental Protection Agency's Risk Management Plan criteria.

One effective way for medium to large facilities to enhance coordination and communication during emergencies for on plant operations and with local community organizations is for employers to establish and equip an emergency control center. The emergency control center would be sited in a safe zone area so that it could be occupied throughout the duration of an emergency. The center would serve as the major communication link between the on-scene incident commander and plant or corporate management as well as with the local community officials. The communication equipment in the emergency control center should include a network to receive and transmit information by telephone, radio or other means. It is important to have a backup communication network in case of power failure or one communication means fails. The center should also be equipped with the plant layout and community maps, utility drawings including fire water, emergency lighting, appropriate reference materials such as a government agency notification list, company personnel phone list, SARA Title III reports and material safety data sheets, emergency plans and procedures manual, a listing with the location of emergency response equipment, mutual aid information, and access to meteorological or weather condition data and any dispersion modeling data.

14. Compliance Audits. Employers need to select a trained individual or assemble a trained team of people to audit the process safety management system and program. A small process or plant may need only one knowledgeable person to conduct an audit. The audit is to include an evaluation of the design and effectiveness of the process safety management system and a field inspection of the safety and health conditions and practices to verify that the employer's systems are effectively implemented. The audit should be conducted or lead by a person knowledgeable in audit techniques and who is impartial towards the facility or area being audited. The essential elements of an audit program include planning, staffing, conducting the audit, evaluation and corrective action, follow-up and documentation.

Planning in advance is essential to the success of the auditing process. Each employer needs to establish the format, staffing, scheduling and verification methods prior to conducting the audit.

The format should be designed to provide the lead auditor with a procedure or checklist which details the requirements of each section of the standard. The names of the audit team members should be listed as part of the format as well. The checklist, if properly designed, could serve as the verification sheet which provides the auditor with the necessary information to expedite the review and assure that no requirements of the standard are omitted. This verification sheet format could also identify those elements that will require evaluation or a response to correct deficiencies. This sheet could also be used for developing the follow-up and documentation requirements.

The selection of effective audit team members is critical to the success of the program. Team members should be chosen for their experience, knowledge, and training and should be familiar with the processes and with auditing techniques, practices and procedures. The size of the team will vary depending on the size and complexity of the process under consideration. For a large, complex, highly instrumented plant, it may be desirable to have team members with expertise in process engineering and design, process chemistry, instrumentation and computer controls, electrical hazards and classifications, safety and health disciplines, maintenance, emergency preparedness, warehousing or shipping, and process safety auditing. The team may use part-time members to provide for the depth of expertise required as well as for what is actually done or followed, compared to what is written.

An effective audit includes a review of the relevant documentation and process safety information, inspection of the physical facilities, and interviews with all levels of plant personnel. Utilizing the audit procedure and checklist developed in the preplanning stage, the audit team can systematically analyze compliance with the provisions of the standard and any other corporate policies that are relevant. For example, the audit team will review all aspects of the training program as part of the overall audit. The team will review the written training program for adequacy of content, frequency of training, effectiveness of training in terms of its goals and objectives as well as to how it fits into meeting the standard's requirements, documentation, etc. Through interviews, the team can determine the employee's knowledge and awareness of the safety procedures, duties, rules, emergency response assignments, etc. During the inspection, the team can observe actual practices such as safety and health policies, procedures, and work authorization practices. This approach enables the team to identify deficiencies and determine where corrective actions or improvements are necessary.

An audit is a technique used to gather sufficient facts and information, including statistical information, to verify compliance with standards. Auditors should select as part of their preplanning a sample size sufficient to give a degree of confidence that the audit reflects the level of compliance with the standard. The audit team, through this systematic analysis, should document areas which require corrective action as well as those areas where the process safety management system is effective and working in an effective manner. This provides a record of the audit procedures and findings, and serves as a baseline of operation data for future audits. It will assist future auditors in determining changes or trends from previous audits.

Corrective action is one of the most important parts of the audit. It includes not only addressing the identified deficiencies, but also planning, followup, and documentation. The corrective action process normally begins with a management review of the audit findings. The purpose of this review is to determine what actions are appropriate, and to establish priorities, timetables, resource allocations and requirements and responsibilities. In some cases, corrective action may involve a simple change in procedure or minor maintenance effort to remedy the concern. Management of change procedures need to be used, as appropriate, even for what may seem to

be a minor change. Many of the deficiencies can be acted on promptly, while some may require engineering studies or indepth review of actual procedures and practices. There may be instances where no action is necessary and this is a valid response to an audit finding. All actions taken, including an explanation where no action is taken on a finding, needs to be documented as to what was done and why.

It is important to assure that each deficiency identified is addressed, the corrective action to be taken noted, and the audit person or team responsible be properly documented by the employer. To control the corrective action process, the employer should consider the use of a tracking system. This tracking system might include periodic status reports shared with affected levels of management, specific reports such as completion of an engineering study, and a final implementation report to provide closure for audit findings that have been through management of change, if appropriate, and then shared with affected employees and management. This type of tracking system provides the employer with the status of the corrective action. It also provides the documentation required to verify that appropriate corrective actions were taken on deficiencies identified in the audit.

Appendix D to 1926.64-Sources of Further Information (Nonmandatory)

1. Center for Chemical Process Safety, American Institute of Chemical Engineers, 345 East 47th Street, New York, NY 10017, (212)705-7319.
2. "Guidelines for Hazard Evaluation Procedures," American Institute of Chemical Engineers; 345 East 47th Street, New York, NY 10017.
3. "Guidelines for Technical Management of Chemical Process Safety," Center for Chemical Process Safety of the American Institute of Chemical Engineers; 345 East 47th Street, New York, NY 10017.
4. "Evaluating Process Safety in the Chemical Industry," Chemical Manufacturers Association; 2501 M Street NW, Washington, DC 20037.
5. "Safe Warehousing of Chemicals," Chemical Manufacturers Association; 2501 M Street NW, Washington, DC 20037.
6. "Management of Process Hazards," American Petroleum Institute (API Recommended Practice 750); 1220 L Street, N.W., Washington, D.C. 20005.
7. "Improving Owner and Contractor Safety Performance," American Petroleum Institute (API Recommended Practice 2220); API, 1220 L Street N.W., Washington, D.C. 20005.
8. Chemical Manufacturers Association (CMA's Manager Guide), First Edition, September 1991; CMA, 2501 M Street, N.W., Washington, D.C. 20037.
9. "Improving Construction Safety Performance," Report A-3, The Business Roundtable; The Business Roundtable, 200 Park Avenue, New York, NY 10166. (Report includes criteria to evaluate contractor safety performance and criteria to enhance contractor safety performance).
10. "Recommended Guidelines for Contractor Safety and Health," Texas Chemical Council; Texas Chemical Council, 1402 Nueces Street, Austin, TX 78701-1534.

11. "Loss Prevention in the Process Industries," Volumes I and II; Frank P. Lees, Butterworth; London 1983.
 12. "Safety and Health Program Management Guidelines," 1989; U.S. Department of Labor, Occupational Safety and Health Administration.
 13. "Safety and Health Guide for the Chemical Industry," 1986, (OSHA 3091); U.S. Department of Labor, Occupational Safety and Health Administration; 200 Constitution Avenue, N.W., Washington, D.C. 20210.
 14. "Review of Emergency Systems," June 1988; U.S. Environmental Protection Agency (EPA), Office of Solid Waste and Emergency Response, Washington, DC 20460.
 15. "Technical Guidance for Hazards Analysis, Emergency Planning for Extremely Hazardous Substances," December 1987; U.S. Environmental Protection Agency (EPA), Federal Emergency Management Administration (FEMA) and U.S. Department of Transportation (DOT), Washington, DC 20460.
 16. "Accident Investigation...A New Approach," 1983, National Safety Council; 444 North Michigan Avenue, Chicago, IL 60611-3991.
 17. "Fire & Explosion Index Hazard Classification Guide," 6th Edition, May 1987, Dow Chemical Company; Midland, Michigan 48674.
 18. "Chemical Exposure Index," May 1988, Dow Chemical Company; Midland, Michigan 48674.
- [57 FR 6356, FEB. 24, 1992; 57 FR 7847, March 4, 1992; 57 FR 23060, June 1, 1992; 57 FR 23060, Aug. 26, 1992]

1926.65 Hazardous waste operations and emergency response. CPL 2-2.51

(a) Scope, application, and definitions.

(1) Scope. This section covers the following operations, unless the employer can demonstrate that the operation does not involve employee exposure or the reasonable possibility for employee exposure to safety or health hazards:

(i) Clean-up operations required by a governmental body, whether Federal, state, local or other involving hazardous substances that are conducted at uncontrolled hazardous waste sites (including, but not limited to, the EPA's National Priority Site List (NPL), state priority site lists, sites recommended for the EPA NPL, and initial investigations of government identified sites which are conducted before the presence or absence of hazardous substances has been ascertained);

(ii) Corrective actions involving clean-up operations at sites covered by the Resource Conservation and Recovery Act of 1976 (RCRA) as amended (42 U.S.C. 6901 et seq);

(iii) Voluntary clean-up operations at sites recognized by Federal, state, local or

other governmental bodies as uncontrolled hazardous waste sites;

(iv) Operations involving hazardous wastes that are conducted at treatment, storage, and disposal (TSD) facilities regulated by 40 CFR Parts 264 and 265 pursuant to RCRA; or by agencies under agreement with U.S.E.P.A. to implement RCRA regulations; and

(v) Emergency response operations for releases of, or substantial threats of releases of, hazardous substances without regard to the location of the hazard.

(2) Application.

(i) All requirements of part 1910 and part 1926 of title 29 of the Code of Federal Regulations apply pursuant to their terms to hazardous waste and emergency response operations whether covered by this section or not. If there is a conflict or overlap, the provision more protective of employee safety and health shall apply without regard to 29 CFR 1926.20(e)(1).

(ii) Hazardous substance clean-up operations within the scope of paragraphs (a)(1)(i) through (a)(1)(iii) of this section must comply with all paragraphs of this section except paragraphs (p) and (q).

(iii) Operations within the scope of paragraph (a)(1)(iv) of this section must comply only with the requirements of paragraph (p) of this section.

* Notes and Exceptions:

(A) All provisions of paragraph (p) of this section cover any treatment, storage or disposal (TSD) operation regulated by 40 CFR parts 264 and 265 or by state law authorized under RCRA, and required to have a permit or interim status from EPA pursuant to 40 CFR 270.1 or from a state agency pursuant to RCRA.

(B) Employers who are not required to have a permit or interim status because they are conditionally exempt small quantity generators under 40 CFR 261.5 or are generators who qualify under 40 CFR 262.34 for exemptions from regulation under 40 CFR 262.34 for exemptions from regulation under 40 CFR parts 264, 265, and 270 ("excepted employers") are not covered by paragraphs (p)(1) through (p)(7) of this section. Excepted employers who are required by the EPA or state agency to have their employees engage in emergency response or who direct their employees to engage in emergency response are covered by paragraph (p)(8) of this section, and cannot be exempted by (p)(8)(i) of this section.

(C) If an area is used primarily for treatment, storage or disposal, any emergency response operations in that area shall comply with paragraph (p) (8) of this section. In other areas not used primarily for treatment, storage, or disposal, any emergency response operations shall comply with paragraph (q) of this section. Compliance with the requirements of paragraph (q) of this section shall be deemed to be in compliance with the requirements of paragraph (p)(8) of this section.

(iv) Emergency response operations for releases of, or substantial threats of releases of, hazardous substances which are not covered by paragraphs (a)(1)(i) through (a)(1)(iv) of this section must only comply with the requirements of paragraph (q) of this section.

(3) Definitions - "Buddy system" means a system of organizing employees into work groups in such a manner that each employee of the work group is designated to be observed by at least one other employee in the work group. The purpose of the buddy system is to provide rapid assistance to employees in the event of an emergency.

"Clean-up operation" means an operation where hazardous substances are removed, contained, incinerated, neutralized, stabilized, cleared-up, or in any other manner processed or handled with the ultimate goal of making the site safer for people or the environment.

"Decontamination" means the removal of hazardous substances from employees and their equipment to the extent necessary to preclude the occurrence of foreseeable adverse health affects.

"Emergency response" or "responding to emergencies" means a response effort by employees from outside the immediate release area or by other designated responders (i.e., mutual aid groups, local fire departments, etc.) to an occurrence which results, or is likely to result, in an uncontrolled release of a hazardous substance. Responses to incidental releases of hazardous substances where the substance can be absorbed, neutralized, or otherwise controlled at the time of release by employees in the immediate release area, or by maintenance personnel are not considered to be emergency responses within the scope of this standard. Responses to releases of hazardous substances where there is no potential safety or health hazard (i.e., fire, explosion, or chemical exposure) are not considered to be emergency responses.

"Facility" means (A) any building, structure, installation, equipment, pipe or pipeline (including any pipe into a sewer or publicly owned treatment works), well, pit, pond, lagoon, impoundment, ditch, storage container, motor vehicle, rolling stock, or aircraft, or (B) any site or area where a hazardous substance has been deposited, stored, disposed of, or placed, or otherwise come to be located; but does not include any consumer product in consumer use or any water-borne vessel.

"Hazardous materials response (HAZMAT) team" means an organized group of employees, designated by the employer, who are expected to perform work to handle and control actual or potential leaks or spills of hazardous substances requiring possible close approach to the substance. The team members perform responses to releases or potential releases of hazardous substances for the purpose of control or stabilization of the incident. A HAZMAT team is not a fire brigade nor is a typical fire brigade a HAZMAT team. A HAZMAT team, however, may be a separate component of a fire brigade or fire department.

"Hazardous substance" means any substance designated or listed under paragraphs (A) through (D) of this definition, exposure to which results or may result in adverse affects on the health or safety of employees:

(A) Any substance defined under section 101(14) of CERCLA;

(B) Any biological agent and other disease causing agent which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any person, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations in such persons or their offspring.

(C) Any substance listed by the U.S. Department of Transportation as hazardous materials under 49 CFR 172.101 and appendices; and

(D) Hazardous waste as herein defined.

"Hazardous waste" means -

(A) A waste or combination of wastes as defined in 40 CFR 261.3, or

(B) Those substances defined as hazardous wastes in 49 CFR 171.8.

"Hazardous waste operation" means any operation conducted within the scope of this standard.

"Hazardous waste site" or "Site" means any facility or location within the scope of this standard at which hazardous waste operations take place.

~~"Health hazard" means a chemical, mixture of chemicals or a pathogen for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. It also includes stress due to temperature extremes. Further definition of the terms used above can be found in Appendix A to 29 CFR 1926.59.~~ means a chemical or a pathogen where acute or chronic health effects may occur in exposed employees. It also includes stress due to temperature extremes. The term *health hazard* includes chemicals that are classified in accordance with the Hazard Communication Standard, § 1910.1200, as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); aspiration toxicity or simple asphyxiant. (See Appendix A to § 1910.1200—Health Hazard Criteria (Mandatory) for the criteria for determining whether a chemical is classified as a health hazard.)

"IDLH" or "Immediately dangerous to life or health" means an atmospheric concentration of any toxic, corrosive or asphyxiant substance that poses an immediate threat to life or would cause irreversible or delayed adverse health effects or would interfere with an individual's ability to escape from a dangerous atmosphere.

"Oxygen deficiency" means that concentration of oxygen by volume below which atmosphere supplying respiratory protection must be provided. It exists in atmospheres where the percentage of oxygen by volume is less than 19.5 percent oxygen.

"Permissible exposure limit" means the exposure, inhalation or dermal permissible exposure limit specified either in 1926.55, elsewhere in subpart D, or in other pertinent sections of this part.

"Published exposure level" means the exposure limits published in "NIOSH

recommendations for Occupational Health Standards" dated 1986 incorporated by reference, or if none is specified, the exposure limits published in the standards specified by the American Conference of Governmental Industrial Hygienists in their publication "Threshold Limit Values and Biological Exposure Indices for 1987 - 88" dated 1987 incorporated by reference.

"Post emergency response" means that portion of an emergency response performed after the immediate threat of a release has been stabilized or eliminated and clean-up of the site has begun. If post emergency response is performed by an employer's own employees who were part of the initial emergency response, it is considered to be part of the initial response and not post emergency response. However, if a group of an employer's own employees, separate from the group providing initial response, performs the clean-up operation, then the separate group of employees would be considered to be performing post-emergency response and subject to * paragraph (q)(11) of this section.

"Qualified person" means a person with specific training, knowledge and experience in the area for which the person has the responsibility and the authority to control.

"Site safety and health supervisor (or official" means the individual located on a hazardous waste site who is responsible to the employer and has the authority and knowledge necessary to implement the site safety and health plan and verify compliance with applicable safety and health requirements.

"Small quantity generator" means a generator of hazardous wastes who in any calendar month generates no more than 1,000 kilograms (2,205 pounds) of hazardous waste in that month.

"Uncontrolled hazardous waste site" means an area identified as an uncontrolled hazardous waste site by a governmental body, whether Federal, state, local or other where an accumulation of hazardous substances creates a threat to the health and safety of individuals or the environment or both. Some sites are found on public lands such as those created by former municipal, county or state landfills where illegal or poorly managed waste disposal has taken place. Other sites are found on private property, often belonging to generators or former generators of hazardous substance wastes. Examples of such sites include, but are not limited to, surface impoundments, landfills, dumps, and tank or drum farms. Normal operations at TSD sites are not covered by this definition.

(b) Safety and health program.

Note to (b): Safety and health programs developed and implemented to meet other federal, state, or local regulations are considered acceptable in meeting this requirement if they cover or are modified to cover the topics required in this paragraph. An additional or separate safety and health program is not required by this paragraph.

(1) General.

(i) Employers shall develop and implement a written safety and health program for their employees involved in hazardous waste operations. The program shall be designed to identify, evaluate, and control safety and health hazards, and provide for emergency response for hazardous waste operations. STEP

(ii) The written safety and health program shall incorporate the following:

STEP

- (A) An organizational structure;
 - (B) A comprehensive workplan;
 - (C) A site-specific safety and health plan which need not repeat the employer's standard operating procedures required in paragraph (b)(1)(ii)(F) of this section;
 - (D) The safety and health training program;
 - (E) The medical surveillance program;
 - (F) The employer's standard operating procedures for safety and health;
- and
- (G) Any necessary interface between general program and site specific activities.

(iii) Site excavation. Site excavations created during initial site preparation or during hazardous waste operations shall be shored or sloped as appropriate to prevent accidental collapse in accordance with Subpart P of 29 CFR Part 1926. STEP

(iv) Contractors and sub-contractors. An employer who retains contractor or sub-contractor services for work in hazardous waste operations shall inform those contractors, sub-contractors, or their representatives of the site emergency response procedures and any potential fire, explosion, health, safety or other hazards of the hazardous waste operation that have been identified by the employer, including those identified in the employer's information program. STEP

(v) Program availability. The written safety and health program shall be made available to any contractor or subcontractor or their representative who will be involved with the hazardous waste operation; to employees; to employee designated representatives; to OSHA personnel, and to personnel of other Federal, state, or local agencies with regulatory authority over the site. STEP

(2) Organizational structure part of the site program.

(i) The organizational structure part of the program shall establish the specific chain of command and specify the overall responsibilities of supervisors and employees. It shall include, at a minimum, the following elements: STEP

(A) A general supervisor who has the responsibility and authority to direct all hazardous waste operations.

(B) A site safety and health supervisor who has the responsibility and authority to develop and implement the site safety and health plan and verify compliance.

(C) All other personnel needed for hazardous waste site operations and emergency response and their general functions and responsibilities.

(D) The lines of authority, responsibility, and communication.

(ii) The organizational structure shall be reviewed and updated as necessary to reflect the current status of waste site operations.

STEP

(3) Comprehensive workplan part of the site program. The comprehensive workplan part of the program shall address the tasks and objectives of the site operations and the logistics and resources required to reach those tasks and objectives. STEP

(i) The comprehensive workplan shall address anticipated clean-up activities as well as normal operating procedures which need not repeat the employer's procedures available elsewhere.

(ii) The comprehensive workplan shall define work tasks and objectives and identify the methods for accomplishing those tasks and objectives.

(iii) The comprehensive workplan shall establish personnel requirements for implementing the plan.

(iv) The comprehensive workplan shall provide for the implementation of the training required in paragraph (e) of this section.

(v) The comprehensive workplan shall provide for the implementation of the required informational programs required in paragraph (i) of this section.

(vi) The comprehensive workplan shall provide for the implementation of the medical surveillance program described in paragraph (f) of this section.

(4) Site-specific safety and health plan part of the program.

(i) General. The site safety and health plan, which must be kept on site, shall address the safety and health hazards of each phase of site operation and include the requirements and procedures for employee protection. STEP

(ii) Elements. The site safety and health plan, as a minimum, shall address the following: STEP

(A) A safety and health risk or hazard analysis for each site task and operation found in the workplan.

(B) Employee training assignments to assure compliance with paragraph (e) of this section.

(C) Personal protective equipment to be used by employees for each of the site tasks and operations being conducted as required by the personal protective equipment program in paragraph (g)(5) of this section.

(D) Medical surveillance requirements in accordance with the program in paragraph (f) of this section.

(E) Frequency and types of air monitoring, personnel monitoring, and environmental sampling techniques and instrumentation to be used, including methods of maintenance and calibration of monitoring and sampling equipment to be used.

(F) Site control measures in accordance with the site control program required in paragraph (d) of this section.

(G) Decontamination procedures in accordance with paragraph (k) of this section.

(H) An emergency response plan meeting the requirements of paragraph (l) of this section for safe and effective responses to emergencies, including the necessary PPE and other equipment.

(I) Confined space entry procedures.

(J) A spill containment program meeting the requirements of paragraph (j) of this section.

(iii) Pre-entry briefing. The site specific safety and health plan shall provide for pre-entry briefings to be held prior to initiating any site activity, and at such other times as necessary to ensure that employees are apprised of the site safety and health plan and that this plan is being followed. The information and data obtained from site characterization and analysis work required in paragraph (c) of this section shall be used to prepare and update the site safety and health plan. STEP

(iv) Effectiveness of site safety and health plan. Inspections shall be conducted by the site safety and health supervisor or, in the absence of that individual, another individual who is knowledgeable in occupational safety and health, acting on behalf of the employer as necessary to determine the effectiveness of the site safety and health plan. Any deficiencies in the effectiveness of the site safety and health plan shall be corrected by the employer.

STEP

(c) Site characterization and analysis

(1) General. Hazardous waste sites shall be evaluated in accordance with this paragraph to identify specific site hazards and to determine the appropriate safety and health control procedures needed to protect employees from the identified hazards. STEP

(2) Preliminary evaluation. A preliminary evaluation of a site's characteristics shall be performed prior to site entry by a qualified person in order to aid in the selection of appropriate employee protection methods prior to site entry. Immediately after initial site entry, a more detailed evaluation of the site's specific characteristics shall be performed by a qualified person in order to further identify existing site hazards and to further aid in the selection of the appropriate engineering controls and personal protective equipment for the tasks to be performed. STEP

(3) Hazard identification. All suspected conditions that may pose inhalation or skin absorption hazards that are immediately dangerous to life or health (IDLH) or other conditions that may cause death or serious harm shall be identified during the preliminary survey and evaluated during the detailed survey. Examples of such hazards include, but are not limited to,

confined space entry, potentially explosive or flammable situations, visible vapor clouds, or areas where biological indicators such as dead animals or vegetation are located.

(4) Required information. The following information to the extent available shall be obtained by the employer prior to allowing employees to enter a site: STEP

- (i) Location and approximate size of the site.
- (ii) Description of the response activity and/or the job task to be performed.
- (iii) Duration of the planned employee activity.
- (iv) Site topography and accessibility by air and roads.
- (v) Safety and health hazards expected at the site.
- (vi) Pathways for hazardous substance dispersion.

(vii) Present status and capabilities of emergency response teams that would provide assistance to hazardous waste clean-up site employees at the time of an emergency.

(viii) Hazardous substances and health hazards involved or expected at the site and their chemical and physical properties.

(5) Personal protective equipment. Personal protective equipment (PPE) shall be provided and used during initial site entry in accordance with the following requirements:

(i) Based upon the results of the preliminary site evaluation, an ensemble of PPE shall be selected and used during initial site entry which will provide protection to a level of exposure below permissible exposure limits and published exposure levels for known or suspected hazardous substances and health hazards and which will provide protection against other known and suspected hazards identified during the preliminary site evaluation. If there is no permissible exposure limit or published exposure level, the employer may use other published studies and information as a guide to appropriate personal protective equipment. STEP

(ii) If positive-pressure self-contained breathing apparatus is not used as part of the entry ensemble, and if respiratory protection is warranted by the potential hazards identified during the preliminary site evaluation, an escape self-contained breathing apparatus of at least five minute's duration shall be carried by employees during initial site entry. STEP

(iii) If the preliminary site evaluation does not produce sufficient information to identify the hazards or suspected hazards of the site an ensemble providing protection equivalent to Level B PPE shall be provided as minimum protection, and direct reading instruments shall be used as appropriate for identifying IDLH conditions. (See appendix B for a description of Level B hazards and the recommendations for Level B protective equipment.)

(iv) Once the hazards of the site have been identified, the appropriate PPE shall be selected and used in accordance with paragraph (g) of this section.

(6) Monitoring. The following monitoring shall be conducted during initial site entry

when the site evaluation produces information that shows the potential for ionizing radiation or IDLH conditions, or when the site information is not sufficient reasonably to eliminate these possible conditions:

(i) Monitoring with direct reading instruments for hazardous levels of ionizing radiation.

(ii) Monitoring the air with appropriate direct reading test equipment for (i.e., combustible gas meters, detector tubes) for IDLH and other conditions that may cause death or serious harm (combustible or explosive atmospheres, oxygen deficiency, toxic substances.)

(iii) Visually observing for signs of actual or potential IDLH or other dangerous conditions.

(iv) An ongoing air monitoring program in accordance with paragraph (h) of this section shall be implemented after site characterization has determined the site is safe for the start-up of operations.

(7) Risk identification. Once the presence and concentrations of specific hazardous substances and health hazards have been established, the risks associated with these substances shall be identified. Employees who will be working on the site shall be informed of any risks that have been identified. In situations covered by the Hazard Communication Standard, 29 CFR 1926.59, training required by that standard need not be duplicated.

Note to (c)(7). - Risks to consider include, but are not limited to:

(a) Exposures exceeding the permissible exposure limits and published exposure levels.

(b) IDLH Concentrations.

(c) Potential Skin Absorption and Irritation Sources.

(d) Potential Eye Irritation Sources.

(e) Explosion Sensitivity and Flammability Ranges.

(f) Oxygen deficiency.

(8) Employee notification. Any information concerning the chemical, physical, and toxicologic properties of each substance known or expected to be present on site that is available to the employer and relevant to the duties an employee is expected to perform shall be made available to the affected employees prior to the commencement of their work activities. The employer may utilize information developed for the hazard communication standard for this purpose.

(d) Site control.

(1) General. Appropriate site control procedures shall be implemented to control employee exposure to hazardous substances before clean-up work begins.

(2) Site control program. A site control program for protecting employees which is part of the employer's site safety and health program required in paragraph (b) of this section shall be developed during the planning stages of a hazardous waste clean-up operation and modified as necessary as new information becomes available.

(3) Elements of the site control program. The site control program shall, as a minimum, include: A site map; site work zones; the use of a "buddy system"; site communications including alerting means for emergencies; the standard operating procedures or safe work practices; and, identification of the nearest medical assistance. Where these requirements are covered elsewhere they need not be repeated.

(e) Training.

(1) General.

(i) All employees working on site (such as but not limited to equipment operators, general laborers and others) exposed to hazardous substances, health hazards, or safety hazards and their supervisors and management responsible for the site shall receive training meeting the requirements of this paragraph before they are permitted to engage in hazardous waste operations that could expose them to hazardous substances, safety, or health hazards, and they shall receive review training as specified in this paragraph.

(ii) Employees shall not be permitted to participate in or supervise field activities until they have been trained to a level required by their job function and responsibility.

(2) Elements to be covered. The training shall thoroughly cover the following:

(i) Names of personnel and alternates responsible for site safety and health;

(ii) Safety, health and other hazards present on the site;

(iii) Use of personal protective equipment;

(iv) Work practices by which the employee can minimize risks from hazards;

(v) Safe use of engineering controls and equipment on the site;

(vi) Medical surveillance requirements including recognition of symptoms and signs which might indicate over exposure to hazards; and

(vii) The contents of paragraphs (G) through (J) of the site safety and health plan set forth in paragraph (b)(4)(ii) of this section.

(3) Initial training.

(i) General site workers (such as equipment operators, general laborers and supervisory personnel) engaged in hazardous substance removal or other activities which expose or potentially expose workers to hazardous substances and health hazards shall receive a minimum of 40 hours of instruction off the site, and a minimum of three days actual field experience under the direct supervision of a trained experienced supervisor.

(ii) Workers on site only occasionally for a specific limited task (such as, but not limited to, ground water monitoring, land surveying, or geophysical surveying) and who are unlikely to be exposed over permissible exposure limits and published exposure limits shall receive a minimum of 24 hours of instruction off the site, and the minimum of one day actual field experience under the direct supervision of a trained, experienced supervisor.

(iii) Workers regularly on site who work in areas which have been monitored and fully characterized indicating that exposures are under permissible exposure limits and published exposure limits where respirators are not necessary, and the characterization indicates that there are no health hazards or the possibility of an emergency developing, shall receive a minimum of 24 hours of instruction off the site, and the minimum of one day actual field experience under the direct supervision of a trained, experienced supervisor.

(iv) Workers with 24 hours of training who are covered by paragraphs * (e)(3)(ii) and (e)(3)(iii) of this section, and who become general site workers or who are required to wear respirators, shall have the additional 16 hours and two days of training necessary to total the training specified in paragraph (e)(3)(i).

(4) Management and supervisor training. On-site management and supervisors directly responsible for or who supervise employees engaged in hazardous waste operations shall receive 40 hours initial training and three days of supervised field experience (the training may be reduced to 24 hours and one day if the only area of their responsibility is employees covered by paragraphs (e)(3)(ii) and (e)(3)(iii)) and at least eight additional hours of specialized training at the time of job assignment on such topics as, but not limited to, the employer's safety and health program and the associated employee training program, personal protective equipment program, spill containment program, and health hazard monitoring procedure and techniques.

(5) Qualifications for trainers. Trainers shall be qualified to instruct employees about the subject matter that is being presented in training. Such trainers shall have satisfactorily completed a training program for teaching the subjects they are expected to teach, or they shall have the academic credentials and instructional experience necessary for teaching the subjects. Instructors shall demonstrate competent instructional skills and knowledge of the applicable subject matter.

(6) Training certification. Employees and supervisors that have received and successfully completed the training and field experience specified in paragraphs (e)(1) through (e)(4) of this section shall be certified by their instructor or the head instructor and trained supervisor as having successfully completed the necessary training. A written certificate shall be given to each person so certified. Any person who has not been so certified or who does not meet the requirements of paragraph (e)(9) of this section shall be prohibited from engaging in hazardous waste operations.

(7) Emergency response. Employees who are engaged in responding to hazardous emergency situations at hazardous waste clean-up sites that may expose them to hazardous substances shall be trained in how to respond to such expected emergencies.

(8) Refresher training. Employees specified in paragraph (e)(1) of this section, and managers and supervisors specified in paragraph (e)(4) of this section, shall receive eight hours of refresher training annually on the items specified in paragraph (e)(2) and/or (e)(4) of this

section, any critique of incidents that have occurred in the past year that can serve as training examples of related work, and other relevant topics.

(9) Equivalent training. Employers who can show by documentation or certification that an employee's work experience and/or training has resulted in training equivalent to that training required in paragraphs * (e)(1) through (e)(4) of this section shall not be required to provide * the initial training requirements of those paragraphs to such employees * and shall provide a copy of the certification or documentation to the * employee upon request. However, certified employees or employees with equivalent training new to a site shall receive appropriate, site specific training before site entry and have appropriate supervised field experience at the new site. Equivalent training includes any academic training or the training that existing employees might have already received from actual hazardous waste site work experience.

(f) Medical surveillance

(1) General. Employers engaged in operations specified in paragraphs (a)(1)(i) through (a)(1)(iv) of this section and not covered by (a)(2)(iii) exceptions and employers of employees specified in paragraph (q)(9) shall institute a medical surveillance program in accordance with this paragraph.

(2) Employees covered. The medical surveillance program shall be instituted by the employer for the following employees:

(i) All employees who are or may be exposed to hazardous substances or health hazards at or above the permissible exposure limits or, if there is no permissible exposure limit, above the published exposure levels for these substances, without regard to the use of respirators, for 30 days or more a year;

(ii) All employees who wear a respirator for 30 days or more a year or as required by 1926.103;

(iii) All employees who are injured, become ill or develop signs or symptoms due to possible overexposure involving hazardous substances or health hazards from an emergency response or hazardous waste operation; and

(iv) Members of HAZMAT teams.

(3) Frequency of medical examinations and consultations. Medical examinations and consultations shall be made available by the employer to each employee covered under paragraph (f)(2) of this section on the following schedules:

(i) For employees covered under paragraphs (f)(2)(i), (f)(2)(ii), and (f)(2)(iv);

(A) Prior to assignment;

(B) At least once every twelve months for each employee covered unless the attending physician believes a longer interval (not greater than biennially) is appropriate;

(C) At termination of employment or reassignment to an area where the employee would not be covered if the employee has not had an examination within the last six

months.

(D) As soon as possible upon notification by an employee that the employee has developed signs or symptoms indicating possible overexposure to hazardous substances or health hazards, or that the employee has been injured or exposed above the permissible exposure limits or published exposure levels in an emergency situation;

(E) At more frequent times, if the examining physician determines that an increased frequency of examination is medically necessary.

(ii) For employees covered under paragraph (f)(2)(iii) and for all employees including those of employers covered by paragraph (a)(1)(v) who may have been injured, received a health impairment, developed signs or symptoms which may have resulted from exposure to hazardous substances resulting from an emergency incident, or exposed during an emergency incident to hazardous substances at concentrations above the permissible exposure limits or the published exposure levels without the necessary personal protective equipment being used:

(A) As soon as possible following the emergency incident or development of signs or symptoms;

(B) At additional times, if the examining physician determines that follow-up examinations or consultations are medically necessary.

(4) Content of medical examinations and consultations.

(i) Medical examinations required by paragraph (f)(3) of this section shall include a medical and work history (or updated history if one is in the employee's file) with special emphasis on symptoms related to the handling of hazardous substances and health hazards, and to fitness for duty including the ability to wear any required PPE under conditions (i.e., temperature extremes) that may be expected at the work site.

(ii) The content of medical examinations or consultations made available to employees pursuant to paragraph (f) shall be determined by the attending physician. The guidelines in the Occupational Safety and Health Guidance Manual for Hazardous Waste Site Activities (See Appendix D, reference # 10) should be consulted.

(5) Examination by a physician and costs. All medical examinations and procedures shall be performed by or under the supervision of a licensed physician, preferably one knowledgeable in occupational medicine, and shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(6) Information provided to the physician. The employer shall provide one copy of this standard and its appendices to the attending physician and in addition the following for each employee:

(i) A description of the employee's duties as they relate to the employee's exposures,

(ii) The employee's exposure levels or anticipated exposure levels.

(iii) A description of any personal protective equipment used or to be used.

(iv) Information from previous medical examinations of the employee which is not readily available to the examining physician.

(v) Information required by 1926.103.

(7) Physician's written opinion.

(i) The employer shall obtain and furnish the employee with a copy of a written opinion from the attending physician containing the following:

(A) The physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of the employee's health from work in hazardous waste operations or emergency response, or from respirator use.

(B) The physician's recommended limitations upon the employee's assigned work.

(C) The results of the medical examination and tests if requested by the employee.

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposures.

(8) Recordkeeping.

(i) An accurate record of the medical surveillance required by paragraph (f) of this section shall be retained. This record shall be retained for the period specified and meet the criteria of 29 CFR 1926.33.

(ii) The record required in paragraph (f)(8)(i) of this section shall include at least the following information:

(A) The name and social security number of the employee;

(B) Physician's written opinions, recommended limitations and results of examinations and tests;

(C) Any employee medical complaints related to exposure to hazardous substances;

(D) A copy of the information provided to the examining physician by the employer, with the exception of the standard and its appendices.

(g) Engineering controls, work practices, and personal protective equipment for employee protection. Engineering controls, work practices and PPE for substances regulated in Subpart Z.
(i) Engineering controls, work practices, personal protective equipment, or a combination of these shall be implemented in accordance with this paragraph to protect employees from exposure to hazardous substances and safety and health hazards.

(1) Engineering controls, work practices and PPE for substances regulated either in 1926.55, elsewhere in Subpart D, or in other pertinent sections of this part.

(i) Engineering controls and work practices shall be instituted to reduce and maintain employee exposure to or below the permissible exposure limits for substances regulated either in 1926.55 or other pertinent sections of this part except to the extent that such controls and practices are not feasible.

Note to (g)(1)(i): Engineering controls which may be feasible include the use of pressurized cabs or control booths on equipment, and/or the use of remotely operated material handling equipment. Work practices which may be feasible are removing all non-essential employees from potential exposure during opening of drums, wetting down dusty operations and locating employees upwind of possible hazards.

(ii) Whenever engineering controls and work practices are not feasible, or not required, any reasonable combination of engineering controls, work practices and PPE shall be used to reduce and maintain employee exposures to or below the permissible exposure limits or dose limits for substances regulated either in 1926.55 or other pertinent sections of this part.

(iii) The employer shall not implement a schedule of employee rotation as a means of compliance with permissible exposure limits or dose limits except when there is no other feasible way of complying with the airborne or dermal dose limits for ionizing radiation.

(iv) The provisions of subpart D shall be followed.

(2) Engineering controls, work practices, and PPE for substances not regulated either in 1926.55, elsewhere in subpart D, or in other pertinent sections of the part. An appropriate combination of engineering controls, work practices, and personal protective equipment shall be used to reduce and maintain employee exposure to or below published exposure levels for hazardous substances and health hazards not regulated either in 1926.55, elsewhere in subpart D, or in other pertinent sections of this part. The employer may use the published literature and MSDS as a guide in making the employer's determination as to what level of protection the employer believes is appropriate for hazardous substances and health hazards for which there is no permissible exposure limit or published exposure limit.

(3) Personal protective equipment selection.

(i) Personal protective equipment (PPE) shall be selected and used which will protect employees from the hazards and potential hazards they are likely to encounter as identified during the site characterization and analysis.

(ii) Personal protective equipment selection shall be based on an evaluation of the performance characteristics of the PPE relative to the requirements and limitations of the site, the task-specific conditions and duration, and the hazards and potential hazards identified at the

site.

(iii) Positive pressure self-contained breathing apparatus, or positive pressure air-line respirators equipped with an escape air supply shall be used when chemical exposure levels present will create a substantial possibility of immediate death, immediate serious illness or injury, or impair the ability to escape.

(iv) Totally-encapsulating chemical protective suits (protection equivalent to Level A protection as recommended in Appendix B) shall be used in conditions where skin absorption of a hazardous substance may result in a substantial possibility of immediate death, immediate serious illness or injury, or impair the ability to escape.

(v) The level of protection provided by PPE selection shall be increased when additional information on site conditions indicates that increased protection is necessary to reduce employee exposures below permissible exposure limits and published exposure levels for hazardous substances and health hazards. (See Appendix B for guidance on selecting PPE ensembles.)

Note to (g)(3): The level of employee protection provided may be decreased when additional information or site conditions show that decreased protection will not result in hazardous exposures to employees.

(vi) Personal protective equipment shall be selected and used to meet the requirements of subpart E of this part and additional requirements specified in this section.

(4) Totally-encapsulating chemical protective suits.

(i) Totally-encapsulating suits shall protect employees from the particular hazards which are identified during site characterization and analysis.

(ii) Totally-encapsulating suits shall be capable of maintaining positive air pressure. (See Appendix A for a test method which may be used to evaluate this requirement.)

(iii) Totally-encapsulating suits shall be capable of preventing inward test gas leakage of more than 0.5 percent. (See Appendix A for a test method which may be used to evaluate this requirement.)

(5) Personal protective equipment (PPE) program. A written personal protective equipment program, which is part of the employer's safety and health program required in paragraph (b) of this section or required in paragraph (p)(1) of this section and which is also a part of the site-specific safety and health plan shall be established. The PPE program shall address the elements listed below. When elements, such as donning and doffing procedures, are provided by the manufacturer of a piece of equipment and are attached to the plan, they need not be rewritten into the plan as long as they adequately address the procedure or element.

(i) PPE selection based upon site hazards,

(ii) PPE use and limitations of the equipment,

(iii) Work mission duration,

- (iv) PPE maintenance and storage,
- (v) PPE decontamination and disposal,
- (vi) PPE training and proper fitting,
- (vii) PPE donning and doffing procedures,
- (viii) PPE inspection procedures prior to, during, and after use,
- (ix) Evaluation of the effectiveness of the PPE program, and
- (x) Limitations during temperature extremes, heat stress, and other appropriate medical considerations.

(h) Monitoring.

(1) General.

(i) Monitoring shall be performed in accordance with this paragraph where there may be a question of employee exposure to hazardous concentrations of hazardous substances in order to assure proper selection of engineering controls, work practices and personal protective equipment so that employees are not exposed to levels which exceed permissible exposure limits, or published exposure levels if there are no permissible exposure limits, for hazardous substances.

(ii) Air monitoring shall be used to identify and quantify airborne levels of hazardous substances and safety and health hazards in order to determine the appropriate level of employee protection needed on site.

(2) Initial entry. Upon initial entry, representative air monitoring shall be conducted to identify any IDLH condition, exposure over permissible exposure limits or published exposure levels, exposure over a radioactive material's dose limits or other dangerous condition such as the presence of flammable atmospheres or oxygen-deficient environments.

(3) Periodic monitoring. Periodic monitoring shall be conducted when the possibility of an IDLH condition or flammable atmosphere has developed or when there is indication that exposures may have risen over permissible exposure limits or published exposure levels since prior monitoring. Situations where it shall be considered whether the possibility that exposures have risen are as follows:

- (i) When work begins on a different portion of the site.
- (ii) When contaminants other than those previously identified are being handled.
- (iii) When a different type of operation is initiated (e.g., drum opening as opposed to exploratory well drilling.)
- (iv) When employees are handling leaking drums or containers or working in

areas with obvious liquid contamination (e.g., a spill or lagoon.)

(4) Monitoring of high-risk employees. After the actual clean-up phase of any hazardous waste operation commences; for example, when soil, surface water or containers are moved or disturbed; the employer shall monitor those employees likely to have the highest exposures to those hazardous substances and health hazards likely to be present above permissible exposure limits or published exposure levels by using personal sampling frequently enough to characterize employee exposures. The employer may utilize a representative sampling approach by documenting that the employees and chemicals chosen for monitoring are based on the criteria stated in the first sentence of this paragraph. If the employees likely to have the highest exposure are over permissible exposure limits or published exposure limits, then monitoring shall continue to determine all employees likely to be above those limits. The employer may utilize a representative sampling approach by documenting that the employees and chemicals chosen for monitoring are based on the criteria stated above.

Note to (h): It is not required to monitor employees engaged in site characterization operations covered by paragraph (c) of this section.

(i) Informational programs. Employers shall develop and implement a program which is part of the employer's safety and health program required in paragraph (b) of this section to inform employees, contractors, and subcontractors (or their representative) actually engaged in hazardous waste operations of the nature, level and degree of exposure likely as a result of participation in such hazardous waste operations. Employees, contractors and subcontractors working outside of the operations part of a site are not covered by this standard.

(j) Handling drums and containers

(1) General.

(i) Hazardous substances and contaminated soils, liquids, and other residues shall be handled, transported, labeled, and disposed of in accordance with this paragraph.

(ii) Drums and containers used during the clean-up shall meet the appropriate DOT, OSHA, and EPA regulations for the wastes that they contain.

(iii) When practical, drums and containers shall be inspected and their integrity shall be assured prior to being moved. Drums or containers that cannot be inspected before being moved because of storage conditions (i.e., buried beneath the earth, stacked behind other drums, stacked several tiers high in a pile, etc.) shall be moved to an accessible location and inspected prior to further handling.

(iv) Unlabelled drums and containers shall be considered to contain hazardous substances and handled accordingly until the contents are positively identified and labeled.

(v) Site operations shall be organized to minimize the amount of drum or container movement.

(vi) Prior to movement of drums or containers, all employees exposed to the

transfer operation shall be warned of the potential hazards associated with the contents of the drums or containers.

(vii) U.S. Department of Transportation specified salvage drums or containers and suitable quantities of proper absorbent shall be kept available and used in areas where spills, leaks, or ruptures may occur.

(viii) Where major spills may occur, a spill containment program, which is part of the employer's safety and health program required in paragraph (b) of this section, shall be implemented to contain and isolate the entire volume of the hazardous substance being transferred.

(ix) Drums and containers that cannot be moved without rupture, leakage, or spillage shall be emptied into a sound container using a device classified for the material being transferred.

(x) A ground-penetrating system or other type of detection system or device shall be used to estimate the location and depth of buried drums or containers.

(xi) Soil or covering material shall be removed with caution to prevent drum or container rupture.

(xii) Fire extinguishing equipment meeting the requirements of subpart F of this part shall be on hand and ready for use to control incipient fires.

(2) Opening drums and containers. The following procedures shall be followed in areas where drums or containers are being opened:

(i) Where an airline respirator system is used, connections to the source of air supply shall be protected from contamination and the entire system shall be protected from physical damage.

(ii) Employees not actually involved in opening drums or containers shall be kept a safe distance from the drums or containers being opened.

(iii) If employees must work near or adjacent to drums or containers being opened, a suitable shield that does not interfere with the work operation shall be placed between the employee and the drums or containers being opened to protect the employee in case of accidental explosion.

(iv) Controls for drum or container opening equipment, monitoring equipment, and fire suppression equipment shall be located behind the explosion-resistant barrier.

(v) When there is a reasonable possibility of flammable atmospheres being present, material handling equipment and hand tools shall be of the type to prevent sources of ignition.

(vi) Drums and containers shall be opened in such a manner that excess interior pressure will be safely relieved. If pressure cannot be relieved from a remote location, appropriate shielding shall be placed between the employee and the drums or containers to

reduce the risk of employee injury.

(vii) Employees shall not stand upon or work from drums or containers.

(3) Material handling equipment. Material handling equipment used to transfer drums and containers shall be selected, positioned and operated to minimize sources of ignition related to the equipment from igniting vapors released from ruptured drums or containers.

(4) Radioactive wastes. Drums and containers containing radioactive wastes shall not be handled until such time as their hazard to employees is properly assessed.

(5) Shock sensitive wastes. As a minimum, the following special precautions shall be taken when drums and containers containing or suspected of containing shock-sensitive wastes are handled:

(i) All non-essential employees shall be evacuated from the area of transfer.

(ii) Material handling equipment shall be provided with explosive containment devices or protective shields to protect equipment operators from exploding containers.

(iii) An employee alarm system capable of being perceived above surrounding light and noise conditions shall be used to signal the commencement and completion of explosive waste handling activities.

(iv) Continuous communications (i.e., portable radios, hand signals, telephones, as appropriate) shall be maintained between the employee-in-charge of the immediate handling area and both the site safety and health supervisor and the command post until such time as the handling operation is completed. Communication equipment or methods that could cause shock sensitive materials to explode shall not be used.

(v) Drums and containers under pressure, as evidenced by bulging or swelling, shall not be moved until such time as the cause for excess pressure is determined and appropriate containment procedures have been implemented to protect employees from explosive relief of the drum.

(vi) Drums and containers containing packaged laboratory wastes shall be considered to contain shock-sensitive or explosive materials until they have been characterized.

Caution: Shipping of shock sensitive wastes may be prohibited under U.S. Department of Transportation regulations. Employers and their shippers should refer to 49 CFR 173.21 and 173.50.

(6) Laboratory waste packs. In addition to the requirements of paragraph (j)(5) of this section, the following precautions shall be taken, as a minimum, in handling laboratory waste packs (lab packs):

(i) Lab packs shall be opened only when necessary and then only by an individual knowledgeable in the inspection, classification, and segregation of the containers

within the pack according to the hazards of the wastes.

(ii) If crystalline material is noted on any container, the contents shall be handled as a shock-sensitive waste until the contents are identified.

(7) Sampling of drum and container contents. Sampling of containers and drums shall be done in accordance with a sampling procedure which is part of the site safety and health plan developed for and available to employees and others at the specific worksite.

(8) Shipping and transport.

(i) Drums and containers shall be identified and classified prior to packaging for shipment.

(ii) Drum or container staging areas shall be kept to the minimum number necessary to identify and classify materials safely and prepare them for transport.

(iii) Staging areas shall be provided with adequate access and egress routes.

(iv) Bulking of hazardous wastes shall be permitted only after a thorough characterization of the materials has been completed.

(9) Tank and vault procedures.

(i) Tanks and vaults containing hazardous substances shall be handled in a manner similar to that for drums and containers, taking into consideration the size of the tank or vault.

(ii) Appropriate tank or vault entry procedures as described in the employer's safety and health plan shall be followed whenever employees must enter a tank or vault.

(k) Decontamination

(1) General. Procedures for all phases of decontamination shall be developed and implemented in accordance with this paragraph.

(2) Decontamination procedures.

(i) A decontamination procedure shall be developed, communicated to employees and implemented before any employees or equipment may enter areas on site where potential for exposure to hazardous substances exists.

(ii) Standard operating procedures shall be developed to minimize employee contact with hazardous substances or with equipment that has contacted hazardous substances.

(iii) All employees leaving a contaminated area shall be appropriately decontaminated; all contaminated clothing and equipment leaving a contaminated area shall be appropriately disposed of or decontaminated.

(iv) Decontamination procedures shall be monitored by the site safety and health supervisor to determine their effectiveness. When such procedures are found to be ineffective,

appropriate steps shall be taken to correct any deficiencies.

(3) Location. Decontamination shall be performed in geographical areas that will minimize the exposure of uncontaminated employees or equipment to contaminated employees or equipment.

(4) Equipment and solvents. All equipment and solvents used for decontamination shall be decontaminated or disposed of properly.

(5) Personal protective clothing and equipment.

(i) Protective clothing and equipment shall be decontaminated, cleaned, laundered, maintained or replaced as needed to maintain their effectiveness.

(ii) Employees whose non-impermeable clothing becomes wetted with hazardous substances shall immediately remove that clothing and proceed to shower. The clothing shall be disposed of or decontaminated before it is removed from the work zone.

(6) Unauthorized employees. Unauthorized employees shall not remove protective clothing or equipment from change rooms.

(7) Commercial laundries or cleaning establishments. Commercial laundries or cleaning establishments that decontaminate protective clothing or equipment shall be informed of the potentially harmful effects of exposures to hazardous substances.

(8) Showers and change rooms. Where the decontamination procedure indicates a need for regular showers and change rooms outside of a contaminated area, they shall be provided and meet the requirements of 29 CFR 1910.141. If temperature conditions prevent the effective use of water, then other effective means for cleansing shall be provided and used.

(1) Emergency response by employees at uncontrolled hazardous waste sites

(1) Emergency response plan.

(i) An emergency response plan shall be developed and implemented by all employers within the scope of paragraphs (a)(1)(i) - (ii) of this section to handle anticipated emergencies prior to the commencement of hazardous waste operations. The plan shall be in writing and available for inspection and copying by employees, their representatives, OSHA personnel and other governmental agencies with relevant responsibilities. STEP

(ii) Employers who will evacuate their employees from the danger area when an emergency occurs, and who do not permit any of their employees to assist in handling the emergency, are exempt from the requirements of this paragraph if they provide an emergency action plan complying with section 1926.35 of this part.

(2) Elements of an emergency response plan. The employer shall develop an emergency response plan for emergencies which shall address, as a minimum, the following:

(i) Pre-emergency planning.

(ii) Personnel roles, lines of authority, training, and communication.

- (iii) Emergency recognition and prevention.
- (iv) Safe distances and places of refuge.
- (v) Site security and control.
- (vi) Evacuation routes and procedures.
- (vii) Decontamination procedures which are not covered by the site safety and health plan.
- (viii) Emergency medical treatment and first aid.
- (ix) Emergency alerting and response procedures.
- (x) Critique of response and follow-up.
- (xi) PPE and emergency equipment.

(3) Procedures for handling emergency incidents.

(i) In addition to the elements for the emergency response plan required in paragraph (1)(2) of this section, the following elements shall be included for emergency response plans:

(A) Site topography, layout, and prevailing weather conditions.

(B) Procedures for reporting incidents to local, state, and federal governmental agencies.

(ii) The emergency response plan shall be a separate section of the Site Safety and Health Plan.

(iii) The emergency response plan shall be compatible and integrated with the disaster, fire and/or emergency response plans of local, state, and federal agencies.

(iv) The emergency response plan shall be rehearsed regularly as part of the overall training program for site operations.

(v) The site emergency response plan shall be reviewed periodically and, as necessary, be amended to keep it current with new or changing site conditions or information.

(vi) An employee alarm system shall be installed in accordance with 29 CFR 1926.159 to notify employees of an emergency situation, to stop work activities if necessary, to lower background noise in order to speed communication, and to begin emergency procedures.

(vii) Based upon the information available at time of the emergency, the employer shall evaluate the incident and the site response capabilities and proceed with the appropriate steps to implement the site emergency response plan.

(m) Illumination. Areas accessible to employees shall be lighted to not less than the minimum

illumination intensities listed in the following Table D-65.1 while any work is in progress:

TABLE D-65.1. - MINIMUM ILLUMINATION INTENSITIES IN FOOT-CANDLES

| Foot-candles : | Area or operations |
|----------------|---|
| 5 | General site areas. |
| 3 | Excavation and waste areas, accessways, active storage areas, loading platforms, refueling, and field maintenance areas. |
| 5 | Indoors: warehouses, corridors, hallways, and exitways. |
| 5 | Tunnels, shafts, and general underground work areas; (Exception: minimum of 10 foot-candles is required at tunnel and shaft heading during drilling, mucking, and scaling. Mine Safety and Health Administration approved cap lights shall be acceptable for use in the tunnel heading. |
| 10 | General shops (e.g., mechanical and electrical equipment rooms, active storerooms, barracks or living quarters, locker or dressing rooms, dining areas, and indoor toilets and workrooms. |
| 30 | First aid stations, infirmaries, and offices. |

(n) Sanitation at temporary workplaces

(1) Potable water.

(i) An adequate supply of potable water shall be provided on the site.

(ii) Portable containers used to dispense drinking water shall be capable of being tightly closed, and equipped with a tap. Water shall not be dipped from containers.

(iii) Any container used to distribute drinking water shall be clearly marked as to the nature of its contents and not used for any other purpose.

(iv) Where single service cups (to be used but once) are supplied, both a sanitary container for the unused cups and a receptacle for disposing of the used cups shall be provided.

(2) Nonpotable water.

(i) Outlets for nonpotable water, such as water for firefighting purposes shall be identified to indicate clearly that the water is unsafe and is not to be used for drinking, washing, or cooking purposes.

(ii) There shall be no cross-connection, open or potential, between a system furnishing potable water and a system furnishing nonpotable water.

(3) Toilet facilities.

(i) Toilets shall be provided for employees according to Table D-65.2.

TABLE D-65.2. - TOILET FACILITIES

| Number of employees | : Minimum number of facilities |
|--------------------------------|---|
| 20 or fewer..... | : One. |
| More than 20, fewer than 200.: | One toilet seat and 1 urinal per 40 : employees. |
| More than 200..... | : One toilet seat and 1 urinal per 50 : employees. |

(ii) Under temporary field conditions, provisions shall be made to assure that at least one toilet facility is available.

(iii) Hazardous waste sites, not provided with a sanitary sewer, shall be provided with the following toilet facilities unless prohibited by local codes:

- (A) Chemical toilets;
- (B) Recirculating toilets;
- (C) Combustion toilets; or
- (D) Flush toilets.

(iv) The requirements of this paragraph for sanitation facilities shall not apply to mobile crews having transportation readily available to nearby toilet facilities.

(v) Doors entering toilet facilities shall be provided with entrance locks controlled from inside the facility.

(4) Food handling. All food service facilities and operations for employees shall meet the applicable laws, ordinances, and regulations of the jurisdictions in which they are located.

(5) Temporary sleeping quarters. When temporary sleeping quarters are provided, they shall be heated, ventilated, and lighted.

(6) Washing facilities. The employer shall provide adequate washing facilities for employees engaged in operations where hazardous substances may be harmful to employees. Such facilities shall be in near proximity to the worksite; in areas where exposures are below permissible exposure limits and published exposure levels and which are under the controls of the employer; and shall be so equipped as to enable employees to remove hazardous substances from themselves.

(7) Showers and change rooms. When hazardous waste clean-up or removal operations commence on a site and the duration of the work will require six months or greater time to complete, the employer shall provide showers and change rooms for all employees exposed to hazardous substances and health hazards involved in hazardous waste clean-up or removal

operations.

(i) Showers shall be provided and shall meet the requirements of 29 CFR 1926.51(f)(4).

(ii) Change rooms shall be provided and shall meet the requirements of 29 CFR 1926.51(i). Change rooms shall consist of two separate change areas separated by the shower area required in paragraph (n)(7)(i) of this section. One change area, with an exit leading off the worksite, shall provide employees with a clean area where they can remove, store, and put on street clothing. The second area, with an exit to the worksite, shall provide employees with an area where they can put on, remove and store work clothing and personal protective equipment.

(iii) Showers and change rooms shall be located in areas where exposures are below the permissible exposure limits and published exposure levels. If this cannot be accomplished, then a ventilation system shall be provided that will supply air that is below the permissible exposure limits and published exposure levels.

(iv) Employers shall assure that employees shower at the end of their work shift and when leaving the hazardous waste site.

(o) New technology programs.

(1) The employer shall develop and implement procedures for the introduction of effective new technologies and equipment developed for the improved protection of employees working with hazardous waste clean-up operations, and the same shall be implemented as part of the site safety and health program to assure that employee protection is being maintained.

(2) New technologies, equipment or control measures available to the industry, such as the use of foams, absorbents, adsorbents, neutralizers, or other means to suppress the level of air contaminants while excavating the site or for spill control, shall be evaluated by employers or their representatives. Such an evaluation shall be done to determine the effectiveness of the new methods, materials, or equipment before implementing their use on a large scale for enhancing employee protection. Information and data from manufacturers or suppliers may be used as part of the employer's evaluation effort. Such evaluations shall be made available to OSHA upon request. * (p) Certain Operations Conducted Under the Resource Conservation and * Recovery Act of 1976 (RCRA). Employers conducting operations at * treatment, storage and disposal (TSD) facilities specified in paragraph * (a)(1)(iv) of this section shall provide and implement the programs * specified in this paragraph. See the "Notes and Exceptions" to paragraph * (a)(2)(iii) of this section for employers not covered.

(p) Certain operations conducted under the Resource Conservation and Recovery Act of 1976 (RCRA). Employers conducting operations at treatment, storage and disposal (TSD) facilities specified in paragraph (a)(1)(iv) of this section shall provide and implement the programs specified in this paragraph. See the "Notes and Exceptions" to paragraph (a)(2)(iii) of this section for employers not covered.).

(1) Safety and health program. The employer shall develop and implement a written safety and health program for employees involved in hazardous waste operations that shall be available for inspection by employees, their representatives and OSHA personnel. The program shall be designed to identify, evaluate and control safety and health hazards in their facilities for

the purpose of employee protection, to provide for emergency response meeting the requirements of paragraph (p)(8) of this section and to address as appropriate site analysis, engineering controls, maximum exposure limits, hazardous waste handling procedures and uses of new technologies.

(2) Hazard communication program. The employer shall implement a hazard communication program meeting the requirements of 29 CFR 1926.59 as part of the employer's safety and program.

Note to - The exemption for hazardous waste provided in 1926.59 is applicable to this section.

(3) Medical surveillance program. The employer shall develop and implement a medical surveillance program meeting the requirements of paragraph (f) of this section.

(4) Decontamination program. The employer shall develop and implement a decontamination procedure meeting the requirements of paragraph (k) of this section.

(5) New technology program. The employer shall develop and implement procedures meeting the requirements of paragraph (o) of this section for introducing new and innovative equipment into the workplace.

(6) Material handling program. Where employees will be handling drums or containers, the employer shall develop and implement procedures meeting the requirements of paragraphs (j)(1)(ii) through (viii) and (xi) of this section, as well as (j)(3) and (j)(8) of this section prior to starting such work.

(7) Training program

(i) New employees. The employer shall develop and implement a training program which is part of the employer's safety and * health program, for employees exposed to health hazards or hazardous * substances at TSD operations to enable the employees to perform their assigned duties and functions in a safe and healthful manner so as not to endanger themselves or other employees. The initial training shall be for 24 hours and refresher training shall be for eight hours annually. Employees who have received the initial training required by this paragraph shall be given a written certificate attesting that they have successfully completed the necessary training.

(ii) Current employees. Employers who can show by an employee's previous work experience and/or training that the employee has had training equivalent to the initial training required by this paragraph, shall be considered as meeting the initial training requirements of this paragraph as to that employee. Equivalent training includes the training that existing employees might have already received from actual site work experience. Current employees shall receive eight hours of refresher training annually.

(iii) Trainers. Trainers who teach initial training shall have satisfactorily completed a training course for teaching the subjects they are expected to teach or they shall have the academic credentials and instruction experience necessary to demonstrate a good command of the subject matter of the courses and competent instructional skills.

(8) Emergency response program

(i) Emergency response plan. An emergency response plan shall be developed and implemented by all employers. Such plans need not duplicate any of the subjects fully addressed in the employer's contingency planning required by permits, such as those issued by the U.S. Environmental Protection Agency, provided that the contingency plan is made part of the emergency response plan. The emergency response plan shall be a written portion of the employers safety and health program required in paragraph (p)(1) of this section. Employers who will evacuate their employees from the worksite location when an emergency occurs, and who do not permit any of their employees to assist in handling the emergency, are exempt from the requirements of paragraph (p)(8) if they provide an emergency action plan complying with section 1926.35 of this part.

(ii) Elements of an emergency response plan. The employer shall develop an emergency response plan for emergencies which shall address, as a minimum, the following areas to the extent that they are not addressed in any specific program required in this paragraph:

- (A) Pre-emergency planning and coordination with outside parties..
- (B) Personnel roles, lines of authority, training, and communication.
- (C) Emergency recognition and prevention.
- (D) Safe distances and places of refuge.
- (E) Site security and control.
- (F) Evacuation routes and procedures.
- (G) Decontamination procedures.
- (H) Emergency medical treatment and first aid.
- (I) Emergency alerting and response procedures.
- (J) Critique of response and follow-up.
- (K) PPE and emergency equipment.

(iii) Training.

(A) Training for emergency response employees shall be completed before they are called upon to perform in real emergencies. Such training shall include the elements of the emergency response plan, standard operating procedures the employer has established for the job, the personal protective equipment to be worn and procedures for handling emergency incidents.

Exception #1: an employer need not train all employees to the degree specified if the employer divides the work force in a manner such that a sufficient number of employees who have responsibility to control emergencies have the training specified, and all other employees, who may first respond to an emergency incident, have sufficient awareness

training to recognize that an emergency response situation exists and that they are instructed in that case to summon the fully trained employees and not attempt control activities for which they are not trained.

Exception #2: An employer need not train all employees to the degree specified if arrangements have been made in advance for an outside fully-trained emergency response team to respond in a reasonable period and all employees, who may come to the incident first, have sufficient awareness training to recognize that an emergency response situation exists and they have been instructed to call the designated outside fully-trained emergency response team for assistance.

(B) Employee members of TSD facility emergency response organizations shall be trained to a level of competence in the recognition of health and safety hazards to protect themselves and other employees. This would include training in the methods used to minimize the risk from safety and health hazards; in the safe use of control equipment; in the selection and use of appropriate personal protective equipment; in the safe operating procedures to be used at the incident scene; in the techniques of coordination with other employees to minimize risks; in the appropriate response to over exposure from health hazards or injury to themselves and other employees; and in the recognition of subsequent symptoms which may result from over exposures.

(C) The employer shall certify that each covered employee has attended and successfully completed the training required in paragraph (p)(8)(iii) of this section, or shall certify the employee's competency at least yearly. The method used to demonstrate competency for certification of training shall be recorded and maintained by the employer.

(iv) Procedures for handling emergency incidents.

(A) In addition to the elements for the emergency response plan required in paragraph (p)(8)(ii) of this section, the following elements shall be included for emergency response plans to the extent that they do not repeat any information already contained in the emergency response plan:

(1) Site topography, layout, and prevailing weather conditions.

(2) Procedures for reporting incidents to local, state, and federal governmental agencies.

(B) The emergency response plan shall be compatible and integrated with the disaster, fire and/or emergency response plans of local, state, and federal agencies.

(C) The emergency response plan shall be rehearsed regularly as part of the overall training program for site operations.

(D) The site emergency response plan shall be reviewed periodically and, as necessary, be amended to keep it current with new or changing site conditions or information.

(E) An employee alarm system shall be installed in accordance with 29 CFR 1926.159 to notify employees of an emergency situation, to stop work activities if necessary, to lower background noise in order to speed communication; and to begin emergency

procedures.

(F) Based upon the information available at time of the emergency, the employer shall evaluate the incident and the site response capabilities and proceed with the appropriate steps to implement the site emergency response plan.

(q) Emergency response to hazardous substance releases. This paragraph covers employers whose employees are engaged in emergency response no matter where it occurs except that it does not cover employees engaged in operations specified in paragraphs (a)(1)(i) through (a)(1)(iv) of this section. Those emergency response organizations who have developed and implemented programs equivalent to this paragraph for handling releases of hazardous substances pursuant to section 303 of the Superfund Amendments and Reauthorization Act of 1986 (Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. 11003) shall be deemed to have met the requirements of this paragraph.

(1) Emergency response plan. An emergency response plan shall be developed and implemented to handle anticipated emergencies prior to the commencement of emergency response operations. The plan shall be in writing and available for inspection and copying by employees, their representatives and OSHA personnel. Employers who will evacuate their employees from the danger area when an emergency occurs, and who do not permit any of their employees to assist in handling the emergency, are exempt from the requirements of this paragraph if they provide an emergency action plan in accordance with section 1926.35 of this part.

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(2) Elements of an emergency response plan. The employer shall develop an emergency response plan for emergencies which shall address, as a minimum, the following areas to the extent that they are not addressed in any specific program required in this paragraph:

- (i) Pre-emergency planning and coordination with outside parties.
- (ii) Personnel roles, lines of authority, training, and communication.
- (iii) Emergency recognition and prevention.
- (iv) Safe distances and places of refuge.
- (v) Site security and control.
- (vi) Evacuation routes and procedures.
- (vii) Decontamination.
- (viii) Emergency medical treatment and first aid.
- (ix) Emergency alerting and response procedures.
- (x) Critique of response and follow-up.
- (xi) PPE and emergency equipment.

(xii) Emergency response organizations may use the local emergency response plan or the state emergency response plan or both, as part of their emergency response plan to avoid duplication. Those items of the emergency response plan that are being properly addressed by the SARA Title III plans may be substituted into their emergency plan or otherwise kept together for the employer and employee's use.

(3) Procedures for handling emergency response.

(i) The senior emergency response official responding to an emergency shall become the individual in charge of a site-specific Incident Command System (ICS). All emergency responders and their communications shall be coordinated and controlled through the individual in charge of the ICS assisted by the senior official present for each employer.

Note to (q)(3)(i). - The "senior official" at an emergency response is the most senior official on the site who has the responsibility for controlling the operations at the site. Initially it is the senior officer on the first-due piece of responding emergency apparatus to arrive on the incident scene. As more senior officers arrive (i.e., battalion chief, fire chief, state law enforcement official, site coordinator, etc.) the position is passed up the line of authority which has been previously established.

(ii) The individual in charge of the ICS shall identify, to the extent possible, all hazardous substances or conditions present and shall address as appropriate site analysis, use of engineering controls, maximum exposure limits, hazardous substance handling procedures, and use of any new technologies.

(iii) Based on the hazardous substances and/or conditions present, the individual in charge of the ICS shall implement appropriate emergency operations, and assure that the personal protective equipment worn is appropriate for the hazards to be encountered. However, personal protective equipment shall meet, at a minimum, the criteria contained in 29 CFR 1926.97 when worn while performing fire fighting operations beyond the incipient stage for any incident.

(iv) Employees engaged in emergency response and exposed to hazardous substances presenting an inhalation hazard or potential inhalation hazard shall wear positive pressure self-contained breathing apparatus while engaged in emergency response, until such time that the individual in charge of the ICS determines through the use of air monitoring that a decreased level of respiratory protection will not result in hazardous exposures to employees.

(v) The individual in charge of the ICS shall limit the number of emergency response personnel at the emergency site, in those areas of potential or actual exposure to incident or site hazards, to those who are actively performing emergency operations. However, operations in hazardous areas shall be performed using the buddy system in groups of two or more.

(vi) Back-up personnel shall stand by with equipment ready to provide assistance or rescue. Advance first aid support personnel, as a minimum, shall also stand by with medical equipment and transportation capability.

(vii) The individual in charge of the ICS shall designate a safety official, who is knowledgeable in the operations being implemented at the emergency response site, with

specific responsibility to identify and evaluate hazards and to provide direction with respect to the safety of operations for the emergency at hand.

(viii) When activities are judged by the safety official to be an IDLH and/or to involve an imminent danger condition, the safety official shall have the authority to alter, suspend, or terminate those activities. The safety official shall immediately inform the individual in charge of the * ICS of any actions needed to be taken to correct these hazards at the emergency scene.

(ix) After emergency operations have terminated, the individual in charge of the ICS shall implement appropriate decontamination procedures.

(x) When deemed necessary for meeting the tasks at hand, approved self-contained compressed air breathing apparatus may be used with approved cylinders from other approved self-contained compressed air breathing apparatus provided that such cylinders are of the same capacity and pressure rating. All compressed air cylinders used with self-contained breathing apparatus shall meet U.S. Department of Transportation and National Institute for Occupational Safety and Health criteria.

(4) Skilled support personnel. Personnel, not necessarily an employer's own employees, who are skilled in the operation of certain equipment, such as mechanized earth moving or digging equipment or crane and hoisting equipment, and who are needed temporarily to perform immediate emergency support work that cannot reasonably be performed in a timely fashion by an employer's own employees, and who will be or may be exposed to the hazards at an emergency response scene, are not required to meet the training required in this paragraph for the employer's regular employees. However, these personnel shall be given an initial briefing at the site prior to their participation in any emergency response. The initial briefing shall include instruction in the wearing of appropriate personal protective equipment, what chemical hazards are involved, and what duties are to be performed. All other appropriate safety and health precautions provided to the employer's own employees shall be used to assure the safety and health of these personnel.

(5) Specialist employees. Employees who, in the course of their regular job duties, work with and are trained in the hazards of specific hazardous substances, and who will be called upon to provide technical advice or assistance at a hazardous substance release incident to the individual in charge, shall receive training or demonstrate competency in the area of their specialization annually.

(6) Training. Training shall be based on the duties and function to be performed by each responder of an emergency response organization. The skill and knowledge levels required for all new responders, those hired after the effective date of this standard, shall be conveyed to them through training before they are permitted to take part in actual emergency operations on an incident. Employees who participate, or are expected to participate, in emergency response, shall be given training in accordance with the following paragraphs:

(i) First responder awareness level. First responders at the awareness level are individuals who are likely to witness or discover a hazardous substance release and who have been trained to initiate an emergency response sequence by notifying the authorities of the release. First responders at the awareness level shall have sufficient training or have had sufficient experience to objectively demonstrate competency in the following areas:

(A) An understanding of what hazardous substances are, and the risks associated with them in an incident.

(B) An understanding of the potential outcomes associated with an emergency created when hazardous substances are present.

(C) The ability to recognize the presence of hazardous substances in an emergency.

(D) The ability to identify the hazardous substances, if possible.

(E) An understanding of the role of the first responder awareness individual in the employer's emergency response plan including site security and control and the U.S. Department of Transportation's Emergency Response Guidebook.

(F) The ability to realize the need for additional resources, and to make appropriate notifications to the communication center.

(ii) First responder operations level. First responders at the operations level are individuals who respond to releases or potential releases of hazardous substances as part of the initial response to the site for the purpose of protecting nearby persons, property, or the environment from the effects of the release. They are trained to respond in a defensive fashion without actually trying to stop the release. Their function is to contain the release from a safe distance, keep it from spreading, and prevent exposures. First responders at the operational level shall have received at least eight hours of training or have had sufficient experience to objectively demonstrate competency in the following areas in addition to those listed for the awareness level and the employer shall so certify:

(A) Knowledge of the basic hazard and risk assessment techniques.

(B) Know how to select and use proper personal protective equipment provided to the first responder operational level.

(C) An understanding of basic hazardous materials terms.

(D) Know how to perform basic control, containment and/or confinement operations within the capabilities of the resources and personal protective equipment available with their unit.

(E) Know how to implement basic decontamination procedures.

(F) An understanding of the relevant standard operating procedures and termination procedures.

(iii) Hazardous materials technician. Hazardous materials technicians are individuals who respond to releases or potential releases for the purpose of stopping the release. They assume a more aggressive role than a first responder at the operations level in that they will approach the point of release in order to plug, patch or otherwise stop the release of a hazardous substance. Hazardous materials technicians shall have received at least 24 hours of training equal

to the first responder operations level and in addition have competency in the following areas and the employer shall so certify:

- (A) Know how to implement the employer's emergency response plan.
- (B) Know the classification, identification and verification of known and unknown materials by using field survey instruments and equipment.
- (C) Be able to function within an assigned role in the Incident Command System.
- (D) Know how to select and use proper specialized chemical personal protective equipment provided to the hazardous materials technician.
- (E) Understand hazard and risk assessment techniques.
- (F) Be able to perform advance control, containment, and/or confinement operations within the capabilities of the resources and personal protective equipment available with the unit.
- (G) Understand and implement decontamination procedures.
- (H) Understand termination procedures.
- (I) Understand basic chemical and toxicological terminology and behavior.

(iv) Hazardous materials specialist. Hazardous materials specialists are individuals who respond with and provide support to hazardous materials technicians. Their duties parallel those of the hazardous materials technician, however, those duties require a more directed or specific knowledge of the various substances they may be called upon to contain. The hazardous materials specialist would also act as the site liaison with Federal, state, local and other government authorities in regards to site activities. Hazardous materials specialists shall have competency in the following areas and the employer shall so certify:

- (A) Know how to implement the local emergency response plan.
- (B) Understand classification, identification and verification of known and unknown materials by using advanced survey instruments and equipment.
- (C) Of the state emergency response plan.
- (D) Be able to select and use proper specialized chemical personal protective equipment provided to the hazardous materials specialist.
- (E) Understand in-depth hazard and risk techniques.
- (F) Be able to perform specialized control, containment, and/or confinement operations within the capabilities of the resources and personal protective equipment available.

(G) Be able to determine and implement decontamination procedures.

(H) Have the ability to develop a site safety and control plan.

(I) Understand chemical, radiological and toxicological terminology and behavior.

(v) On scene incident commander. Incident commanders, who will assume control of the incident scene beyond the first responder awareness level, shall receive at least 24 hours of training equal to the first responder operations level and in addition have competency in the following areas and the employer shall so certify:

(A) Know and be able to implement the employer's incident command system.

(B) Know how to implement the employer's emergency response plan.

(C) Know and understand the hazards and risks associated with employees working in chemical protective clothing.

(D) Know how to implement the local emergency response plan.

(E) Know of the state emergency response plan and of the Federal Regional Response Team.

(F) Know and understand the importance of decontamination procedures.

(7) Trainers. Trainers who teach any of the above training subjects shall have satisfactorily completed a training course for teaching the subjects they are expected to teach, such as the courses offered by the * U.S. National Fire Academy, or they shall have the training and/or academic credentials and instructional experience necessary to demonstrate competent instructional skills and a good command of the subject matter of the courses they are to teach.

(8) Refresher training.

(i) Those employees who are trained in accordance with paragraph (q)(6) of this section shall receive annual refresher training of sufficient content and duration to maintain their competencies, or shall demonstrate competency in those areas at least yearly.

(ii) A statement shall be made of the training or competency, and if a statement of competency is made, the employer shall keep a record of the methodology used to demonstrate competency.

(9) Medical surveillance and consultation.

(i) Members of an organized and designated HAZMAT team and hazardous materials specialists shall receive a baseline physical examination and be provided with medical surveillance as required in paragraph (f) of this section.

(ii) Any emergency response employees who exhibits signs or symptoms which

may have resulted from exposure to hazardous substances during the course of an emergency incident, either immediately or subsequently, shall be provided with medical consultation as required in paragraph (f)(3)(ii) of this section.

(10) Chemical protective clothing. Chemical protective clothing and equipment to be used by organized and designated HAZMAT team members, or to be used by hazardous materials specialists, shall meet the requirements of paragraphs (g)(3) through (5) of this section.

(11) Post-emergency response operations. Upon completion of the emergency response, if it is determined that it is necessary to remove hazardous substances, health hazards, and materials contaminated with them (such as contaminated soil or other elements of the natural environment) from the site of the incident, the employer conducting the clean-up shall comply with one of the following:

(i) Meet all the requirements of paragraphs (b) through (o) of this section; or

(ii) Where the clean-up is done on plant property using plant or workplace employees, such employees shall have completed the training requirements of the following: 29 CFR 1926.35; 1926.59; 1926.103, and other appropriate safety and health training made necessary by the tasks that they are expected to be performed such as personal protective equipment and decontamination procedures. All equipment to be used in the performance of the clean-up work shall be in serviceable condition and shall have been inspected prior to use.

APPENDICES TO - HAZARDOUS WASTE OPERATIONS AND EMERGENCY RESPONSE

NOTE: The following appendices serve as non-mandatory guidelines to assist employees and employers in complying with the appropriate requirements of this section. However (g) makes mandatory in certain circumstances the use of Level A and Level B PPE protection.

App A Personal protective equipment test methods

Appendix A to - Personal protective equipment test methods

This appendix sets forth the non-mandatory examples of tests which may be used to evaluate compliance with (g)(4) (ii) and (iii). Other tests and other challenge agents may be used to evaluate compliance.

A. Totally-Encapsulating chemical protective suit pressure test

1.0 - Scope

1.1 This practice measures the ability of a gas tight totally-encapsulating chemical protective suit material, seams, and closures to maintain a fixed positive pressure. The results of this practice allow the gas tight integrity of a totally-encapsulating chemical protective suit to be evaluated.

1.2 Resistance of the suit materials to permeation, penetration, and degradation by specific hazardous substances is not determined by this test method.

2.0 - Definition of Terms

2.1 "Totally-encapsulated chemical protective suit (TECP suit)" means a full body garment which is constructed of protective clothing materials; covers the wearer's torso, head, arms, legs and respirator; may cover the wearer's hands and feet with tightly attached gloves and boots; completely encloses the wearer and respirator by itself or in combination with the wearer's gloves and boots.

2.2 "Protective clothing material" means any material or combination of materials used in an item of clothing for the purpose of isolating parts of the body from direct contact with a potentially hazardous liquid or gaseous chemicals.

2.3 "Gas tight" means, for the purpose of this test method, the limited flow of a gas under pressure from the inside of a TECP suit to atmosphere at a prescribed pressure and time interval.

3.0 - Summary of test method

3.1 The TECP suit is visually inspected and modified for the test. The test apparatus is attached to the suit to permit inflation to the pre-test suit expansion pressure for removal of suit wrinkles and creases. The pressure is lowered to the test pressure and monitored for three minutes. If the pressure drop is excessive, the TECP suit fails the test and is removed from service. The test is repeated after leak location and repair.

4.0 - Required Supplies

4.1 Source of compressed air.

4.2 Test apparatus for suit testing including a pressure measurement device with a sensitivity of at least 1/4 inch water gauge.

4.3 Vent valve closure plugs or sealing tape.

4.4 Soapy water solution and soft brush.

4.5 Stop watch or appropriate timing device.

5.0 - Safety Precautions

5.1 Care shall be taken to provide the correct pressure safety devices required for the source of compressed air used.

6.0 - Test Procedure

6.1 Prior to each test, the tester shall perform a visual inspection of the suit. Check the suit for seam integrity by visually examining the seams and gently pulling on the seams. Ensure that all air supply lines, fittings, visor, zippers, and valves are secure and show no signs of deterioration.

6.1.1 Seal off the vent valves along with any other normal inlet or exhaust points (such as

umbilical air line fittings or face piece opening) with tape or other appropriate means (caps, plugs, fixture, etc.). Care should be exercised in the sealing process not to damage any of the suit components.

6.1.2 Close all closure assemblies.

6.1.3 Prepare the suit for inflation by providing an improvised connection point on the suit for connecting an airline. Attach the pressure test apparatus to the suit to permit suit inflation from a compressed air source equipped with a pressure indicating regulator. The leak tightness of the pressure test apparatus should be tested before and after each test by closing off the end of the tubing attached to the suit and assuring a pressure of three inches water gauge for three minutes can be maintained. If a component is removed for the test, that component shall be replaced and a second test conducted with another component removed to permit a complete test of the ensemble.

6.1.4 The pre-test expansion pressure (A) and the suit test pressure (B) shall be supplied by the suit manufacturer, but in no case shall they be less than: (A) = three inches water gauge and (B) = two inches water gauge. The ending suit pressure (C) shall be no less than 80 percent of the test pressure (B); i.e., the pressure drop shall not exceed 20 percent of the test pressure (B).

6.1.5 Inflate the suit until the pressure inside is equal to pressure (A), the pre-test expansion suit pressure. Allow at least one minute to fill out the wrinkles in the suit. Release sufficient air to reduce the suit pressure to pressure (B), the suit test pressure. Begin timing. At the end of three minutes, record the suit pressure as pressure (C), the ending suit pressure. The difference between the suit test pressure and the ending suit test pressure (B - C) shall be defined as the suit pressure drop.

6.1.6 If the suit pressure drop is more than 20 percent of the suit test pressure (B) during the three minute test period, the suit fails the test and shall be removed from service.

7.0 - Retest Procedure

7.1 If the suit fails the test check for leaks by inflating the suit to pressure (A) and brushing or wiping the entire suit (including seams, closures, lens gaskets, glove-to-sleeve joints, etc.) with a mild soap and water solution. Observe the suit for the formation of soap bubbles, which is an indication of a leak. Repair all identified leaks.

7.2 Retest the TECP suit as outlined in Test procedure 6.0.

8.0 - Report

8.1 Each TECP suit tested by this practice shall have the following information recorded.

8.1.1 Unique identification number, identifying brand name, date of purchase, material of construction, and unique fit features; e.g., special breathing apparatus.

8.1.2 The actual values for test pressures, (A), (B), and (C) shall be recorded along with the specific observation times. If the ending pressure (C) is less than 80 percent of the test pressure (B), the suit shall be identified as failing the test. When possible, the specific leak location shall be identified in the test records. Retest pressure data shall be recorded as an additional test.

8.1.3 The source of the test apparatus used shall be identified and the sensitivity of the pressure gauge shall be recorded.

8.1.4 Records shall be kept for each pressure test even if repairs are being made at the test location.

Caution

Visually inspect all parts of the suit to be sure they are positioned correctly and secured tightly before putting the suit back into service. Special care should be taken to examine each exhaust valve to make sure it is not blocked.

Care should also be exercised to assure that the inside and outside of the suit is completely dry before it is put into storage.

B. Totally-encapsulating chemical protective suit qualitative leak test

1.0 - Scope

1.1 This practice semi-qualitatively tests gas tight totally-encapsulating chemical protective suit integrity by detecting inward leakage of ammonia vapor. Since no modifications are made to the suit to carry out this test, the results from this practice provide a realistic test for the integrity of the entire suit.

1.2 Resistance of the suit materials to permeation, penetration, and degradation is not determined by this test method. ASTM test methods are available to test suit materials for these characteristics and the tests are usually conducted by the manufacturers of the suits.

2.0 - Definition of Terms

2.1 "Totally-encapsulated chemical protective suit (TECP suit)" means a full body garment which is constructed of protective clothing materials; covers the wearer's torso, head, arms, legs and respirator; may cover the wearer's hands and feet with tightly attached gloves and boots; completely encloses the wearer and respirator by itself or in combination with the wearer's gloves, and boots.

2.2 "Protective clothing material" means any material or combination of materials used in an item of clothing for the purpose of isolating parts of the body from direct contact with a potentially hazardous liquid or gaseous chemicals.

2.3 "Gas tight" means, for the purpose of this test method the limited flow of a gas under pressure from the inside of a TECP suit to atmosphere at a prescribed pressure and time interval.

2.4 "Intrusion Coefficient" means a number expressing the level of protection provided by a gas tight totally-encapsulating chemical protective suit. The intrusion coefficient is calculated by dividing the test room challenge agent concentration by the concentration of challenge agent found inside the suit. The accuracy of the intrusion coefficient is dependent on the challenge agent monitoring methods. The larger the intrusion coefficient the greater the protection

provided by the TECP suit.

3.0 - Summary of recommended practice

3.1 The volume of concentrated aqueous ammonia solution (ammonia hydroxide, NH_4OH) required to generate the test atmosphere is determined using the directions outlined in 6.1. The suit is donned by a person wearing the appropriate respiratory equipment (either a self-contained breathing apparatus or a supplied air respirator) and worn inside the enclosed test room. The concentrated aqueous ammonia solution is taken by the suited individual into the test room and poured into an open plastic pan. A two-minute evaporation period is observed before the test room concentration is measured using a high range ammonia length of stain detector tube. When the ammonia vapor reaches a concentration of between 1000 and 1200 ppm, the suited individual starts a standardized exercise protocol to stress and flex the suit. After this protocol is completed the test room concentration is measured again. The suited individual exits the test room and his stand-by person measures the ammonia concentration inside the suit using a low range ammonia length of stain detector tube or other more sensitive ammonia detector. A stand-by person is required to observe the test individual during the test procedure, aid the person in donning and doffing the TECP suit; and monitor the suit interior. The intrusion coefficient of the suit can be calculated by dividing the average test area concentration by the interior suit concentration. A colorimetric indicator strip of bromophenol blue is placed on the inside of the suit face piece lens so that the suited individual is able to detect a color change and know if the suit has a significant leak. If a color change is observed the individual shall leave the test room immediately.

4.0 - Required supplies * 4.1 A supply of concentrated aqueous ammonium hydroxide (58% by weight).

4.2 A supply of bromophenol/blue indicating paper, sensitive to 5-10 ppm ammonia or greater over a two-minute period of exposure. [pH 3.0(yellow) to pH 4.6(blue)]

4.3 A supply of high range (0.5 - 10 volume percent) and low range (5 - 700 ppm) detector tubes for ammonia and the corresponding sampling pump. More sensitive ammonia detectors can be substituted for the low range detector tubes to improve the sensitivity of this practice.

4.4 A plastic pan (PVC) at least 12":14":1" and a half pint plastic container (PVC) with tightly closing lid.

4.5 A graduated cylinder or other volumetric measuring device of at least 50 milliliters in volume with an accuracy of at least + or - 1 milliliters.

5.0 - Safety precautions

5.1 Concentrated aqueous ammonium hydroxide, NH_4OH , is a corrosive volatile liquid requiring eye, skin, and respiratory protection. The person conducting test shall review the MSDS for aqueous ammonia. * 5.2 Since the established permissible exposure limit for ammonia is 35 ppm as a 15 minute STEL, only persons wearing a positive pressure self-contained breathing apparatus or a supplied air respirator shall be in the chamber. Normally only the person wearing the total-encapsulating suit will be inside the chamber. A stand-by person shall have a positive pressure self-contained breathing apparatus, or a supplied air respirator, available to enter the test area should the suited individual need assistance.

5.3 A method to monitor the suited individual must be used during this test. Visual contact is the simplest but other methods using communication devices are acceptable.

5.4 The test room shall be large enough to allow the exercise protocol to be carried out and then to be ventilated to allow for easy exhaust of the ammonia test atmosphere after the test(s) are completed.

5.5 Individuals shall be medically screened for the use of respiratory protection and checked for allergies to ammonia before participating in this test procedure.

6.0 - Test procedure

6.1.1 Measure the test area to the nearest foot and calculate its volume in cubic feet. Multiply the test area volume by 0.2 milliliters of concentrated aqueous ammonia solution per cubic foot of test area volume to determine the approximate volume of concentrated aqueous ammonia required to generate 1000 ppm in the test area.

6.1.2 Measure this volume from the supply of concentrated ammonia and place it into a closed plastic container.

6.1.3 Place the container, several high range ammonia detector tubes, and the pump in the clean test pan and locate it near the test area entry door so that the suited individual has easy access to these supplies.

6.2.1 In a non-contaminated atmosphere, open a pre-sealed ammonia indicator strip and fasten one end of the strip to the inside of suit face shield lens where it can be seen by the wearer. Moisten the indicator strip with distilled water. Care shall be taken not to contaminate the detector part of the indicator paper by touching it. A small piece of masking tape or equivalent should be used to attach the indicator strip to the interior of the suit face shield.

6.2.2 If problems are encountered with this method of attachment, the indicator strip can be attached to the outside of the respirator face piece being used during the test.

6.3 Don the respiratory protective device normally used with the suit, and then don the TECP suit to be tested. Check to be sure all openings which are intended to be sealed (zippers, gloves, etc.) are completely sealed. DO NOT, however, plug off any venting valves.

6.4 Step into the enclosed test room such as a closet, bathroom, or test booth, equipped with an exhaust fan. No air should be exhausted from the chamber during the test because this will dilute the ammonia challenge concentrations.

6.5 Open the container with the pre-measured volume of concentrated aqueous ammonia within the enclosed test room, and pour the liquid into the empty plastic test pan. Wait two minutes to allow for adequate volatilization of the concentrated aqueous ammonia. A small mixing fan can be used near the evaporation pan to increase the evaporation rate of ammonia solution.

6.6 After two minutes a determination of the ammonia concentration within the chamber should be made using the high range colorimetric detector tube. A concentration of 1000 ppm ammonia or greater shall be generated before the exercises are started.

6.7 To test the integrity of the suit the following four minute exercise protocol should be followed:

6.7.1 Raising the arms above the head with at least 15 raising motions completed in one minute.

6.7.2 Walking in place for one minute with at least 15 raising motions of each leg in a one-minute period.

6.7.3 Touching the toes with a least 10 complete motions of the arms from above the head to touching of the toes in a one-minute period.

6.7.4 Knee bends with at least 10 complete standing and squatting motions in a one-minute period.

6.8 If at any time during the test the colorimetric indicating paper should change colors, the test should be stopped and section 6.10 and 6.12 initiated (See 4.2).

6.9 After completion of the test exercise, the test area concentration should be measured again using the high range colorimetric detector tube.

6.10 Exit the test area.

6.11 The opening created by the suit zipper or other appropriate suit penetration should be used to determine the ammonia concentration in the suit with the low range length of stain detector tube or other ammonia monitor. The internal TECP suit air should be sampled far enough from the enclosed test area to prevent a false ammonia reading.

6.12 After completion of the measurement of the suit interior ammonia concentration the test is concluded and the suit is doffed and the respirator removed.

6.13 The ventilating fan for the test room should be turned on and allowed to run for enough time to remove the ammonia gas. The fan shall be vented to the outside of the building.

6.14 Any detectable ammonia in the suit interior (five ppm (NH₃)) or more for the length of stain detector tube) indicates the suit has failed the test. When other ammonia detectors are used a lower level of detection is possible, and it should be specified as the pass/fail criteria.

6.15 By following this test method, an intrusion coefficient of approximately 200 or more can be measured with the suit in a completely operational condition. If the coefficient is 200 or more, then the suit is suitable for emergency response and field use.

7.0 - Retest procedures

7.1 If the suit fails this test, check for leaks by following the pressure test in test A above.

7.2 Retest the TECP suit as outlined in the test procedure 6.0.

8.0 - Report

8.1 Each gas tight totally-encapsulating chemical protective suit tested by this practice shall have the following information recorded.

8.1.1 Unique identification number identifying brand name, date of purchase, material of construction, and unique suit features; e.g., special breathing apparatus.

8.1.2 General description of test room used for test.

8.1.3 Brand name and purchase date of ammonia detector strips and color change data.

8.1.4 Brand name, sampling range, and expiration date of the length of stain ammonia detector tubes. The brand name and model of the sampling pump should also be recorded. If another type of ammonia detector is used, it should be identified along with its minimum detection limit for ammonia.

8.1.5 Actual test results shall list the two test area concentrations, their average, the interior suit concentration, and the calculated intrusion coefficient. Retest data shall be recorded as an additional test.

8.2 The evaluation of the data shall be specified as "suit passed" or "suit failed," and the date of the test. Any detectable ammonia (five ppm or greater for the length of stain detector tube) in the suit interior indicates the suit has failed this test. When other ammonia detectors are used, a lower level of detection is possible and it should be specified as the pass fail criteria.

Caution

Visually inspect all parts of the suit to be sure they are positioned correctly and secured tightly before putting the suit back into service. Special care should be taken to examine each exhaust valve to make sure it is not blocked.

Care should also be exercised to assure that the inside and outside of the suit is completely dry before it is put into storage.

Appendix B to - General description and discussion of the levels of protection and protective gear

This appendix sets forth information about personal protective equipment (PPE) protection levels which may be used to assist employers in complying with the PPE requirements of this section.

As required by the standard, PPE must be selected which will protect employees from the specific hazards which they are likely to encounter during their work on-site.

Selection of the appropriate PPE is a complex process which should take into consideration a variety of factors. Key factors involved in this process are identification of the hazards, or suspected hazards; their routes of potential hazard to employees (inhalation, skin absorption, ingestion, and eye or skin contact); and the performance of the PPE materials (and seams) in providing a barrier to these hazards. The amount of protection provided by PPE is material-hazard specific. That is, protective equipment materials will protect well against some hazardous substances and poorly, or not at all, against others. In many instances, protective equipment

materials cannot be found which will provide continuous protection from the particular hazardous substance. In these cases the breakthrough time of the protective material should exceed the work durations.

Other factors in this selection process to be considered are matching the PPE to the employee's work requirements and task-specific conditions. The durability of PPE materials, such as tear strength and seam strength, should be considered in relation to the employee's tasks. The effects of PPE in relation to heat stress and task duration are a factor in selecting and using PPE. In some cases layers of PPE may be necessary to provide sufficient protection, or to protect expensive PPE inner garments, suits or equipment.

The more that is known about the hazards at the site, the easier the job of PPE selection becomes. As more information about the hazards and conditions at the site becomes available, the site supervisor can make decisions to up-grade or down-grade the level of PPE protection to match the tasks at hand.

The following are guidelines which an employer can use to begin the selection of the appropriate PPE. As noted above, the site information may suggest the use of combinations of PPE selected from the different protection levels (i.e., A, B, C, or D) as being more suitable to the hazards of the work. It should be cautioned that the listing below does not fully address the performance of the specific PPE material in relation to the specific hazards at the job site, and that PPE selection, evaluation and re-selection is an ongoing process until sufficient information about the hazards and PPE performance is obtained.

Part A. Personal protective equipment is divided into four categories based on the degree of protection afforded. (See Part B of this appendix for further explanation of Levels A, B, C, and D hazards.)

I. Level A - To be selected when the greatest level of skin, respiratory, and eye protection is required.

The following constitute Level A equipment; it may be used as appropriate;

1. Positive pressure, full face-piece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA, approved by the National Institute for Occupational Safety and Health (NIOSH).

2. Totally-encapsulating chemical-protective suit.

3. Coveralls.(1)

4. Long underwear.(1)

5. Gloves, outer, chemical-resistant.

6. Gloves, inner, chemical-resistant.

7. Boots, chemical-resistant, steel toe and shank.

8. Hard hat (under suit).(1)

9. Disposable protective suit, gloves and boots (depending on suit construction, may be worn over totally-encapsulating suit). FOOTNOTE(1) Optional, as applicable.

II. Level B - The highest level of respiratory protection is necessary but a lesser level of skin protection is needed.

The following constitute Level B equipment; it may be used as appropriate.

1. Positive pressure, full-facepiece self-contained breathing apparatus (SCBA), or positive pressure supplied air respirator with escape SCBA (NIOSH approved).

2. Hooded chemical-resistant clothing (overalls and long-sleeved jacket; coveralls; one or two-piece chemical-splash suit; disposable chemical-resistant overalls).

3. Coveralls.(1)

4. Gloves, outer, chemical-resistant.

5. Gloves, inner, chemical-resistant.

6. Boots, outer, chemical-resistant steel toe and shank.

7. Boot-covers, outer, chemical-resistant (disposable).(1)

8. Hard hat.(1)

9. [Reserved]

10. Face shield.

III. Level C - The concentration(s) and type(s) of airborne substance(s) is known and the criteria for using air purifying respirators are met.

The following constitute Level C equipment; it may be used as appropriate.

1. Full-face or half-mask, air purifying respirators (NIOSH approved).

2. Hooded chemical-resistant clothing (overalls; two-piece chemical-splash suit; disposable chemical-resistant overalls).

3. Coveralls.(1)

4. Gloves, outer, chemical-resistant.

5. Gloves, inner, chemical-resistant.

6. Boots (outer), chemical-resistant steel toe and shank.(1)

7. Boot-covers, outer, chemical-resistant (disposable).(1)

8. Hard hat. (1)
9. Escape mask.(1)
10. Face shield.(1)

IV. Level D - A work uniform affording minimal protection: used for nuisance contamination only.

The following constitute Level D equipment; it may be used as appropriate:

1. Coveralls.
2. Gloves.(1)
3. Boots/shoes, chemical-resistant steel toe and shank.
4. Boots, outer, chemical-resistant (disposable).(1)
5. Safety glasses or chemical splash goggles.(1)
6. Hard hat.(1)
7. Escape mask.(1)
8. Face shield.(1)

Part B. The types of hazards for which levels A, B, C, and D protection are appropriate are described below:

I. Level A - Level A protection should be used when:

1. The hazardous substance has been identified and requires the highest level of protection for skin, eyes, and the respiratory system based on either the measured (or potential for) high concentration of atmospheric vapors, gases, or particulates; or the site operations and work functions involve a high potential for splash, immersion, or exposure to unexpected vapors, gases, or particulates of materials that are harmful to skin or capable of being absorbed through the skin,
2. Substances with a high degree of hazard to the skin are known or suspected to be present, and skin contact is possible; or
3. Operations are being conducted in confined, poorly ventilated areas, and the absence of conditions requiring Level A have not yet been determined.

II. Level B protection should be used when:

1. The type and atmospheric concentration of substances have been identified and require a high level of respiratory protection, but less skin protection.

2. The atmosphere contains less than 19.5 percent oxygen; or

3. The presence of incompletely identified vapors or gases is indicated by a direct-reading organic vapor detection instrument, but vapors and gases are not suspected of containing high levels of chemicals harmful to skin or capable of being absorbed through the skin.

Note: This involves atmospheres with IDLH concentrations of specific substances that present severe inhalation hazards and that do not represent a severe skin hazard; or that do not meet the criteria for use of air-purifying respirators.

III. Level C - Level C protection should be used when:

1. The atmospheric contaminants, liquid splashes, or other direct contact will not adversely affect or be absorbed through any exposed skin;

2. The types of air contaminants have been identified, concentrations measured, and an air-purifying respirator is available that can remove the contaminants; and

3. All criteria for the use of air-purifying respirators are met.

IV. Level D - Level D protection should be used when:

1. The atmosphere contains no known hazard; and

2. Work functions preclude splashes, immersion, or the potential for unexpected inhalation of or contact with hazardous levels of any chemicals.

Note: As stated before, combinations of personal protective equipment other than those described for Levels A, B, C, and D protection may be more appropriate and may be used to provide the proper level of protection.

As an aid in selecting suitable chemical protective clothing, it should be noted that the National Fire Protection Association (NFPA) has developed standards on chemical protective clothing. The standards that have been adopted include:

NFPA 1991 - Standard on Vapor-Protective Suits for Hazardous Chemical Emergencies (EPA Level A Protective Clothing)

NFPA 1992 - Standard on Liquid Splash-Protective Suits for Hazardous Chemical Emergencies (EPA Level B Protective Clothing).

NFPA 1993 - Standard on Liquid Splash-Protective Suits for Non-emergency, Non-flammable Hazardous Chemical Situations (EPA Level B Protective Clothing).

These standards apply documentation and performance requirements to the manufacture of chemical protective suits. Chemical protective suits meeting these requirements are labelled as compliant with the appropriate standard. It is recommended that chemical protective suits that meet these standards be used.

App C Compliance guidelines

Appendix C to - Compliance guidelines

1. Occupational Safety and Health Program. Each hazardous waste site clean-up effort will require an occupational safety and health program headed by the site coordinator or the employer's representative. The purpose of the program will be the protection of employees at the site and will be an extension of the employer's overall safety and health program. The program will need to be developed before work begins on the site and implemented as work proceeds as stated in paragraph (b). The program is to facilitate coordination and communication of safety and health issues among personnel responsible for the various activities which will take place at the site. It will provide the overall means for planning and implementing the needed safety and health training and job orientation of employees who will be working at the site. The program will provide the means for identifying and controlling worksite hazards and the means for monitoring program effectiveness. The program will need to cover the responsibilities and authority of the site coordinator or the employers manager on site for the safety and health of employees at the site, and the relationships with contractors or support services as to what each employer's safety and health responsibilities are for their employees on the site. Each contractor on the site needs to have its own safety and health program so structured that it will smoothly interface with the program of the site coordinator or principal contractor.

Also those employers involved with treating, storing or disposal of hazardous waste as covered in paragraph (p) must have implemented a safety and health program for their employees. This program is to include the hazard communication program required in paragraph (p)(1) and the training required in paragraphs (p)(7) and (p)(8) as parts of the employers comprehensive overall safety and health program. This program is to be in writing.

Each site or workplace safety and health program will need to include the following: (1) Policy statements of the line of authority and accountability for implementing the program, the objectives of the program and the role of the site safety and health supervisor or manager and staff; (2) means or methods for the development of procedures for identifying and controlling workplace hazards at the site; (3) means or methods for the development and communication to employees of the various plans, work rules, standard operating procedures and practices that pertain to individual employees and supervisors; (4) means for the training of supervisors and employees to develop the needed skills and knowledge to perform their work in a safe and healthful manner; (5) means to anticipate and prepare for emergency situations and; (6) means for obtaining information feedback to aid in evaluating the program and for improving the effectiveness of the program. The management and employees should be trying continually to improve the effectiveness of the program thereby enhancing the protection being afforded those working on the site.

Accidents on the site or workplace should be investigated to provide information on how such occurrences can be avoided in the future. When injuries or illnesses occur on the site or workplace, they will need to be investigated to determine what needs to be done to prevent this incident from occurring again. Such information will need to be used as feedback on the effectiveness of the program and the information turned into positive steps to prevent any reoccurrence. Receipt of employee suggestions or complaints relating to safety and health issues involved with site or workplace activities is also a feedback mechanism that can be used effectively to improve the program and may serve in part as an evaluative tool(s).

For the development and implementation of the program to be the most effective, professional safety and health personnel should be used. Certified Safety Professionals, Board Certified Industrial Hygienists or Registered Professional Safety Engineers are good examples of professional stature for safety and health managers who will administer the employer's program.

2. Training. The training programs for employees subject to the requirements of paragraph (e) of this standard should address: the safety and health hazards employees should expect to find on hazardous waste clean-up sites; what control measures or techniques are effective for those hazards; what monitoring procedures are effective in characterizing exposure levels; what makes an effective employer's safety and health program; what a site safety and health plan should include; hands on training with personal protective equipment and clothing they may be expected to use; the contents of the OSHA standard relevant to the employee's duties and function; and employee's responsibilities under OSHA and other regulations. Supervisors will need training in their responsibilities under the safety and health program and its subject areas such as the spill containment program, the personal protective equipment program, the medical surveillance program, the emergency response plan and other areas.

The training programs for employees subject to the requirements of paragraph (p) of this standard should address: the employer's safety and health program elements impacting employees; the hazard communication program; the hazards and the controls for such hazards that employees need to know for their job duties and functions. All require annual refresher training.

The training programs for employees covered by the requirements of paragraph (q) of this standard should address those competencies required for the various levels of response such as: the hazards associated with hazardous substances; hazard identification and awareness; notification of appropriate persons; the need for and use of personal protective equipment including respirators; the decontamination procedures to be used; preplanning activities for hazardous substance incidents including the emergency response plan; company standard operating procedures for hazardous substance emergency responses; the use of the incident command system and other subjects. Hands-on training should be stressed whenever possible. Critiques done after an incident which include an evaluation of what worked and what did not and how could the incident be better handled the next time may be counted as training time.

For hazardous materials specialists (usually members of hazardous materials teams), the training should address the care, use and/or testing of chemical protective clothing including totally encapsulating suits, the medical surveillance program, the standard operating procedures for the hazardous materials team including the use of plugging and patching equipment and other subject areas.

Officers and leaders who may be expected to be in charge at an incident should be fully knowledgeable of their company's incident command system. They should know where and how to obtain additional assistance and be familiar with the local district's emergency response plan and the state emergency response plan.

Specialist employees such as technical experts, medical experts or environmental experts that work with hazardous materials in their regular jobs, who may be sent to the incident scene by the shipper, manufacturer or governmental agency to advise and assist the person in charge of the incident should have training on an annual basis. Their training should include the care and use

of personal protective equipment including respirators; knowledge of the incident command system and how they are to relate to it; and those areas needed to keep them current in their respective field as it relates to safety and health involving specific hazardous substances.

Those skilled support personnel, such as employees who work for public works departments or equipment operators who operate bulldozers, sand trucks, backhoes, etc., who may be called to the incident scene to provide emergency support assistance, should have at least a safety and health briefing before entering the area of potential or actual exposure. These skilled support personnel, who have not been a part of the emergency response plan and do not meet the training requirements, should be made aware of the hazards they face and should be provided all necessary protective clothing and equipment required for their tasks. * There are two National Fire Protection Association standards. NFPA 472 - "Standard for Professional Competence of Responders to Hazardous Material Incidents" and NFPA 471 - "Recommended Practice for Responding to Hazardous Material Incidents", which are excellent resource documents to aid fire departments and other emergency response organizations in developing their training program materials. NFPA 472 provides guidance on the skills and knowledge needed for first responder awareness level, first responder operations level, hazmat technicians, and hazmat specialist. It also offers guidance for the officer corp who will be in charge of hazardous substance incidents.

3. Decontamination. Decontamination procedures should be tailored to the specific hazards of the site and may vary in complexity and number of steps, depending on the level of hazard and the employee's exposure to the hazard. Decontamination procedures and PPE decontamination methods will vary depending upon the specific substance, since one procedure or method may not work for all substances. Evaluation of decontamination methods and procedures should be performed, as necessary, to assure that employees * are not exposed to hazards by reusing PPE. References in Appendix D may be used for guidance in establishing an effective decontamination program. In addition, the U.S.Coast Guard's Manual, "Policy Guidance for Response to Hazardous Chemical Releases," U.S. Department of Transportation, Washington, DC (COMDTINST M16465.30) is a good reference for establishing an effective decontamination program.

4. Emergency response plans. States, along with designated districts within the states, will be developing or have developed emergency response plans. These state and district plans should be utilized in the emergency response plans called for in the standard. Each employer should assure that its emergency response plan is compatible with the local plan. The major reference being used to aid in developing the state and local district plans is the Hazardous Materials Emergency Planning Guide, NRT - 1. The current Emergency Response Guidebook from the U.S. Department of Transportation, CMA's CHEMTREC and the Fire Service Emergency Management Handbook may also be used as resources.

Employers involved with treatment, storage, and disposal facilities for hazardous waste, which have the required contingency plan called for by their permit, would not need to duplicate the same planning elements. Those items of the emergency response plan may be substituted into the emergency response plan required in or otherwise kept together for employer and employee use.

5. Personal protective equipment programs. The purpose of personal protective clothing and equipment (PPE) is to shield or isolate individuals from the chemical, physical, and biologic hazards that may be encountered at a hazardous substance site.

As discussed in Appendix B, no single combination of protective equipment and clothing is

capable of protecting against all hazards. Thus PPE should be used in conjunction with other protective methods and its effectiveness evaluated periodically.

The use of PPE can itself create significant worker hazards, such as heat stress, physical and psychological stress, and impaired vision, mobility and communication. For any given situation, equipment and clothing should be selected that provide an adequate level of protection. However, over-protection, as well as under-protection, can be hazardous and should be avoided where possible. Two basic objectives of any PPE program should be to protect the wearer from safety and health hazards, and to prevent injury to the wearer from incorrect use and/or malfunction of the PPE. To accomplish these goals, a comprehensive PPE program should include hazard identification, medical monitoring, environmental surveillance, selection, use, maintenance, and decontamination of PPE and its associated training.

The written PPE program should include policy statements, procedures, and guidelines. Copies should be made available to all employees, and a reference copy should be made available at the worksite. Technical data on equipment, maintenance manuals, relevant regulations, and other essential information should also be collected and maintained.

6. Incident command system (ICS). Paragraph (q)(3)(ii) requires the implementation of an ICS. The ICS is an organized approach to effectively control and manage operations at an emergency incident. The individual in charge of the ICS is the senior official responding to the incident. The ICS is not much different than the "command post" approach used for many years by the fire service. During large complex fires involving several companies and many pieces of apparatus, a command post would be established. This enabled one individual to be in charge of managing the incident, rather than having several officers from different companies making separate, and sometimes conflicting, decisions. The individual in charge of the command post would delegate responsibility for performing various tasks to subordinate officers. Additionally, all communications were routed through the command post to reduce the number of radio transmissions and eliminate confusion. However, strategy, tactics, and all decisions were made by one individual.

The ICS is a very similar system, except it is implemented for emergency response to all incidents, both large and small, that involve hazardous substances.

For a small incident, the individual in charge of the ICS may perform many tasks of the ICS. There may not be any, or little, delegation of tasks to subordinates. For example, in response to a small incident, the individual in charge of the ICS, in addition to normal command activities, may become the safety officer and may designate only one employee (with proper equipment) as a backup to provide assistance if needed. OSHA does recommend, however, that at least two employees be designated as back-up personnel since the assistance needed may include rescue.

To illustrate the operation of the ICS, the following scenario might develop during a small incident, such as an overturned tank truck with a small leak of flammable liquid.

The first responding senior officer would implement and take command of the ICS. That person would size-up the incident and determine if additional personnel and apparatus were necessary; would determine what actions to take to control the leak; and determine the proper level of personal protective equipment. If additional assistance is not needed, the individual in charge of the ICS would implement actions to stop and control the leak using the fewest number of personnel that can effectively accomplish the tasks. The individual in charge of the ICS then

would designate himself as the safety officer and two other employees as a back-up in case rescue may become necessary. In this scenario, decontamination procedures would not be necessary.

A large complex incident may require many employees and difficult, time-consuming efforts to control. In these situations, the individual in charge of the ICS will want to delegate different tasks to subordinates in order to maintain a span of control that will keep the number of subordinates, that are reporting, to a manageable level.

Delegation of task at large incidents may be by location, where the incident scene is divided into sectors, and subordinate officers coordinate activities within the sector that they have been assigned.

Delegation of tasks can also be by function. Some of the functions that the individual in charge of the ICS may want to delegate at a large incident are: medical services; evacuation; water supply; resources (equipment, apparatus); media relations; safety; and, site control (integrate activities with police for crowd and traffic control). Also for a large incident, the individual in charge of the ICS will designate several employees as back-up personnel; and a number of safety officers to monitor conditions and recommend safety precautions.

Therefore, no matter what size or complexity an incident may be, by implementing an ICS there will be one individual in charge who makes the decisions and gives directions; and, all actions, and communications are coordinated through one central point of command. Such a system should reduce confusion, improve safety, organize and coordinate actions, and should facilitate effective management of the incident.

7. Site Safety and Control Plans. The safety and security of response personnel and others in the area of an emergency response incident site should be of primary concern to the incident commander. The use of a site safety and control plan could greatly assist those in charge of assuring the safety and health of employees on the site.

A comprehensive site safety and control plan should include the following: summary analysis of hazards on the site and a risk analysis of those hazards; site map or sketch; site work zones (clean zone, transition or decontamination zone, work or hot zone); use of the buddy system; site communications; command post or command center; standard operating procedures and safe work practices; medical assistance and triage area; hazard monitoring plan (air contaminate monitoring, etc.); decontamination procedures and area; and other relevant areas. This plan should be a part of the employer's emergency response plan or an extension of it to the specific site.

8. Medical surveillance programs. Workers handling hazardous substances may be exposed to toxic chemicals, safety hazards, biologic hazards, and radiation. Therefore, a medical surveillance program is essential to assess and monitor workers' health and fitness for employment in hazardous waste operations and during the course of work; to provide emergency and other treatment as needed; and to keep accurate records for future reference.

The Occupational Safety and Health Guidance Manual for Hazardous Waste Site Activities developed by the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), the U.S. Coast Guard (USCG), and the Environmental Protection Agency (EPA); October 1985 provides an excellent example of the types of medical testing that should be done as part of a medical surveillance program. * 9. New Technology and Spill Containment Programs. Where hazardous substances may be released by

spilling from a container that will expose employees to the hazards of the materials, the employer will need to implement a program to contain and control the spilled material. Diking and ditching, as well as use of absorbents like diatomaceous earth, are traditional techniques which have proven to be effective over the years. However, in recent years new products have come into the marketplace, the use of which complement and increase the effectiveness of these traditional methods. These new products also provide emergency responders and others with additional tools or agents to use to reduce the hazards of spilled materials.

These agents can be rapidly applied over a large area and can be uniformly applied or otherwise can be used to build a small dam, thus improving the workers' ability to control spilled material. These application techniques enhance the intimate contact between the agent and the spilled material allowing for the quickest effect by the agent or quickest control of the spilled material. Agents are available to solidify liquid spilled materials, to suppress vapor generation from spilled materials, and to do both. Some special agents, which when applied as recommended by the manufacturer, will react in a controlled manner with the spilled material to neutralize acids or caustics, or greatly reduce the level of hazard of the spilled material.

There are several modern methods and devices for use by emergency response personnel or others involved with spill control efforts to safely apply spill control agents to control spilled material hazards. These include portable pressurized applicators similar to hand-held portable fire extinguishing devices, and nozzle and hose systems similar to portable fire fighting foam systems which allow the operator to apply the agent without having to come into contact with the spilled material. The operator is able to apply the agent to the spilled material from a remote position.

The solidification of liquids provides for rapid containment and isolation of hazardous substance spills. By directing the agent at run-off points or at the edges of the spill, the reactant solid will automatically create a barrier to slow or stop the spread of the material. Clean-up of hazardous substances is greatly improved when solidifying agents, acid or caustic neutralizers, or activated carbon adsorbents are used. properly applied, these agents can totally solidify liquid hazardous substances or neutralize or absorb them, which results in materials which are less hazardous and easier to handle, transport, and dispose of. The concept of spill treatment, to create less hazardous substances, will improve the safety and level of protection of employees working at spill clean-up operations or emergency response operations to spills of hazardous substances.

The use of vapor suppression agents for volatile hazardous substances, such as flammable liquids and those substances, such as flammable liquids and those substances which present an inhalation hazard, is important for protecting workers. The rapid and uniform distribution of the agent over the surface of the spilled material can provide quick vapor knockdown. There are temporary and long-term foam-type agents which are effective on vapors and dusts, and activated carbon adsorption agents which are effective for vapor control and soaking-up of the liquid. The proper use of hose lines or hand-held portable pressurized applicators provides good mobility and permits the worker to deliver the agent from a safe distance without having to step into the untreated spilled material. Some of these systems can be recharged in the field to provide coverage of larger spill areas than the design limits of a single charged applicator unit. Some of the more effective agents can solidify the liquid flammable hazardous substances and at the same time elevate the flashpoint above 140 degrees F so the resulting substance may be handled as a nonhazardous waste material if it meets the U.S. Environmental Protection Agency's 40 CFR part 261 requirements (See particularly 261.21).

All workers performing hazardous substance spill control work are expected to wear the proper protective clothing and equipment for the materials present and to follow the employer's established standard operating procedures for spill control. All involved workers need to be trained in the established operating procedures; in the use and care of spill control equipment;

and in the associated hazards and control of such hazards of spill containment work.

These new tools and agents are the things that employers will want to evaluate as part of their new technology program. The treatment of spills of hazardous substances or wastes at an emergency incident as part of the immediate spill containment and control efforts is sometimes acceptable to EPA and a permit exception is described in 40 CFR 264.1(g)(8) and 265.1(c)(11).

App D References

The following references may be consulted for further information on the subject of this standard:

1. OSHA Instruction DFO CPL 2.70 - January 29, 1986, Special Emphasis Program: Hazardous Waste Sites.
2. OSHA Instruction DFO CPL 2-2.37A - January 29, 1986, Technical Assistance and Guidelines for Superfund and Other Hazardous Waste Site Activities.
3. OSHA Instruction DTS CPL 2.74 - January 29, 1986, Hazardous Waste Activity Form, OSHA 175.
4. Hazardous Waste Inspections Reference Manual, U.S. Department of Labor, Occupational Safety and Health Administration, 1986.
5. Memorandum of Understanding Among the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, the United States Coast Guard, and the United States Environmental Protection Agency, Guidance for Worker Protection During Hazardous Waste Site Investigations and Clean-up and Hazardous Substance Emergencies. December 18, 1980.
6. National Priorities List, 1st Edition, October 1984; U.S. Environmental Protection Agency, Revised periodically.
7. The Decontamination of Response Personnel, Field Standard Operating Procedures (F.S.O.P.) 7; U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, Hazardous Response Support Division, December 1984.
8. Preparation of a Site Safety Plan, Field Standard Operating Procedures (F.S.O.P.) 9; U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, Hazardous Response Support Division, April 1985.
9. Standard Operating Safety Guidelines; U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, Hazardous Response Support Division, Environmental Response Team; November 1984.
10. Occupational Safety and Health Guidance Manual for Hazardous Waste Site Activities, National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), U.S. Coast Guard (USCG), and Environmental Protection Agency (EPA); October 1985.

11. Protecting Health and Safety at Hazardous Waste Sites: An Overview, U.S. Environmental Protection Agency, EPA/625/9-85/006; September 1985.
12. Hazardous Waste Sites and Hazardous Substance Emergencies, NIOSH Worker Bulletin, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health; December 1982.
13. Personal Protective Equipment for Hazardous Materials Incidents: A Selection Guide; U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health; October 1984.
14. Fire Service Emergency Management Handbook, Federal Emergency Management Agency, Washington, DC, January 1985.
15. Emergency Response Guidebook, U.S. Department of Transportation, Washington, DC, 1987.
16. Report to the Congress on Hazardous Materials Training. Planning and Preparedness, Federal Emergency Management Agency, Washington, DC, July 1986.
17. Workbook for Fire Command, Alan V. Brunacini and J. David Beageron, National Fire Protection Association, Batterymarch Park, Quincy, MA 02269, 1985.
18. Fire Command, Alan B. Brunacini, National Fire Protection * Association, Batterymarch Park, Quincy, MA 02269, 1985.
19. Incident Command System, Fire Protection Publications, Oklahoma State University, Stillwater, OK 74078, 1983.
20. Site Emergency Response Planning, Chemical Manufacturers Association, Washington, DC 20037, 1986.
21. Hazardous Materials Emergency Planning Guide, NRT-1, Environmental Protection Agency, Washington, DC, March 1987.
22. Community Teamwork: Working Together to Promote Hazardous Materials Transportation Safety. U.S. Department of Transportation, Washington, DC, May 1983.
23. Disaster Planning Guide for Business and Industry, Federal Emergency Management Agency, Publication No. FEMA 141, August 1987.

(The Office of Management and Budget has approved the information collection requirements in this section under control number 1218-0139)

* [55 FR 14073, Apr 13, 1990; 56 FR 15832, Apr 18, 1991]

Appendix E - Training Curriculum Guidelines.

The following non-mandatory general criteria may be used for assistance in developing site-

specific training curriculum used to meet the training requirements of 29 CFR (e); 29 CFR (p)(7), p(8)(iii); and 29 CFR (q)(6), (q)(7), and (q)(8). These are generic guidelines and they are not presented as a complete training curriculum for any specific employer. Site-specific training programs must be developed on the basis of a needs assessment of the hazardous waste site. RCRA/TSD, or emergency response operation in accordance with 29 CFR .

It is noted that the legal requirements are set forth in the regulatory text of 1926.65. The guidance set forth here presents a highly effective program that in the areas covered would meet or exceed the regulatory requirements. In addition, other approaches could meet the regulatory requirements.

Suggested General Criteria

Definitions:

"Competent" means possessing the skills, knowledge, and judgement to perform assigned tasks or activities satisfactorily as determined by the employer.

"Demonstration" means the showing by actual use of equipment or procedures.

"Hands-on training" means training in a simulated work environment that permits each student to have experience performing tasks, making decisions, or using equipment appropriate to the job assignment for which the training is being conducted.

"Initial training" means training required prior to beginning work.

"Lecture" means an interactive discourse with a class lead by an instructor.

"Proficient" means meeting a stated level of achievement.

"Site-specific" means individual training directed to the operations of a specific job site.

"Training hours" means the number of hours devoted to lecture, learning activities, small group work sessions, demonstration, evaluations, or hands-on experience.

Suggested Core Criteria:

1. Training facility. The training facility should have available sufficient resources, equipment, and site locations to perform didactic and hands-on training when appropriate. Training facilities should have sufficient organization, support staff, and services to conduct training in each of the courses offered.
2. Training Director. Each training program should be under the direction of a training director who is responsible for the program. The Training Director should have a minimum of two years of employee education experience.
3. Instructors. Instructors should be deemed competent on the basis of previous documented experience in their area of instruction, successful completion of a "train-the-trainer" program specific to the topics they will teach, and an evaluation of instructional competence by the Training Director.

Instructors should be required to maintain professional competency by participating in continuing education or professional development programs or by completing successfully an annual refresher course and having an annual review by the Training Director.

The annual review by the Training Director should include observation of an instructor's delivery, a review of those observations with the trainer, and an analysis of any instructor or class evaluations completed by the students during the previous year.

4. Course materials. The Training Director should approve all course materials to be used by the training provider. Course materials should be reviewed and updated at least annually. Materials and equipment should be in good working order and maintained properly.

All written and audio-visual materials in training curricula should be peer reviewed by technically competent outside reviewers or by a standing advisory committee.

Reviews should possess expertise in the following disciplines where applicable: occupational health, industrial hygiene and safety, chemical/environmental engineering, employee education, or emergency response. One or more of the peer reviewers should be an employee experienced in the work activities to which the training is directed.

5. Students. The program for accepting students should include:

a. Assurance that the student is or will be involved in work where chemical exposures are likely and that the student possesses the skills necessary to perform the work.

b. A policy on the necessary medical clearance.

6. Ratios. Student-instructor ratios should not exceed 30 students per instructor. Hands-on activity requiring the use of personal protective equipment should have the following student-instructor ratios. For Level C or Level D personal protective equipment, the ratio should be 10 students per instructor. For Level A or Level B personal protective equipment, the ratio should be 5 students per instructor.

7. Proficiency assessment. Proficiency should be evaluated and documented by the use of a written assessment and a skill demonstration selected and developed by the Training Director and training staff. The assessment and demonstration should evaluate the knowledge and individual skills developed in the course of training. The level of minimum achievement necessary for proficiency shall be specified in writing by the Training Director.

If a written test is used, there should be a minimum of 50 questions. If a written test is used in combination with a skills demonstration, a minimum of 25 questions should be used. If a skills demonstration is used, the tasks chosen and the means to rate successful completion should be fully documented by the Training Director.

The content of the written test or of the skill demonstration shall be relevant to the objectives of the course. The written test and skill demonstration should be updated as necessary to reflect changes in the curriculum and any update should be approved by the Training Director.

The proficiency assessment methods, regardless of the approach or combination of approaches used, should be justified, documented and approved by the Training Director.

The proficiency of those taking the additional courses for supervisors should be evaluated and documented by using proficiency assessment methods acceptable to the Training Director. These proficiency assessment methods must reflect the additional responsibilities borne by supervisory personnel in hazardous waste operations or emergency response.

8. Course certificate. Written documentation should be provided to each student who satisfactorily completes the training course. The documentation should include:

- a. Student's name.
- b. Course title.
- c. Course date.
- d. Statement that the student has successfully completed the course.
- e. Name and address of the training provider.
- f. An individual identification number for the certificate.
- g. List of the levels of personal protective equipment used by the student to complete the course.

This documentation may include a certificate and an appropriate wallet-sized laminated card with a photograph of the student and the above information. When such course certificate cards are used, the individual identification number for the training certificate should be shown on the card.

9. Recordkeeping. Training providers should maintain records listing the dates courses were presented, the names of the individual course attenders, the names of those students successfully completing each course, and the number of training certificates issued to each successful student. These records should be maintained for a minimum of five years after the date an individual participated in a training program offered by the training provider. These records should be available and provided upon the student's request or as mandated by law.

10. Program quality control. The Training Director should conduct or direct an annual written audit of the training program. Program modifications to address deficiencies, if any, should be documented, approved and implemented by the training provider. The audit and the program modification documents should be maintained at the training facility.

Suggested Program Quality Control Criteria

Factors listed here are suggested criteria for determining the quality and appropriateness of employee health and safety training for hazardous waste operations and emergency response.

A. Training Plan

Adequacy and appropriateness of the training program's curriculum development, instructor training, distribution of course materials, and direct student training should be considered, including

1. The duration of training, course content, and course schedules/agendas;
2. The different training requirements of the various target populations, as specified in the appropriate generic training curriculum;

3. The process for the development of curriculum, which includes appropriate technical input, outside review, evaluation, program pretesting;
4. The adequate and appropriate inclusion of hands-on, demonstration, and instruction methods;
5. Adequate monitoring of student safety, progress and performance during the training.

B. Program management, Training Director, staff, and consultants.

Adequacy and appropriateness of staff performance and delivering an effective training program should be considered, including:

1. Demonstration of the training director's leadership in assuring quality of health and safety training.
 2. Demonstration of the competency of the staff to meet the demands of delivering high quality hazardous waste employee health and safety training.
 3. Organization charts establishing clear lines of authority.
 4. Clearly defined staff duties including the relationship of the training staff to the overall program.
 5. Evidence that the training organizational structure suits the needs of the training program.
 6. Appropriateness and adequacy of the training methods used by the instructors.
 7. Sufficiency of the time committed by the training director and staff to the training program.
 8. Adequacy of the ratio of training staff to students.
 9. Availability and commitment of the training program of adequate human and equipment resources in the areas of:
 - a. Health effects,
 - b. Safety,
 - c. Personal protective equipment (PPE),
 - d. Operational procedures,
 - e. Employee protection practices/procedures.
 10. Appropriateness of management controls.
 11. Adequacy of the organization and appropriate resources assigned to assure appropriate training.
 12. In the case of multiple-site training programs, adequacy of satellite centers management.
- C. Training facilities and resources.

Adequacy and appropriateness of the facilities and resources for supporting the training program should be considered, including:

1. Space and equipment to conduct the training.
2. Facilities for representative hands-on training.
3. In the case of multiple-site programs, equipment and facilities at the satellite centers.
4. Adequacy and appropriateness of the quality control and evaluations program to account for instructor performance.
5. Adequacy and appropriateness of the quality control and evaluation program to ensure appropriate course evaluation, feedback, updating, and corrective action.
6. Adequacy and appropriateness of disciplines and expertise being used within the quality control and evaluation program.
7. Adequacy and appropriateness of the role of student evaluations to provide feedback for training program improvement.

D. Quality control and evaluation.

Adequacy and appropriateness of quality control and evaluation plans for training programs should be considered, including:

1. A balanced advisory committee and/or competent outside reviewers to give overall policy guidelines;
2. Clear and adequate definition of the composition and active programmatic role of the advisory committee or outside reviewers.
3. Adequacy of the minutes or reports of the advisory committee or outside reviewers' meetings or written communication.
4. Adequacy and appropriateness of the quality control and evaluations program to account for instructor performance.
5. Adequacy and appropriateness of the quality control and evaluation program to ensure appropriate course evaluation, feedback, updating and corrective action.
6. Adequacy and appropriateness of disciplines and expertise being used within the quality control and evaluation program.
7. Adequacy and appropriateness of the role of student evaluations to provide feedback for training program improvement.

E. Students

Adequacy and appropriateness of the program for accepting students should be considered, including:

1. Assurance that the student already possess the necessary skills for their job, including necessary documentation.
2. Appropriateness of methods the program uses to ensure that recruits are capable of satisfactorily completing training.
3. Review and compliance with any medical clearance policy.

F. Institutional Environment and Administrative Support

The adequacy and appropriateness of the institutional environment and administrative support system for the training program should be considered, including:

1. Adequacy of the institutional commitment to the employee training program.
2. Adequacy and appropriateness of the administrative structure and administrative support.

G. Summary of Evaluation Questions

Key questions for evaluating the quality and appropriateness of an overall training program should include the following:

1. Are the program objectives clearly stated?
2. Is the program accomplishing its objectives?
3. Are appropriate facilities and staff available?
4. Is there an appropriate mix of classroom, demonstration, and hands-on training?
5. Is the program providing quality employee health and safety training that fully meets the intent of regulatory requirements?
6. What is the program's main strength?
7. What are the program's main weaknesses?
8. What is recommended to improve the program?
9. Are instructors instructing according to their training outlines?
10. Is the evaluation tool current and appropriate for the program content?
11. Is the course material current and relevant to the target group?

Suggested Training Curriculum Guidelines

The following training curriculum guidelines are for those operations specifically identified in 29 CFR 1926.65 as requiring training. Issues such as qualifications of instructors, training certification, and similar criteria appropriate to all categories of operations addressed in 1926.65

have been covered in the preceding section and are not re-addressed in each of the generic guidelines. Basic core requirements for training programs that are addressed include:

1. General Hazardous Waste Operations
2. RCRA operations-Treatment, storage, and disposal facilities.
3. Emergency Response.
- A. General Hazardous Waste Operations and Site-specific Training

1. Off-site training.

Minimum training course content for hazardous waste operations, required by 29 CFR 1926.65(e) should include the following topics and procedures:

a. Regulatory knowledge

- (1) A review of 29 CFR 1926.65 and the core elements of an occupational safety and health program.
- (2) The content of a medical surveillance program as outlined in 29 CFR 1926.65(f).
- (3) The content of an effective site safety and health plan consistent with the requirements of 29 CFR 1926.65(b)(4)(ii).
- (4) Emergency response plan and procedures as outlined in 29 CFR 1910.38 and 29 CFR 1926.65(l).
- (5) Adequate illumination.
- (6) Sanitation recommendation and equipment.
- (7) Review and explanation of OSHA's hazard-communication standard (29 CFR 1910.1200) and lock-out-tag-out standard (29 CFR 1910.147).
- (8) Review of other applicable standards including but not limited to those in the construction standards (29 CFR 1926).
- (9) Rights and responsibilities of employers and employees under applicable OSHA and EPA laws.

b. Technical knowledge.

- (1) Type of potential exposures to chemical, biological, and radiological hazards; types of human responses to these hazards and recognition of those responses; principles of toxicology and information about acute and chronic hazards; health and safety considerations of new technology.

(2) Fundamentals of chemical hazards including but not limited to vapor pressure, boiling points, flash points, ph, other physical and chemical properties.

(3) Fire and explosion hazards of chemicals.

(4) General safety hazards such as but not limited to electrical hazards, powered equipment hazards, motor vehicle hazards, walking-working surface hazards, excavation hazards, and hazards associated with working in hot and cold temperature extremes.

(5) Review and knowledge of confined space entry procedures in 29 CFR 1910.146.

(6) Work practices to minimize employee risk from site hazards.

(7) Safe use of engineering controls, equipment, and any new relevant safety technology or safety procedures.

(8) Review and demonstration of competency with air sampling and monitoring equipment that may be used in a site monitoring program.

(9) Container sampling procedures and safeguarding; general drum and container handling procedures including special requirement for laboratory waste packs, shock-sensitive wastes, and radioactive wastes.

(10) The elements of a spill control program.

(11) Proper use and limitations of material handling equipment.

(12) Procedures for safe and healthful preparation of containers for shipping and transport.

(13) Methods of communication including those used while wearing respiratory protection.

c. Technical skills

(1) Selection, use maintenance, and limitations of personal protective equipment including the components and procedures for carrying out a respirator program to comply with 29 CFR 1910.134.

(2) Instruction in decontamination programs including personnel, equipment, and hardware; hands-on training including level A, B, and C ensembles and appropriate decontamination lines; field activities including the donning and doffing of protective equipment to a level commensurate with the employee's anticipated job function and responsibility and to the degree required by potential hazards.

(3) Sources for additional hazard information; exercises using relevant manuals and hazard coding systems.

d. Additional suggested items.

(1) A laminated, dated card or certificate with photo, denoting limitations and level of protection for which the employee is trained should be issued to those students successfully completing a

course.

(2) Attendance should be required at all training modules, with successful completion of exercises and a final written or oral examination with at least 50 questions.

(3) A minimum of one-third of the program should be devoted to hands-on exercises.

1926.66 Spray finishing using flammable and combustible materials.

(a) Definitions applicable to this section

(1) Aerated solid powders. Aerated powders shall mean any powdered material used as a coating material which shall be fluidized within a container by passing air uniformly from below. It is common practice to fluidize such materials to form a fluidized powder bed and then dip the part to be coated into the bed in a manner similar to that used in liquid dipping. Such beds are also used as sources for powder spray operations.

(2) Spraying area. Any area in which dangerous quantities of flammable vapors or mists, or combustible residues, dusts, or deposits are present due to the operation of spraying processes.

(3) Spray booth. A power-ventilated structure provided to enclose or accommodate a spraying operation to confine and limit the escape of spray, vapor, and residue, and to safely conduct or direct them to an exhaust system.

(4) Waterwash spray booth. A spray booth equipped with a water washing system designed to minimize dusts or residues entering exhaust ducts and to permit the recovery of overspray finishing material.

(5) Dry spray booth. A spray booth not equipped with a water washing system as described in paragraph (a)(4) of this section. A dry spray booth may be equipped with (i) Distribution or baffle plates to promote an even flow of air through the booth or cause the deposit of overspray before it enters the exhaust duct; or (ii) Overspray dry filters to minimize dusts; or (iii) overspray dry filters to minimize dusts or residues entering exhaust ducts; or (iv) Overspray dry filter rolls designed to minimize dusts or residues entering exhaust ducts; or (v) Where dry powders are being sprayed, with powder collection systems so arranged in the exhaust to capture oversprayed material.

(6) Fluidized bed. A container holding powder coating material which is aerated from below so as to form an air-supported expanded cloud of such material through which the preheated object to be coated is immersed and transported.

(7) Electrostatic fluidized bed. A container holding powder coating material which is aerated from below so as to form an air-supported expanded cloud of such material which is electrically charged with a charge opposite to the charge of the object to be coated; such object is transported, through the container immediately above the charged and aerated materials in order to be coated.

(8) Approved. Shall mean approved and listed by a nationally recognized testing laboratory. See 1910.7 for definition of nationally recognized testing laboratory.

(9) Listed. See "approved" in 1910.107(a)(8).

(b) Spray booths

spray booths-(1) Construction. Spray booths shall be substantially constructed of steel, securely and rigidly supported, or of concrete or masonry except that aluminum or other substantial noncombustible material may be used for intermittent or low volume spraying. Spray booths shall be designed to sweep air currents toward the exhaust outlet. STEP

(2) Interiors. The interior surfaces of spray booths shall be smooth and continuous without edges and otherwise designed to prevent pocketing of residues and facilitate cleaning and washing without injury.

STEP

(3) Floors. The floor surface of a spray booth and operator's working area, if combustible, shall be covered with noncombustible material of such character as to facilitate the safe cleaning and removal of residues. STEP

(4) Distribution or baffle plates. Distribution or baffle plates, if installed to promote an even flow of air through the booth or cause the deposit of overspray before it enters the exhaust duct, shall be of noncombustible material and readily removable or accessible on both sides for cleaning. Such plates shall not be located in exhaust ducts.

(5) Dry type overspray collectors - (exhaust air filters). In conventional dry type spray booths, overspray dry filters or filter rolls, if installed, shall conform to the following:

(i) The spraying operations except electrostatic spraying operations shall be so designed, installed and maintained that the average air velocity over the open face of the booth (or booth cross section during spraying operations) shall be not less than 100 linear feet per minute. Electrostatic spraying operations may be conducted with an air velocity over the open face of the booth of not less than 60 linear feet per minute, or more, depending on the volume of the finishing material being applied and its flammability and explosion characteristics. Visible gauges or audible alarm or pressure activated devices shall be installed to indicate or insure that the required air velocity is maintained. Filter rolls shall be inspected to insure proper replacement of filter media.

STD 1-5.10 STEP

(ii) All discarded filter pads and filter rolls shall be immediately removed to a safe, well-detached location or placed in a water-filled metal container and disposed of at the close of the day's operation unless maintained completely in water. STEP

(iii) The location of filters in a spray booth shall be so as to not reduce the effective booth enclosure of the articles being sprayed.

(iv) Space within the spray booth on the downstream and upstream sides of filters shall be protected with approved automatic sprinklers. STD 1-5.11 STEP

(v) Filters or filter rolls shall not be used when applying a spray material known to be highly susceptible to spontaneous heating and ignition.

(vi) Clean filters or filter rolls shall be noncombustible or of a type having a combustibility not in excess of class 2 filters as listed by Underwriters' Laboratories, Inc. Filters and filter rolls shall not be alternately used for different types of coating materials, where the combination of materials may be conducive to spontaneous ignition. See also paragraph (g)(6) of this section.

(6) Frontal area. Each spray booth having a frontal area larger than 9 square feet shall have a metal deflector or curtain not less than 2 1/2 inches (5.35 c.m) deep installed at the upper outer edge of the booth over the opening. STEP

(7) Conveyors. Where conveyors are arranged to carry work into or out of spray booths, the openings therefor shall be as small as practical.

(8) Separation of operations. Each spray booth shall be separated from other operations by not less than 3 feet (0.912m.), or by a greater distance, or by such partition or wall as to reduce the danger from juxtaposition of hazardous operations. See also paragraph (c)(1) of this section.

STEP

(9) Cleaning. Spray booths shall be so installed that all portions are readily accessible for cleaning. A clear space of not less than 3 feet (0.912m.) on all sides shall be kept free from storage or combustible construction.

STEP

(10) Illumination. When spraying areas are illuminated through glass panels or other transparent materials, only fixed lighting units shall be used as a source of illumination. Panels shall effectively isolate the spraying area from the area in which the lighting unit is located, and shall be of a noncombustible material of such a nature or so protected that breakage will be unlikely. Panels shall be so arranged that normal accumulations of residue on the exposed surface of the panel will not be raised to a dangerous temperature by radiation or conduction from the source of illumination.

(c) Electrical and other sources of ignition

(1) Conformance. All electrical equipment, open flames and other sources of ignition shall conform to the requirements of this paragraph, except as follows:

(i) Electrostatic apparatus shall conform to the requirements of paragraphs (e) and (f) of this section;

(ii) Drying, curing, and fusion apparatus shall conform to the requirements of paragraph (g) of this section;

(iii) [reserved]

(iv) Powder coating equipment shall conform to the requirements of paragraph (c)(1) of this section.

(2) Minimum separation. There shall be no open flame or spark producing equipment in any spraying area nor within 20 feet (6.08.m) thereof, unless separated by a partition. STEP

(3) Hot surfaces. Space-heating appliances, steampipes, or hot surfaces shall not be located in a spraying area where deposits of combustible residues may readily accumulate.

(4) Wiring conformance. Electrical wiring and equipment shall conform to the provisions of this paragraph and shall otherwise be in accordance with Subpart S of this part.

(5) Combustible residues, areas. Unless specifically approved for locations containing both deposits of readily ignitable residue and explosive vapors, there shall be no electrical equipment in any spraying area, whereon deposits of combustible residues may readily accumulate, except wiring in rigid conduit or in boxes or fittings containing no taps, splices, or terminal connections. STEP

(6) Wiring type approved. Electrical wiring and equipment not subject to deposits of combustible residues but located in a spraying area as herein defined shall be of explosion-proof type approved for Class I, group D locations and shall otherwise conform to the provisions of Subpart S of this part, for Class I, Division 1, Hazardous Locations. Electrical wiring, motors, and other equipment outside of but within 20 feet (6.08m) of any spraying area, and not separated therefrom by partitions, shall not produce sparks under normal operating conditions and shall otherwise conform to the provisions of Subpart S of this part for Class I, Division 2 Hazardous Locations. STEP

(7) Lamps. Electric lamps outside of, but within 20 feet (6.08m) of any spraying area, and not separated therefrom by a partition, shall be totally enclosed to prevent the falling of hot particles and shall be protected from mechanical injury by suitable guards or by location.
STEP

(8) Portable lamps. Portable electric lamps shall not be used in any spraying area during spraying operations. Portable electric lamps, if used during cleaning or repairing operations, shall be of the type approved for hazardous Class I locations.

(9) Grounding.

(i) All metal parts of spray booths, exhaust ducts, and piping systems conveying flammable or combustible liquids or aerated solids shall be properly electrically grounded in an effective and permanent manner.

(ii) [Reserved]

(d) Ventilation

Ventilation-(1) Conformance. Ventilating and exhaust systems shall be in accordance with the Standard for Blower and Exhaust Systems for Vapor Removal, NFPA No. 91-1961, where applicable and shall also conform to the provisions of this section.

(2) General. All spraying areas shall be provided with mechanical ventilation adequate to remove flammable vapors, mists, or powders to a safe location and to confine and control combustible residues so that life is not endangered. Mechanical ventilation shall be kept in

operation at all times while spraying operations are being conducted and for a sufficient time thereafter to allow vapors from drying coated articles and drying finishing material residue to be exhausted. STEP

(3) Independent exhaust. Each spray booth shall have an independent exhaust duct system discharging to the exterior of the building, except that multiple cabinet spray booths in which identical spray finishing material is used with a combined frontal area of not more than 18 square feet may have a common exhaust. If more than one fan serves one booth, all fans shall be so interconnected that one fan cannot operate without all fans being operated.

(4) Fan-rotating element. The fan-rotating element shall be nonferrous or nonsparking or the casing shall consist of or be lined with such material. There shall be ample clearance between the fan-rotating element and the fan casing to avoid a fire by friction, necessary allowance being made for ordinary expansion and loading to prevent contact between moving parts and the duct or fan housing. Fan blades shall be mounted on a shaft sufficiently heavy to maintain perfect alignment even when the blades of the fan are heavily loaded, the shaft preferably to have bearings outside the duct and booth. All bearings shall be of the self-lubricating type, or lubricated from the outside duct. STEP

(5) Electric motors. Electric motors driving exhaust fans shall not be placed inside booths or ducts. See also paragraph (c) of this section.
STEP

(6) Belts. Belts shall not enter the duct or booth unless the belt and pulley within the duct or booth are thoroughly enclosed.

(7) Exhaust ducts. Exhaust ducts shall be constructed of steel and shall be substantially supported. Exhaust ducts without dampers are preferred; however, if dampers are installed, they shall be maintained so that they will be in a full open position at all times the ventilating system is in operation.

(i) Exhaust ducts shall be protected against mechanical damage and have a clearance from unprotected combustible construction or other combustible material of not less than 18 inches(45.72cm).

(ii) If combustible construction is provided with the following protection applied to all surfaces within 18 inches(45.72 cm), clearances may be reduced to the distances indicated:

(a) 28-gage sheet metal on 12 inches.

1/4 -inch asbestos mill board

(b) 28-gage sheet metal on 9 inches.

1/8 -inch asbestos mill board

spaced out 1 inch on

noncombustible spacers

(c) 22-gage sheet metal on 1-inch 3 inches.

rockwool batts reinforced with

wire mesh or the equivalent

(d) Where ducts are protected with

an approved automatic sprinkler system,

properly maintained, the clearance

required in subdivision (i) of this

subparagraph may be reduced to 6 inches

(8) Discharge clearance. Unless the spray booth exhaust duct terminal is from a water-wash spray booth, the terminal discharge point shall be not less than 6 feet from any combustible exterior wall or roof nor discharge in the direction of any combustible construction or unprotected opening in any noncombustible exterior wall within 25 feet(7.6m).

(9) Air exhaust. Air exhaust from spray operations shall not be directed so that it will contaminate makeup air being introduced into the spraying area or other ventilating intakes, nor directed so as to create a nuisance. Air exhausted from spray operations shall not be recirculated.

(10) Access doors. When necessary to facilitate cleaning, exhaust ducts shall be provided with an ample number of access doors.

(11) Room intakes. Air intake openings to rooms containing spray finishing operations shall be adequate for the efficient operation of exhaust fans and shall be so located as to minimize the creation of dead air pockets.

(12) Drying spaces. Freshly sprayed articles shall be dried only in spaces provided with adequate ventilation to prevent the formation of explosive vapors. In the event adequate and reliable ventilation is not provided such drying spaces shall be considered a spraying area. See also paragraph (j) of this section.

(e) Flammable and combustible liquids - storage and handling

(1) Conformance. The storage of flammable or combustible liquids in connection with spraying operations shall conform to the requirements of 1910.106, where applicable.

(2) Quantity. The quantity of flammable or combustible liquids kept in the vicinity of spraying operations shall be the minimum required for operations and should ordinarily not exceed a supply for 1 day or one shift. Bulk storage of portable containers of flammable or combustible liquids shall be in a separate, constructed building detached from other important buildings or cut off in a standard manner. STEP

(3) Containers. Original closed containers, approved portable tanks, approved safety cans or a properly arranged system of piping shall be used for bringing flammable or

combustible liquids into spray finishing room. Open or glass containers shall not be used. STEP

(4) Transferring liquids. Except as provided in paragraph (e)(5) of this section the withdrawal of flammable and combustible liquids from containers having a capacity of greater than 60 gallons shall be by approved pumps. The withdrawal of flammable or combustible liquids from containers and the filling of containers, including portable mixing tanks, shall be done only in a suitable mixing room or in a spraying area when the ventilating system is in operation. Adequate precautions shall be taken to protect against liquid spillage and sources of ignition.

(5) Spraying containers. Containers supplying spray nozzles shall be of closed type or provided with metal covers kept closed. Containers not resting on floors shall be on metal supports or suspended by wire cables. Containers supplying spray nozzles by gravity flow shall not exceed 10 gallons capacity. Original shipping containers shall not be subject to air pressure for supplying spray nozzles. Containers under air pressure supplying spray nozzles shall be of limited capacity, not exceeding that necessary for 1 day's operation; shall be designed and approved for such use; shall be provided with a visible pressure gage; and shall be provided with a relief valve set to operate in conformance with the requirements of the Code for Unfired Pressure Vessels, Section VIII of the ASME Boiler and Pressure Vessel Code - 1968. Containers under air pressure supplying spray nozzles, air-storage tanks and coolers shall conform to the standards of the Code for Unfired Pressure Vessels, Section VIII of the ASME Boiler and Pressure Vessel Code - 1968 for construction, tests, and maintenance. STEP

(6) Pipes and hoses.

(i) All containers or piping to which is attached a hose or flexible connection shall be provided with a shutoff valve at the connection. Such valves shall be kept shut when spraying operations are not being conducted.

(ii) When a pump is used to deliver products, automatic means shall be provided to prevent pressure in excess of the design working pressure of accessories, piping, and hose.

(iii) All pressure hose and couplings shall be inspected at regular intervals appropriate to this service. The hose and couplings shall be tested with the hose extended, and using the "inservice maximum operating pressures." Any hose showing material deteriorations, signs of leakage, or weakness in its carcass or at the couplings, shall be withdrawn from service and repaired or discarded.

(iv) Piping systems conveying flammable or combustible liquids shall be of steel or other material having comparable properties of resistance to heat and physical damage. Piping systems shall be properly bonded and grounded.

(7) Spray liquid heaters. Electrically powered spray liquid heaters shall be approved and listed for the specific location in which used (see paragraph (c) of this section). Heaters shall not be located in spray booths nor other locations subject to the accumulation of deposits or combustible residue. If an electric motor is used, see paragraph (c) of this section.

(8) Pump relief. If flammable or combustible liquids are supplied to spray nozzles by positive displacement pumps, the pump discharge line shall be provided with an approved relief valve discharging to a pump suction or a safe detached location, or a device provided to stop the prime mover if the discharge pressure exceeds the safe operating pressure of the system.

(9) Grounding. Whenever flammable or combustible liquids are transferred from one container to another, both containers shall be effectively bonded and grounded to prevent discharge sparks of static electricity. STEP

(f) Protection

(1) Conformance. In sprinklered buildings, the automatic sprinkler system in rooms containing spray finishing operations shall conform to the requirements of 1910.159. In unsprinklered buildings where sprinklers are installed only to protect spraying areas, the installation shall conform to such standards insofar as they are applicable. Sprinkler heads shall be located so as to provide water distribution throughout the entire booth. STD 1-5.11

(2) Valve access. Automatic sprinklers protecting each spray booth (together with its connecting exhaust) shall be under an accessibly located separate outside stem and yoke (OS&Y) subcontrol valve.

(3) Cleaning of heads. Sprinklers protecting spraying areas shall be kept as free from deposits as practical by cleaning daily if necessary. (See also paragraph (g) of this section.)

(4) Portable extinguishers. An adequate supply of suitable portable fire extinguishers shall be installed near all spraying areas.

(g) Operations and maintenance

(1) Spraying. Spraying shall not be conducted outside of predetermined spraying areas. STEP

(2) Cleaning. All spraying areas shall be kept as free from the accumulation of deposits of combustible residues as practical, with cleaning conducted daily if necessary. Scrapers, spuds, or other such tools used for cleaning purposes shall be of nonsparking material. STEP

(3) Residue disposal. Residue scrapings and debris contaminated with residue shall be immediately removed from the premises and properly disposed of. Approved metal waste cans shall be provided wherever rags or waste are impregnated with finishing material and all such rags or waste deposited therein immediately after use. The contents of waste cans shall be properly disposed of at least once daily or at the end of each shift. STD 1-5.13 STEP

(4) Clothing storage. Spray finishing employees' clothing shall not be left on the premises overnight unless kept in metal lockers.

(5) Cleaning solvents. The use of solvents for cleaning operations shall be restricted to those having flashpoints not less than 100 deg. F.; however, for cleaning spray nozzles and auxiliary equipment, solvents having flashpoints not less than those normally used in spray operations may be used. Such cleaning shall be conducted inside spray booths and ventilating equipment operated during cleaning.

(6) Hazardous materials combinations. Spray booths shall not be alternately used for different types of coating materials, where the combination of the materials may be conducive to

spontaneous ignition, unless all deposits of the first used material are removed from the booth and exhaust ducts prior to spraying with the second used material.

(7) "No Smoking" signs. "No smoking" signs in large letters on contrasting color background shall be conspicuously posted at all spraying areas and paint storage rooms. STEP

(e) Fixed electrostatic apparatus

(1) Conformance. Where installation and use of electrostatic spraying equipment is used, such installation and use shall conform to all other paragraphs of this section, and shall also conform to the requirements of this paragraph.

(2) Type approval. Electrostatic apparatus and devices used in connection with coating operations shall be of approved types.

(3) Location. Transformers, power packs, control apparatus, and all other electrical portions of the equipment, with the exception of high-voltage grids, electrodes, and electrostatic atomizing heads and their connections, shall be located outside of the spraying area, or shall otherwise conform to the requirements of paragraph (c) of this section.

(4) Support. Electrodes and electrostatic atomizing heads shall be adequately supported in permanent locations and shall be effectively insulated from the ground. Electrodes and electrostatic atomizing heads which are permanently attached to their bases, supports, or reciprocators, shall be deemed to comply with this section. Insulators shall be nonporous and noncombustible.

(5) Insulators, grounding. High-voltage leads to electrodes shall be properly insulated and protected from mechanical injury or exposure to destructive chemicals. Electrostatic atomizing heads shall be effectively and permanently supported on suitable insulators and shall be effectively guarded against accidental contact or grounding. An automatic means shall be provided for grounding the electrode system when it is electrically deenergized for any reason. All insulators shall be kept clean and dry.

(6) Safe distance. A safe distance shall be maintained between goods being painted and electrodes or electrostatic atomizing heads or conductors of at least twice the sparking distance. A suitable sign indicating this safe distance shall be conspicuously posted near the assembly.

(7) Conveyors required. Goods being painted using this process are to be supported on conveyors. The conveyors shall be so arranged as to maintain safe distances between the goods and the electrodes or electrostatic atomizing heads at all times. Any irregularly shaped or other goods subject to possible swinging or movement shall be rigidly supported to prevent such swinging or movement which would reduce the clearance to less than that specified in paragraph (e)(6) of this section.

(8) Prohibition. This process is not acceptable where goods being coated are manipulated by hand. When finishing materials are applied by electrostatic equipment which is manipulated by hand, see paragraph (f) of this section for applicable requirements.

(9) Fail-safe controls. Electrostatic apparatus shall be equipped with automatic controls which will operate without time delay to disconnect the power supply to the high voltage

transformer and to signal the operator under any of the following conditions:

- (i) Stoppage of ventilating fans or failure of ventilating equipment from any cause.
- (ii) Stoppage of the conveyor carrying goods through the high voltage field.
- (iii) Occurrence of a ground or of an imminent ground at any point on the high voltage system.
- (iv) Reduction of clearance below that specified in paragraph (e)(6) of this section.

(10) Guarding. Adequate booths, fencing, railings, or guards shall be so placed about the equipment that they, either by their location or character or both, assure that a safe isolation of the process is maintained from plant storage or personnel. Such railings, fencing, and guards shall be of conducting material, adequately grounded.

(11) Ventilation. Where electrostatic atomization is used the spraying area shall be so ventilated as to insure safe conditions from a fire and health standpoint.

(12) Fire protection. All areas used for spraying, including the interior of the booth, shall be protected by automatic sprinklers where this protection is available. Where this protection is not available, other approved automatic extinguishing equipment shall be provided.

STD 1-5.1

(f) Electrostatic hand spraying equipment

(1) Application. This paragraph shall apply to any equipment using electrostatically charged elements for the atomization and/or, precipitation of materials for coatings on articles, or for other similar purposes in which the atomizing device is hand held and manipulated during the spraying operation.

(2) Conformance. Electrostatic hand spraying equipment shall conform with the other provisions of this section.

(3) Equipment approval and specifications. Electrostatic hand spray apparatus and devices used in connection with coating operations shall be of approved types. The high voltage circuits shall be designed so as to not produce a spark of sufficient intensity to ignite any vapor-air mixtures nor result in appreciable shock hazard upon coming in contact with a grounded object under all normal operating conditions. The electrostatically charged exposed elements of the handgun shall be capable of being energized only by a switch which also controls the coating material supply.

(4) Electrical support equipment. Transformers, powerpacks, control apparatus, and all other electrical portions of the equipment, with the exception of the handgun itself and its connections to the power supply shall be located outside of the spraying area or shall otherwise conform to the requirements of paragraph (c) of this section.

(5) Spray gun ground. The handle of the spraying gun shall be electrically connected to

ground by a metallic connection and to be so constructed that the operator in normal operating position is in intimate electrical contact with the grounded handle.

(6) Grounding - general. All electrically conductive objects in the spraying area shall be adequately grounded. This requirement shall apply to paint containers, wash cans, and any other objects or devices in the area. The equipment shall carry a prominent permanently installed warning regarding the necessity for this grounding feature.

(7) Maintenance of grounds. Objects being painted or coated shall be maintained in metallic contact with the conveyor or other grounded support. Hooks shall be regularly cleaned to insure this contact and areas of contact shall be sharp points or knife edges where possible. Points of support of the object shall be concealed from random spray where feasible and where the objects being sprayed are supported from a conveyor, the point of attachment to the conveyor shall be so located as to not collect spray material during normal operation.

(8) Interlocks. The electrical equipment shall be so interlocked with the ventilation of the spraying area that the equipment cannot be operated unless the ventilation fans are in operation.

(9) Ventilation. The spraying operation shall take place within a spray area which is adequately ventilated to remove solvent vapors released from the operation.

(g) Drying, curing, or fusion apparatus

(1) Conformance. Drying, curing, or fusion apparatus in connection with spray application of flammable and combustible finishes shall conform to the Standard for Ovens and Furnaces, NFPA 86A-1969, where applicable and shall also conform with the following requirements of this paragraph.

(2) Alternate use prohibited. Spray booths, rooms, or other enclosures used for spraying operations shall not alternately be used for the purpose of drying by any arrangement which will cause a material increase in the surface temperature of the spray booth, room, or enclosure.

(3) Adjacent system interlocked. Except as specifically provided in paragraph (g)(4) of this section, drying, curing, or fusion units utilizing a heating system having open flames or which may produce sparks shall not be installed in a spraying area, but may be installed adjacent thereto when equipped with an interlocked ventilating system arranged to:

(i) Thoroughly ventilate the drying space before the heating system can be started;

(ii) Maintain a safe atmosphere at any source of ignition;

(iii) Automatically shut down the heating system in the event of failure of the ventilating system.

(4) Alternate use permitted. Automobile refinishing spray booths or enclosures, otherwise installed and maintained in full conformity with this section, may alternately be used for drying with portable electrical infrared drying apparatus when conforming with the following:

(i) Interior (especially floors) of spray enclosures shall be kept free of overspray deposits.

(ii) During spray operations, the drying apparatus and electrical connections and wiring thereto shall not be located within spray enclosure nor in any other location where spray residues may be deposited thereon.

(iii) The spraying apparatus, the drying apparatus, and the ventilating system of the spray enclosure shall be equipped with suitable interlocks so arranged that:

(a) The spraying apparatus cannot be operated while the drying apparatus is inside the spray enclosure.

(b) The spray enclosure will be purged of spray vapors for a period of not less than 3 minutes before the drying apparatus can be energized.

(c) The ventilating system will maintain a safe atmosphere within the enclosure during the drying process and the drying apparatus will automatically shut off in the event of failure of the ventilating system.

(iv) All electrical wiring and equipment of the drying apparatus shall conform with the applicable sections of Subpart S of this part. Only equipment of a type approved for Class I, Division 2 hazardous locations shall be located within 18 inches (45.72cm) of floor level. All metallic parts of the drying apparatus shall be properly electrically bonded and grounded.

(v) The drying apparatus shall contain a prominently located, permanently attached warning sign indicating that ventilation should be maintained during the drying period and that spraying should not be conducted in the vicinity that spray will deposit on apparatus.

Subpart F - Fire Protection and Prevention

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|----------|---|
| 1926.150 | Fire protection. |
| 1926.151 | Fire prevention. |
| 1926.152 | Flammable and combustible liquids. |
| 1926.153 | Liquefied petroleum gas (LP-Gas). |
| 1926.154 | Temporary heating devices. |
| 1926.155 | Definitions applicable to this subpart. |
| 1926.156 | Fixed extinguishing systems, general. [Removed] |
| 1926.157 | Fixed extinguishing systems, gaseous agent. [Removed] |
| 1926.158 | Fire detection systems. [Removed] |
| 1926.159 | Employee alarm systems. [Removed] |

SUBPART F -- Fire Protection and Prevention

AUTHORITY: ~~Sec. 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 333); secs. 4, 6, and 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), or 6-96 (62 FR 111) as applicable; and 29 CFR part 1911. Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), 3-2000 (62 FR 50017), 5-2002 (67 FR 650008), 5-2007 (72 FR 31159), 4-2010 (75 FR 55355), or 1-2012 (77 FR 3912), as applicable; and 29 CFR part 1911.~~

1926.150 Fire protection.

(a) General requirements.

(1) The employer shall be responsible for the development of a fire protection program to be followed throughout all phases of the construction and demolition work, and he shall provide for the firefighting equipment as specified in this subpart. As fire hazards occur, there shall be no delay in providing the necessary equipment.

STEP

(2) Access to all available firefighting equipment shall be maintained at all times.

STEP

(3) All firefighting equipment, provided by the employer, shall be conspicuously located. STEP

(4) All firefighting equipment shall be periodically inspected and maintained in operating condition. Defective equipment shall be immediately replaced. STEP

(5) As warranted by the project, the employer shall provide a trained and equipped firefighting organization (Fire Brigade) to assure adequate protection to life.

(b) Water supply.

(1) A temporary or permanent water supply, of sufficient volume, duration, and pressure, required to properly operate the firefighting equipment shall be made available as soon as combustible materials accumulate.

(2) Where underground water mains are to be provided, they shall be installed, completed, and made available for use as soon as practicable.

(c) Portable firefighting equipment

(1) Fire extinguishers and small hose lines.

(i) A fire extinguisher, rated not less than 2A, shall be provided for each 3,000 square feet of the protected building area, or major fraction thereof. Travel distance from any point of the protected area to the nearest fire extinguisher shall not exceed 100 feet.

STEP

(ii) One 55-gallon open drum of water with two fire pails may be substituted for a fire extinguisher having a 2A rating.

(iii) A 1/2-inch diameter garden-type hose line, not to exceed 100 feet in length and equipped with a nozzle, may be substituted for a 2A-rated fire extinguisher, providing it is capable of discharging a minimum of 5 gallons per minute with a minimum hose stream range of 30 feet horizontally. The garden-type hose lines shall be mounted on conventional racks or reels. The number and location of hose racks or reels shall be such that at least one hose stream can be applied to all points in the area. STEP

(iv) One or more fire extinguishers, rated not less than 2A, shall be provided on each floor. In multistory buildings, at least one fire extinguisher shall be located adjacent to stairway.

STEP

(v) Extinguishers and water drums, subject to freezing, shall be protected from freezing.

(vi) A fire extinguisher, rated not less than 10B, shall be provided within 50 feet of wherever more than 5 gallons of flammable or combustible liquids or 5 pounds of flammable gas are being used on the jobsite. This requirement does not apply to the integral fuel tanks of motor vehicles. STEP

(vii) Carbon tetrachloride and other toxic vaporizing liquid fire extinguishers are prohibited. STEP














(viii) Portable fire extinguishers shall be inspected periodically and maintained in accordance with Maintenance and Use of Portable Fire Extinguishers, NFPA No. 10A-1970. STEP

(ix) Fire extinguishers which have been listed or approved by a nationally recognized testing laboratory, shall be used to meet the requirements of this subpart.

(x) Table F-1 may be used as a guide for selecting the appropriate portable fire extinguishers.

TABLE F-1 FIRE EXTINGUISHERS DATA

Table F-1 FIRE EXTINGUISHERS DATA

|  | WATER TYPE | | | | FOAM | CARBON DIOXIDE | DRY CHEMICAL | | | |
|--|---|--|---|---|-----------------------------------|--|--|---|---|--|
| |  STORED PRESSURE |  CARTRIDGE OPERATED |  WATER PUMP TANK |  SODA ACID | | | SODIUM OR POTASSIUM BICARBONATE | | MULT-PURPOSE ABC | |
| | | | | | | |  CARTRIDGE OPERATED |  STORED PRESSURE |  STORED PRESSURE |  CARTRIDGE OPERATED |
| CLASS A FIRES WOOD, PAPER, TRASH HAVING GLOWING EMBERS  | YES | YES | YES | YES | YES | NO (EXT WILL CORRODE/EMIT SULFUR DIOXIDE) | NO (EXT WILL CORRODE/EMIT SULFUR DIOXIDE) | NO (EXT WILL CORRODE/EMIT SULFUR DIOXIDE) | YES | YES |
| CLASS B FIRES FLAMMABLE LIQUIDS, GASOLINE, OIL, PAINTS, GREASE, ETC.  | NO | NO | NO | NO | YES | YES | YES | YES | YES | YES |
| CLASS C FIRES ELECTRICAL EQUIPMENT  | NO | NO | NO | NO | NO | YES | YES | YES | YES | YES |
| CLASS D FIRES COMBUSTIBLE METALS  | SPECIAL EXTINGUISHING AGENTS APPROVED BY RECOGNIZED TESTING | | | | | | | | | |
| METHOD OF OPERATION | PULL PIN- SQUEEZE HANDLE | TURN UPSIDE DOWN AND BUMP | PUMP HANDLE | TURN UPSIDE DOWN | TURN UPSIDE DOWN | PULL PIN- SQUEEZE LEVER | RUPTURE CARTRIDGE SQUEEZE LEVER | PULL PIN- SQUEEZE HANDLE | PULL PIN- SQUEEZE HANDLE | RUPTURE CARTRIDGE SQUEEZE LEVER |
| RANGE | 30' - 40' | 30' - 40' | 30' - 40' | 30' - 40' | 30' - 40' | 3' - 8' | 5' - 30' | 5' - 30' | 5' - 30' | 5' - 30' |
| MAINTENANCE | CHECK AIR PRESSURE GAUGE MONTHLY | WEIGH GAS CARTRIDGE ADD WATER IF REQUIRED ANNUALLY | DISCHARGE AND FILL WITH WATER ANNUALLY | DISCHARGE ANNUALLY RECHARGE | DISCHARGE ANNUALLY RECHARGE | WEIGH SEMI- ANNUALLY | WEIGH GAS CARTRIDGE. CHECK CONDITION OF DRY CHEMICAL ANNUALLY | CHECK GAS PRESSURE GAUGE AND CONDITION OF DRY CHEMICAL ANNUALLY | CHECK GAS PRESSURE GAUGE AND CONDITION OF DRY CHEMICAL ANNUALLY | WEIGH GAS CARTRIDGE. CHECK CONDITION OF DRY CHEMICAL ANNUALLY |

(2) Fire hose and connections.

(i) One hundred feet, or less, of 1 1/2-inch hose, with a nozzle capable of discharging water at 25 gallons or more per minute, may be substituted for a fire extinguisher rated not more than 2A in the designated area provided that the hose line can reach all points in the area.

(ii) If fire hose connections are not compatible with local firefighting equipment, the contractor shall provide adapters, or equivalent, to permit connections.

(iii) During demolition involving combustible materials, charged hose lines, supplied by hydrants, water tank trucks with pumps, or equivalent, shall be made available.

(d) Fixed firefighting equipment

(1) Sprinkler protection.

(i) If the facility being constructed includes the installation of automatic sprinkler protection, the installation shall closely follow the construction and be placed in service as soon as applicable laws permit following completion of each story.

(ii) During demolition or alterations, existing automatic sprinkler installations shall be retained in service as long as reasonable. The operation of sprinkler control valves shall be permitted only by properly authorized persons. Modification of sprinkler systems to permit alterations or additional demolition should be expedited so that the automatic protection may be returned to service as quickly as possible. Sprinkler control valves shall be checked daily at close of work to ascertain that the protection is in service.

(2) Standpipes. In all structures in which standpipes are required, or where standpipes exist in structures being altered, they shall be brought up as soon as applicable laws permit, and shall be maintained as construction progresses in such a manner that they are always ready for fire protection use. The standpipes shall be provided with Siamese fire department connections on the outside of the structure, at the street level, which shall be conspicuously marked. There shall be at least one standard hose outlet at each floor.

(e) Fire alarm devices.

(1) An alarm system, e.g., telephone system, siren, etc., shall be established by the employer whereby employees on the site and the local fire department can be alerted for an emergency. STEP

(2) The alarm code and reporting instructions shall be conspicuously posted at phones and at employee entrances. STEP

(f) Fire cutoffs.

(1) Fire walls and exit stairways, required for the completed buildings, shall be given construction priority. Fire doors, with automatic closing devices, shall be hung on openings as soon as practicable.

(2) Fire cutoffs shall be retained in buildings undergoing alterations or demolition until

operations necessitate their removal.

1926.151 Fire prevention

(a) Ignition hazards.

(1) Electrical wiring and equipment for light, heat, or power purposes shall be installed in compliance with the requirements of Subpart K of this part.

(2) Internal combustion engine powered equipment shall be so located that the exhausts are well away from combustible materials. When the exhausts are piped to outside the building under construction, a clearance of at least 6 inches shall be maintained between such piping and combustible material.

(3) Smoking shall be prohibited at or in the vicinity of operations which constitute a fire hazard, and shall be conspicuously posted: "No Smoking or Open Flame." STEP

(4) Portable battery powered lighting equipment, used in connection with the storage, handling, or use of flammable gases or liquids, shall be of the type approved for the hazardous locations.

(5) The nozzle of air, inert gas, and steam lines or hoses, when used in the cleaning or ventilation of tanks and vessels that contain hazardous concentrations of flammable gases or vapors, shall be bonded to the tank or vessel shell. Bonding devices shall not be attached or detached in hazardous concentrations of flammable gases or vapors.

(b) Temporary buildings.

(1) No temporary building shall be erected where it will adversely affect any means of exit.

(2) Temporary buildings, when located within another building or structure, shall be of either noncombustible construction or of combustible construction having a fire resistance of not less than 1 hour. STEP

(3) Temporary buildings, located other than inside another building and not used for the storage, handling, or use of flammable or combustible liquids, flammable gases, explosives, or blasting agents, or similar hazardous occupancies, shall be located at a distance of not less than 10 feet from another building or structure. Groups of temporary buildings, not exceeding 2,000 square feet in aggregate, shall, for the purposes of this part, be considered a single temporary building.

(c) Open yard storage.

(1) Combustible materials shall be piled with due regard to the stability of piles and in no case higher than 20 feet.

(2) Driveways between and around combustible storage piles shall be at least 15 feet wide and maintained free from accumulation of rubbish, equipment, or other articles or materials. Driveways shall be so spaced that a maximum grid system unit of 50 feet by 150 feet is produced.

(3) The entire storage site shall be kept free from accumulation of unnecessary combustible materials. Weeds and grass shall be kept down and a regular procedure provided for the periodic cleanup of the entire area.

(4) When there is a danger of an underground fire, that land shall not be used for combustible or flammable storage.

(5) Method of piling shall be solid wherever possible and in orderly and regular piles. No combustible material shall be stored outdoors within 10 feet of a building or structure.

(6) Portable fire extinguishing equipment, suitable for the fire hazard involved, shall be provided at convenient, conspicuously accessible locations in the yard area. Portable fire extinguishers, rated not less than 2A, shall be placed so that maximum travel distance to the nearest unit shall not exceed 100 feet.

(d) Indoor storage.

(1) Storage shall not obstruct, or adversely affect, means of exit.

(2) All materials shall be stored, handled, and piled with due regard to their fire characteristics. STEP

(3) Noncompatible materials, which may create a fire hazard, shall be segregated by a barrier having a fire resistance of at least 1 hour.

(4) Material shall be piled to minimize the spread of fire internally and to permit convenient access for firefighting. Stable piling shall be maintained at all times. Aisle space shall be maintained to safely accommodate the widest vehicle that may be used within the building for firefighting purposes.

(5) Clearance of at least 36 inches shall be maintained between the top level of the stored material and the sprinkler deflectors.

(6) Clearance shall be maintained around lights and heating units to prevent ignition of combustible materials.

(7) A clearance of 24 inches shall be maintained around the path of travel of fire doors unless a barricade is provided, in which case no clearance is needed. Material shall not be stored within 36 inches of a fire door opening.

[44 FR 8577, Feb. 9, 1979; 44 FR 20940, Apr. 6, 1979, as amended at 51 FR 25318, July 11, 1986]

1926.152 Flammable ~~and combustible~~ liquids.

(a) General requirements.

(1) Only approved containers and portable tanks shall be used for storage and handling of flammable ~~and combustible~~ liquids. Approved safety cans or Department of Transportation approved containers shall be used for the handling and use of flammable liquids in quantities of 5 gallons or less, except that this shall not apply to those flammable liquid materials which are highly viscid (extremely hard to pour), which may be used and handled in original shipping containers. For quantities of one gallon or less, the original container may be used for storage, use and handling of flammable liquids.

(2) Flammable ~~or combustible~~ liquids shall not be stored in areas used for exits, stairways, or normally used for the safe passage of people.

STEP

(b) Indoor storage of flammable ~~and combustible~~ liquids.

(1) No more than 25 gallons of flammable ~~or combustible~~ liquids shall be stored in a room outside of an approved storage cabinet. For storage of liquefied petroleum gas, see 1926.153. STEP

(2) Quantities of flammable ~~and combustible~~ liquid in excess of 25 gallons shall be stored in an acceptable or approved cabinet meeting the following requirements:

(i) Acceptable wooden storage cabinets shall be constructed in the following manner, or equivalent: The bottom, sides, and top shall be constructed of an exterior grade of plywood at least 1 inch in thickness, which shall not break down or delaminate under standard fire test conditions. All joints shall be rabbeted and shall be fastened in two directions with flathead wood screws. When more than one door is used, there shall be a rabbeted overlap of not less than 1 inch. Steel hinges shall be mounted in such a manner as to not lose their holding capacity due to loosening or burning out of the screws when subjected to fire. Such cabinets shall be painted inside and out with fire retardant paint.

(ii) Approved metal storage cabinets will be acceptable.

(iii) ~~Cabinets shall be labeled in conspicuous lettering, "Flammable Keep Fire Away."~~ Cabinets shall be labeled in conspicuous lettering, "Flammable-Keep Away from Open Flames."

~~(3) Not more than 60 gallons of flammable or 120 gallons of combustible liquids shall be stored in any one storage cabinet. Not more than three such cabinets may be located in a single storage area. Quantities in excess of this shall be stored in an inside storage room. Not more than 60 gallons of Category 1, 2 and/or 3 flammable liquids or 120 gallons of Category 4~~

flammable liquids shall be stored in any one storage cabinet. Not more than three such cabinets may be located in a single storage area. Quantities in excess of this shall be stored in an inside storage room.

(4)

(i) Inside storage rooms shall be constructed to meet the required fire-resistive rating for their use. Such construction shall comply with the test specifications set forth in Standard Methods of Fire Test of Building Construction and Material, NFPA 251-1969.

(ii) Where an automatic extinguishing system is provided, the system shall be designed and installed in an approved manner. Openings to other rooms or buildings shall be provided with noncombustible liquid-tight raised sills or ramps at least 4 inches in height, or the floor in the storage area shall be at least 4 inches below the surrounding floor. Openings shall be provided with approved self-closing fire doors. The room shall be liquid-tight where the walls join the floor. A permissible alternate to the sill or ramp is an open-grated trench, inside of the room, which drains to a safe location. Where other portions of the building or other buildings are exposed, windows shall be protected as set forth in the Standard for Fire Doors and Windows, NFPA No. 80-1970, for Class E or F openings. Wood of at least 1-inch nominal thickness may be used for shelving, racks, dunnage, scuffboards, floor overlay, and similar installations.

(iii) Materials which will react with water and create a fire hazard shall not be stored in the same room with flammable ~~or combustible~~ liquids.

(iv) Storage in inside storage rooms shall comply with Table F-2 following:

TABLE F-2

| Fire protection provided | Fire resistance | Maximum size | Total allowable quantities gals./sq. ft./floor area |
|---------------------------------|------------------------|---------------------|--|
| Yes | 2 hrs | 500 sq. ft | 10 |
| No | 2 hrs | 500 sq. ft | 4 |
| Yes | 1 hr | 150 sq. ft | 5 |
| No | 1 hr | 150 sq. ft | 2 |

NOTE: Fire protection system shall be sprinkler, water spray, carbon dioxide or other system approved by a nationally recognized testing laboratory for this purpose.

(v) Electrical wiring and equipment located in inside storage rooms shall be approved for Class I, Division 1, Hazardous Locations. For definition of Class I, Division 1, Hazardous Locations, see 1926.449.

(vi) Every inside storage room shall be provided with either a gravity or a mechanical exhausting system. Such system shall commence not more than 12 inches above the floor and be designed to provide for a complete change of air within the room at least 6 times per hour. If a mechanical exhausting system is used, it shall be controlled by a switch located outside of the door. The ventilating equipment and any lighting fixtures shall be operated by the same switch. An electric pilot light shall be installed adjacent to the switch if Category 1, 2, or 3 flammable liquids are dispensed within the room. Where gravity ventilation is provided, the fresh air intake, as well as the exhausting outlet from the room, shall be on the exterior of the building in which the room is located.

(vii) In every inside storage room there shall be maintained one clear aisle at least 3 feet wide. Containers over 30 gallons capacity shall not be stacked one upon the other.

(viii) Flammable ~~and combustible~~ liquids in excess of that permitted in inside storage rooms shall be stored outside of buildings in accordance with paragraph (c) of this section.

(5) Quantity. The quantity of flammable or combustible liquids kept in the vicinity of spraying operations shall be the minimum required for operations and should ordinarily not exceed a supply for 1 day or one shift. Bulk storage of portable containers of flammable ~~or combustible~~ liquids shall be in a separate, constructed building detached from other important buildings or cut off in a standard manner. STEP

(c) Storage outside buildings.

(1) Storage of containers (not more than 60 gallons each) shall not exceed 1,100 gallons in any one pile or area. Piles or groups of containers shall be separated by a 5-foot clearance. Piles or groups of containers shall not be nearer than 20 feet to a building.

(2) Within 200 feet of each pile of containers, there shall be a 12-foot-wide access way to permit approach of fire control apparatus.

(3) The storage area shall be graded in a manner to divert possible spills away from buildings or other exposures, or shall be surrounded by a curb or earth dike at least 12 inches high. When curbs or dikes are used, provisions shall be made for draining off accumulations of ground or rain water, or spills of flammable ~~or combustible~~ liquids. Drains shall terminate at a safe location and shall be accessible to operation under fire conditions. STEP

(4) Outdoor portable tank storage:

(i) Portable tanks shall not be nearer than 20 feet from any building. Two or more portable tanks, grouped together, having a combined capacity in excess of 2,200 gallons, shall be separated by a 5-foot-clear area. Individual portable tanks exceeding 1,100 gallons shall

be separated by a 5-foot-clear area. STEP

(ii) Within 200 feet of each portable tank, there shall be a 12-foot-wide access way to permit approach of fire control apparatus.

(5) Storage areas shall be kept free of weeds, debris, and other combustible material not necessary to the storage. STEP

(6) Portable tanks, not exceeding 660 gallons, shall be provided with emergency venting and other devices, as required by chapters III and IV of NFPA 30-1969, The Flammable and Combustible Liquids Code.
STEP

(7) Portable tanks, in excess of 660 gallons, shall have emergency venting and other devices, as required by chapters II and III of The Flammable and Combustible Liquids Code, NFPA 30-1969.

(d) Fire control for flammable ~~or combustible~~ liquid storage.

(1) At least one portable fire extinguisher, having a rating of not less than 20-B units, shall be located outside of, but not more than 10 feet from, the door opening into any room used for storage of more than 60 gallons of flammable ~~or combustible~~ liquids.

(2) At least one portable fire extinguisher having a rating of not less than 20-B units shall be located not less than 25 feet, nor more than 75 feet, from any flammable liquid storage area located outside.
STEP

(3) When sprinklers are provided, they shall be installed in accordance with the Standard for the Installation of Sprinkler Systems, NFPA 13-1969.

(4) At least one portable fire extinguisher having a rating of not less than 20-B:C units shall be provided on all tank trucks or other vehicles used for transporting and/or dispensing flammable ~~or combustible~~ liquids.

(e) Dispensing liquids.

(1) Areas in which flammable ~~or combustible~~ liquids are transferred at one time, in quantities greater than 5 gallons from one tank or container to another tank or container, shall be separated from other operations by 25-foot distance or by construction having a fire resistance of at least 1 hour. Drainage or other means shall be provided to control spills. Adequate natural or mechanical ventilation shall be provided to maintain the concentration of flammable vapor at or below 10 percent of the lower flammable limit. STEP

(2) Transfer of Category 1, 2, or 3 flammable liquids from one container to another shall be done only when containers are electrically interconnected (bonded).

STEP

(3) Flammable ~~or combustible~~ liquids shall be drawn from or transferred into vessels, containers, or tanks within a building or outside only through a closed piping system, from safety cans, by means of a device drawing through the top, or from a container, or portable tanks, by gravity or pump, through an approved self-closing valve. Transferring by means of air pressure on the container or portable tanks is prohibited.

STEP

(4) The dispensing units shall be protected against collision damage.

STEP

(5) Dispensing devices and nozzles for Category 1, 2, or 3 flammable liquids shall be of an approved type.

(f) Handling liquids at point of final use.

(1) Category 1, 2, or 3 flammable liquids shall be kept in closed containers when not actually in use. STEP

(2) Leakage or spillage of flammable ~~or combustible~~ liquids shall be disposed of promptly and safely.

(3) Category 1, 2, or 3 flammable liquids may be used only where there are no open flames or other sources of ignition within 50 feet of the operation, unless conditions warrant greater clearance.

(g) Service and refueling areas.

(1) Flammable ~~or combustible~~ liquids shall be stored in approved closed containers, in tanks located underground, or in aboveground portable tanks. STEP

(2) The tank trucks shall comply with the requirements covered in the Standard for Tank Vehicles for Flammable and Combustible Liquids, NFPA No. 385-1966.

(3) The dispensing hose shall be an approved type. STEP

(4) The dispensing nozzle shall be an approved automatic-closing type without a latch-open device.

(5) Underground tanks shall not be abandoned.

(6) Clearly identified and easily accessible switch(es) shall be provided at a location

remote from dispensing devices to shut off the power to all dispensing devices in the event of an emergency.

(7)

(i) Heating equipment of an approved type may be installed in the lubrication or service area where there is no dispensing or transferring of Category 1, 2, or 3 flammable liquids, provided the bottom of the heating unit is at least 18 inches above the floor and is protected from physical damage.

(ii) Heating equipment installed in lubrication or service areas, where Category 1, 2, or 3 flammable liquids are dispensed, shall be of an approved type for garages, and shall be installed at least 8 feet above the floor.

(8) There shall be no smoking or open flames in the areas used for fueling, servicing fuel systems for internal combustion engines, receiving or dispensing of flammable ~~or combustible~~ liquids.

(9) Conspicuous and legible signs prohibiting smoking shall be posted.
STEP

(10) The motors of all equipment being fueled shall be shut off during the fueling operation.

(11) Each service or fueling area shall be provided with at least one fire extinguisher having a rating of not less than 20-B:C located so that an extinguisher will be within 75 feet of each pump, dispenser, underground fill pipe opening, and lubrication or service area.

STEP

(h) Scope. This section applies to the handling, storage, and use of flammable ~~and combustible~~ liquids with a flashpoint ~~below 200 F (93.33 C)~~ at or below 199.4 °F (93 °C). This section does not apply to:

(1) Bulk transportation of flammable ~~and combustible~~ liquids; and

(2) Storage, handling, and use of fuel oil tanks and containers connected with oil burning equipment.

(i) Tank storage

(1) Design and construction of tanks

(i) Materials.

(A) Tanks shall be built of steel except as provided in paragraphs (i)(1)(i)(B) through (E) of this section.

(B) Tanks may be built of materials other than steel for installation underground or if required by the properties of the liquid stored. Tanks located above ground or inside buildings shall be of noncombustible construction.

(C) Tanks built of materials other than steel shall be designed to specifications embodying principles recognized as good engineering design for the material used.

(D) Unlined concrete tanks may be used for storing flammable ~~or combustible~~ liquids having a gravity of 40 API or heavier. Concrete tanks with special lining may be used for other services provided the design is in accordance with sound engineering practice.

(E) [Reserved]

(F) Special engineering consideration shall be required if the specific gravity of the liquid to be stored exceeds that of water or if the tanks are designed to contain flammable ~~or combustible~~ liquids at a liquid temperature below 0 deg. F.

(ii) Fabrication.

(A) [Reserved]

(B) Metal tanks shall be welded, riveted, and caulked, brazed, or bolted, or constructed by use of a combination of these methods. Filler metal used in brazing shall be nonferrous metal or an alloy having a melting point above 1000 F. and below that of the metal joined.

(iii) Atmospheric tanks.

(A) Atmospheric tanks shall be built in accordance with acceptable good standards of design. Atmospheric tanks may be built in accordance with:

(1) Underwriters' Laboratories, Inc., Subjects No. 142, Standard for Steel Aboveground Tanks for Flammable and Combustible Liquids, 1968; No. 58, Standard for Steel Underground Tanks for Flammable and Combustible Liquids, Fifth Edition, December 1961; or No. 80, Standard for Steel Inside Tanks for Oil-Burner Fuel, September 1963.

(2) American Petroleum Institute Standards No. 12A, Specification for Oil Storage Tanks with Riveted Shells, Seventh Edition, September 1951, or No. 650, Welded Steel Tanks for Oil Storage, Third Edition, 1966.

(3) American Petroleum Institute Standards No. 12B, Specification for Bolted Production Tanks, Eleventh Edition, May 1958, and Supplement 1, March 1962; No. 12D, Specification for Large Welded Production Tanks, Seventh Edition, August 1957; or No. 12F, Specification for Small Welded Production Tanks, Fifth Edition, March 1961. Tanks built in accordance with these standards shall be used only as production tanks for storage of crude petroleum in oil-producing areas.

(B) Tanks designed for underground service not exceeding 2,500 gallons (9,462.5 L) capacity may be used aboveground.

(C) Low-pressure tanks and pressure vessels may be used as atmospheric tanks.

(D) Atmospheric tanks shall not be used for the storage of a flammable ~~or combustible~~ liquid at a temperature at or above its boiling point.

(iv) Low pressure tanks.

(A) The normal operating pressure of the tank shall not exceed the design pressure of the tank.

(B) Low-pressure tanks shall be built in accordance with acceptable standards of design. Low-pressure tanks may be built in accordance with:

(1) American Petroleum Institute Standard No. 620. Recommended Rules for the Design and Construction of Large, Welded, Low-Pressure Storage Tanks, Third Edition, 1966.

(2) The principles of the Code for Unfired Pressure Vessels, Section VIII of the ASME Boiler and Pressure Vessels Code, 1968.

(C) Atmospheric tanks built according to Underwriters' Laboratories, Inc., requirements in paragraph (i)(1)(iii)(A) of this section and shall be limited to 2.5 p.s.i.g. under emergency venting conditions. This paragraph may be used for operating pressures not exceeding 1 p.s.i.g.

(D) Pressure vessels may be used as low-pressure tanks.

(v) Pressure vessels.

(A) The normal operating pressure of the vessel shall not exceed the design pressure of the vessel.

(B) Pressure vessels shall be built in accordance with the Code for

Unfired Pressure Vessels, Section VIII of the ASME Boiler and Pressure Vessel Code 1968.

(vi) Provisions for internal corrosion. When tanks are not designed in accordance with the American Petroleum Institute, American Society of Mechanical Engineers, or the Underwriters' Laboratories, Inc.'s, standards, or if corrosion is anticipated beyond that provided for in the design formulas used, additional metal thickness or suitable protective coatings or linings shall be provided to compensate for the corrosion loss expected during the design life of the tank.

(2) Installation of outside aboveground tanks.

(i) [Reserved]

(ii) Spacing (shell-to-shell) between aboveground tanks.

(A) The distance between any two flammable ~~or combustible~~ liquid storage tanks shall not be less than 3 feet (0.912 m).

(B) Except as provided in paragraph (i)(2)(ii)(C) of this section, the distance between any two adjacent tanks shall not be less than one-sixth the sum of their diameters. When the diameter of one tank is less than one-half the diameter of the adjacent tank, the distance between the two tanks shall not be less than one-half the diameter of the smaller tank.

(C) Where crude petroleum in conjunction with production facilities are located in noncongested areas and have capacities not exceeding 126,000 gallons (3,000 barrels), the distance between such tanks shall not be less than 3 feet (0.912 m).

(D) Where unstable flammable ~~or combustible~~ liquids are stored, the distance between such tanks shall not be less than one-half the sum of their diameters.

(E) When tanks are compacted in three or more rows or in an irregular pattern, greater spacing or other means shall be provided so that inside tanks are accessible for firefighting purposes.

(F) The minimum separation between a liquefied petroleum gas container and a flammable ~~or combustible~~ liquid storage tank shall be feet (6.08 m),, except in the case of flammable ~~or combustible~~ liquid tanks operating at pressures exceeding 2.5 p.s.i.g. or equipped with emergency venting which will permit pressures to exceed 2.5 p.s.i.g. in which case the provisions of paragraphs (i)(2)(ii) (A) and (B) of this section shall apply. Suitable means shall be taken to prevent the accumulation of flammable ~~or combustible~~ liquids under adjacent liquefied petroleum gas containers such as by diversion curbs or grading. When flammable ~~or combustible~~ liquid storage tanks are within a diked area, the liquefied petroleum gas containers shall be outside the diked area and at least 10 feet (3.04 m) away from the centerline of the wall of the diked area. The foregoing provisions shall not apply when liquefied petroleum gas containers of

125 gallons (473.125 L) or less capacity are installed adjacent to fuel oil supply tanks of 550 gallons (2,081.75 L) or less capacity.

(iii) [Reserved]

(iv) Normal venting for aboveground tanks.

(A) Atmospheric storage tanks shall be adequately vented to prevent the development of vacuum or pressure sufficient to distort the roof of a cone roof tank or exceeding the design pressure in the case of other atmospheric tanks, as a result of filling or emptying, and atmospheric temperature changes.

(B) Normal vents shall be sized either in accordance with:

(1) The American Petroleum Institute Standard 2000 (1968), Venting Atmospheric and Low-Pressure Storage Tanks; or

(2) other accepted standard; or

(3) shall be at least as large as the filling or withdrawal connection, whichever is larger but in no case less than 1 1/4 inch (3.175 cm) nominal inside diameter.

(C) Low-pressure tanks and pressure vessels shall be adequately vented to prevent development of pressure or vacuum, as a result of filling or emptying and atmospheric temperature changes, from exceeding the design pressure of the tank or vessel. Protection shall also be provided to prevent overpressure from any pump discharging into the tank or vessel when the pump discharge pressure can exceed the design pressure of the tank or vessel.

(D) If any tank or pressure vessel has more than one fill or withdrawal connection and simultaneous filling or withdrawal can be made, the vent size shall be based on the maximum anticipated simultaneous flow.

(E) Unless the vent is designed to limit the internal pressure 2.5 p.s.i. or less, the outlet of vents and vent drains shall be arranged to discharge in such a manner as to prevent localized overheating of any part of the tank in the event vapors from such vents are ignited.

~~(F) Tanks and pressure vessels storing Class IA liquids shall be equipped with venting devices which shall be normally closed except when venting to pressure or vacuum conditions. Tanks and pressure vessels storing Class IB and IC liquids shall be equipped with venting devices which shall be normally closed except when venting under pressure or vacuum conditions, or with approved flame arresters.~~

~~Exemption: Tanks of 3,000 bbls. (84 m(3)) capacity or less containing crude petroleum in crude producing areas; and, outside aboveground atmospheric tanks under 1,000 gallons (3,785 L) capacity containing other than Class IA flammable liquids may have open vents. (See paragraph (i)(2)(vi)(B) of this section.) Tanks and pressure vessels storing Category 1 flammable liquids shall be equipped with venting devices that shall be normally closed except when venting to pressure or vacuum conditions. Tanks and pressure vessels storing Category 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be equipped with venting devices that shall be normally closed except when venting under pressure or vacuum conditions, or with approved flame arresters.~~

Exemption: Tanks of 3,000 bbls (barrels) (84 m(3)) capacity or less containing crude petroleum in crude-producing areas; and, outside aboveground atmospheric tanks under 1,000 gallons (3,785 L) capacity containing other than Category 1 flammable liquids may have open vents. (See paragraph (i)(2)(vi)(B) of this section.)

~~(G) Flame arresters or venting devices required in paragraph (i)(2)(iv)(F) of this section may be omitted for Class IB and IC liquids where conditions are such that their use may, in case of obstruction, result in tank damage. Flame arresters or venting devices required in paragraph (i)(2)(iv)(F) of this section may be omitted for Category 2 flammable liquids or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C) where conditions are such that their use may, in case of obstruction, result in tank damage.~~

(v) Emergency relief venting for fire exposure for aboveground tanks.

(A) Every aboveground storage tank shall have some form of construction or device that will relieve excessive internal pressure caused by exposure fires.

(B) In a vertical tank the construction referred to in paragraph (i)(2)(v)(A) of this section may take the form of a floating roof, lifter roof, a weak roof-to-shell seam, or other approved pressure relieving construction. The weak roof-to-shell seam shall be constructed to fail preferential to any other seam.

(C) Where entire dependence for emergency relief is placed upon pressure relieving devices, the total venting capacity of both normal and emergency vents shall be enough to prevent rupture of the shell or bottom of the tank if vertical, or of the shell or heads if horizontal. If unstable liquids are stored, the effects of heat or gas resulting from polymerization, decomposition, condensation, or self-reactivity shall be taken into account. The total capacity of both normal and emergency venting devices shall be not less than that derived from Table F-10 except as provided in paragraph (i)(2)(v) (E) or (F) of this section. Such device may be a self-closing manhole cover, or one using long bolts that permit the cover to lift under internal pressure, or an additional or larger relief valve or valves. The wetted area of the tank shall be calculated on the basis of 55 percent of the total exposed area of a sphere or spheroid, 75 percent of the total exposed area of a horizontal tank and the first 30 feet (9.12 m) above grade of the exposed shell area of a vertical tank.

TABLE F-10 - WETTED AREA VERSUS CUBIC FEET FREE AIR PER HOUR

[14.7 psia and 60 deg. F.]

| Square feet (m ²) | CFH (m ³ H) | Square feet (m ²) | CFH (m ³ H) | Square feet (m ²) | CFH (m ³ H) |
|----------------------------------|------------------------|----------------------------------|------------------------|----------------------------------|------------------------|
| 20 (1.84) | 21,100 (590.8) | 200 (18.4) | 211,000 (5,908) | 1,000 (90.2) | 524,000 (14,672) |
| 30 (2.76) | 31,600 (884.8) | 250 (23) | 239,000 (6,692) | 1,200 (110.4) | 557,000 (15,596) |
| 40 (3.68) | 42,100 (1,178.8) | 300 (27.6) | 265,000 (7,420) | 1,400 (128.8) | 587,000 (16,436) |
| 50 (4.6) | 52,700 (1,475.6) | 350 (32.2) | 288,000 (8,064) | 1,600 (147.2) | 614,000 (17,192) |
| 60 (5.52) | 63,200 (1,769.6) | 400 (36.8) | 312,000 (8,736) | 1,800 (165.6) | 639,000 (17,892) |
| 70 (6.44) | 73,700 (2,063.6) | 500 (46) | 354,000 (9,912) | 2,000 (180.4) | 662,000 (18,536) |
| 80 (7.36) | 84,200 (2,357.6) | 600 (55.2) | 392,000 (10,976) | 2,400 (220.8) | 704,000 (19,712) |
| 90 (8.28) | 94,800 (2,654.4) | 700 (64.4) | 428,000 (11,984) | 2,800 (257.6) | 742,000 (20,776) |
| 100 (9.2) | 105,000 (2,940) | 800 (73.6) | 462,000 (12,936) | and | |
| 120 (11.04) | 126,000 (3,528) | 900 (82.8) | 493,000 (13,804) | over | |
| 140 (12.88) | 147,000 (4,116) | 1,000 (90.2) | 524,000 (14,672) | | |
| 160 (14.72) | 168,000 (4,704) | | | | |
| 180 (16.56) | 190,000 (5,320) | | | | |
| 200 (18.4) | 211,000 (5,908) | | | | |

(D) For tanks and storage vessels designed for pressure over 1 p.s.i.g., the total rate of venting shall be determined in accordance with Table F-10, except that when the exposed wetted area of the surface is greater than 2,800 square feet (257.6 m²), the total rate of venting shall be calculated by the following formula:

$$CFH = 1,107A(0.82)$$

Where:

CFH = Venting requirement, in cubic feet (meters) of free air per hour.

A = Exposed wetted surface, in square feet (m²).

NOTE: The foregoing formula is based on $Q = 21,000A(0.82)$.

(E) The total emergency relief venting capacity for any specific stable liquid may be determined by the following formula:

$$V = 1337 \text{ divided by } L \text{ square root of } M$$

V = Cubic feet (meters) of free air per hour from Table F-10.

L = Latent heat of vaporization of specific liquid in B.t.u. per pound.

M = Molecular weight of specific liquids.

(F) The required airflow rate of paragraph (i)(2)(v) (C) or (E) of this section may be multiplied by the appropriate factor listed in the following schedule when protection is provided as indicated. Only one factor may be used for any one tank.

0.5 for drainage in accordance with paragraph (i)(2)(vii)(B) of this section for tanks over 200 square feet (18.4 m²) of wetted area.

0.3 for approved water spray.

0.3 for approved insulation.

0.15 for approved water spray with approved insulation.

(G) The outlet of all vents and vent drains on tanks equipped with emergency venting to permit pressures exceeding 2.5 p.s.i.g. shall be arranged to discharge in such a way as to prevent localized overheating of any part of the tank, in the event vapors from such vents are ignited.

(H) Each commercial tank venting device shall have stamped on it the opening pressure, the pressure at which the valve reaches the full open position, and the flow capacity at the latter pressure, expressed in cubic feet (meters) per hour of air at 60 deg. F. (15.55 C) and at a pressure of 14.7 p.s.i.a.

(I) The flow capacity of tank venting devices 12 inches (30.48 cm) and smaller in nominal pipe size shall be determined by actual test of each type and size of vent.

These flow tests may be conducted by the manufacturer if certified by a qualified impartial observer, or may be conducted by an outside agency. The flow capacity of tank venting devices larger than 12 inches (30.48 cm) nominal pipe size, including manhole covers with long bolts or equivalent, may be calculated provided that the opening pressure is actually measured, the rating pressure and corresponding free orifice area are stated, the word "calculated" appears on the nameplate, and the computation is based on a flow coefficient of 0.5 applied to the rated orifice area.

(vi) Vent piping for aboveground tanks.

(A) Vent piping shall be constructed in accordance with paragraph (c) of this section.

~~(B) Where vent pipe outlets for tanks storing Class I liquids are adjacent to buildings or public ways, they shall be located so that the vapors are released at a safe point outside of buildings and not less than 12 feet (3.648 m) above the adjacent ground level. In order to aid their dispersion, vapors shall be discharged upward or horizontally away from closely adjacent walls. Vent outlets shall be located so that flammable vapors will not be trapped by eaves or other obstructions and shall be at least 5 feet (1.52 m) from building openings.~~ Where vent pipe outlets for tanks storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are adjacent to buildings or public ways, they shall be located so that the vapors are released at a safe point outside of buildings and not less than 12 feet (3.658 m) above the adjacent ground level. In order to aid their dispersion, vapors shall be discharged upward or horizontally away from closely adjacent walls. Vent outlets shall be located so that flammable vapors will not be trapped by eaves or other obstructions and shall be at least 5 feet (1.52 m) from building openings.

(C) When tank vent piping is manifolded, pipe sizes shall be such as to discharge, within the pressure limitations of the system, the vapors they may be required to handle when manifolded tanks are subject to the same fire exposure.

(vii) Drainage, dikes, and walls for aboveground tanks
STD 1-5.2

(A) Drainage and diked areas. The area surrounding a tank or a group of tanks shall be provided with drainage as in paragraph (i)(2)(vii)(B) of this section, or shall be diked as provided in subdivision (i)(2)(vii)(C) of this section, to prevent accidental discharge of liquid from endangering adjoining property or reaching waterways.

(B) Drainage. Where protection of adjoining property or waterways is by means of a natural or manmade drainage system, such systems shall comply with the following:

(1) [Reserved]

(2) The drainage system shall terminate in vacant land or other area or in an impounding basin having a capacity not smaller than that of the largest tank served. This termination area and the route of the drainage system shall be so located that, if the flammable or combustible liquids in the drainage system are ignited, the fire will not seriously expose tanks or adjoining property.

(C) Diked areas. Where protection of adjoining property or waterways is accomplished by retaining the liquid around the tank by means of a dike, the volume of the diked area shall comply with the following requirements:

(1) Except as provided in paragraph (i)(2)(vii)(C)(2) of this section, the volumetric capacity of the diked area shall not be less than the greatest amount of liquid that can be released from the largest tank within the diked area, assuming a full tank. The capacity of the diked area enclosing more than one tank shall be calculated by deducting the volume of the tanks other than the largest tank below the height of the dike.

(2) For a tank or group of tanks with fixed roofs containing crude petroleum with boilover characteristics, the volumetric capacity of the diked area shall be not less than the capacity of the largest tank served by the enclosure, assuming a full tank. The capacity of the diked enclosure shall be calculated by deducting the volume below the height of the dike of all tanks within the enclosure.

(3) Walls of the diked area shall be of earth, steel, concrete or solid masonry designed to be liquidtight and to withstand a full hydrostatic head. Earthen walls 3 feet (0.912 m) or more in height shall have a flat section at the top not less than 2 feet (0.608 m) wide. The slope of an earthen wall shall be consistent with the angle of repose of the material of which the wall is constructed.

(4) The walls of the diked area shall be restricted to an average height of 6 feet (1.824 m) above interior grade.

STD 1-5.4

(5) [Reserved]

(6) No loose combustible material, empty or full drum or barrel, shall be permitted within the diked area.

(viii) Tank openings other than vents for aboveground tanks.

(A)-(C) [Reserved]

(D) Openings for gaging shall be provided with a vaportight cap or cover.

~~(E) For Class IB and Class IC liquids other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity. A fill pipe entering the top of a tank shall terminate within 6 inches (15.24 cm) of the bottom of the tank and shall be installed to avoid excessive vibration. For Category 2 flammable liquids or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity. A fill pipe entering the top of a tank shall terminate within 6 inches (15.24 cm) of the bottom of the tank and shall be installed to avoid excessive vibration.~~

(F) Filling and emptying connections which are made and broken shall be located outside of buildings at a location free from any source of ignition and not less than 5 feet (1.52 m) away from any building opening. Such connection shall be closed and liquidtight when not in use. The connection shall be properly identified.

(3) Installation of underground tanks

~~(i) Location. Excavation for underground storage tanks shall be made with due care to avoid undermining of foundations of existing structures. Underground tanks or tanks under buildings shall be so located with respect to existing building foundations and supports that the loads carried by the latter cannot be transmitted to the tank. The distance from any part of a tank storing Class I liquids to the nearest wall of any basement or pit shall be not less than 1 foot (0.304 m), and to any property line that may be built upon, not less than 3 feet (0.912 m). The distance from any part of a tank storing Class II or Class III liquids to the nearest wall of any basement, pit or property line shall be not less than 1 foot (0.304 m). Evacuation for underground storage tanks shall be made with due care to avoid undermining of foundations of existing structures. Underground tanks or tanks under buildings shall be so located with respect to existing building foundations and supports that the loads carried by the latter cannot be transmitted to the tank. The distance from any part of a tank storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), to the nearest wall of any basement or pit shall be not less than 1 foot (0.304 m), and to any property line that may be built upon, not less than 3 feet (0.912 m). The distance from any part of a tank storing Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids to the nearest wall of any basement, pit or property line shall be not less than 1 foot (0.304 m).~~

(ii) Depth and cover. Underground tanks shall be set on firm foundations and surrounded with at least 6 inches (15.24 cm) of noncorrosive, inert materials such as clean sand, earth, or gravel well tamped in place. The tank shall be placed in the hole with care since dropping or rolling the tank into the hole can break a weld, puncture or damage the tank, or scrape off the protective coating of coated tanks. Tanks shall be covered with a minimum of 2 feet (0.608 m) of earth, or shall be covered with not less than 1 foot (0.304 m) of earth, on top of which shall be placed a slab of reinforced concrete not less than 4 inches (10.16 cm) thick. When underground tanks are, or are likely to be, subject to traffic, they shall be protected against

damage from vehicles passing over them by at least 3 feet (0.912 m) of earth cover, or 18 inches (45.72 cm) of well-tamped earth, plus 6 inches (15.24 cm) of reinforced concrete or 8 inches (20.32 cm) of asphaltic concrete. When asphaltic or reinforced concrete paving is used as part of the protection, it shall extend at least 1 foot (0.304 m) horizontally beyond the outline of the tank in all directions.

(iii) Corrosion protection. Corrosion protection for the tank and its piping shall be provided by one or more of the following methods:

(A) Use of protective coatings or wrappings;

(B) Cathodic protection; or,

(C) Corrosion resistant materials of construction.

(iv) Vents.

~~(A) Location and arrangement of vents for Class I liquids. Vent pipes from tanks storing Class I liquids shall be so located that the discharge point is outside of buildings, higher than the fill pipe opening, and not less than 12 feet (3.648 m) above the adjacent ground level. Vent pipes shall discharge only upward in order to disperse vapors. Vent pipes 2 inches (5.08 cm) or less in nominal inside diameter shall not be obstructed by devices that will cause excessive back pressure. Vent pipe outlets shall be so located that flammable vapors will not enter building openings, or be trapped under eaves or other obstructions. If the vent pipe is less than 10 feet (3.04 m) in length, or greater than 2 inches (5.08 cm) in nominal inside diameter, the outlet shall be provided with a vacuum and pressure relief device or there shall be an approved flame arrester located in the vent line at the outlet or within the approved distance from the outlet.~~ Location and arrangement of vents for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C). Vent pipes from tanks storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be so located that the discharge point is outside of buildings, higher than the fill pipe opening, and not less than 12 feet (3.658 m) above the adjacent ground level. Vent pipes shall discharge only upward in order to disperse vapors. Vent pipes 2 inches (5.08 cm) or less in nominal inside diameter shall not be obstructed by devices that will cause excessive back pressure. Vent pipe outlets shall be so located that flammable vapors will not enter building openings, or be trapped under eaves or other obstructions. If the vent pipe is less than 10 feet (3.04 m) in length, or greater than 2 inches (5.08 cm) in nominal inside diameter, the outlet shall be provided with a vacuum and pressure relief device or there shall be an approved flame arrester located in the vent line at the outlet or within the approved distance from the outlet.

(B) Size of vents. Each tank shall be vented through piping adequate in size to prevent blow-back of vapor or liquid at the fill opening while the tank is being filled. Vent pipes shall be not less than 1 1/4 inch (3.175 cm) nominal inside diameter.

TABLE F-11 - VENT LINE DIAMETERS

| Maximum flow GPM (L) | Pipe length ¹ | | |
|----------------------|--------------------------|-------------------|-------------------|
| | 50 feet (15.2 m) | 100 feet (30.4 m) | 200 feet (60.8 m) |
| | Inches (cm) | Inches (cm) | Inches (cm) |
| 100 (378.5) | 1 1/4 (3.175) | 1 1/4 (3.175) | 1 1/4 (3.175) |
| 200 (757) | 1 1/4 (3.175) | 1 1/4 (3.175) | 1 1/4 (3.175) |
| 300 (1,135.5) | 1 1/4 (3.175) | 1 1/4 (3.175) | 1 1/2 (3.81) |
| 400 (1,514) | 1 1/4 (3.175) | 1 1/2 (3.81) | 2 (5.08) |
| 500 (1,892.5) | 1 1/2 (3.81) | 1 1/2 (3.81) | 2 (5.08) |
| 600 (2,271) | 1 1/2 (3.81) | 2 (5.08) | 2 (5.08) |
| 700 (2,649.5) | 2 (5.08) | 2 (5.08) | 2 (5.08) |
| 800 (3,028) | 2 (5.08) | 2 (5.08) | 3 (7.62) |
| 900 (3,406.5) | 2 (5.08) | 2 (5.08) | 3 (7.62) |
| 1,000 (3,785) | 2 (5.08) | 2 (5.08) | 3 (7.62) |

FOOTNOTE(1) Vent lines of 50 ft., 100 ft., and 200 ft. of pipe plus 7 ells.

~~(C) Location and arrangement of vents for Class II or Class III liquids. Vent pipes from tanks storing Class II or Class III flammable liquids shall terminate outside of the building and higher than the fill pipe opening. Vent outlets shall be above normal snow level. They may be fitted with return bends, coarse screens or other devices to minimize ingress of foreign material.~~ Location and arrangement of vents for Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids. Vent pipes from tanks storing Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids shall terminate outside of the building and higher than the fill pipe opening. Vent outlets shall be above normal snow level. They may be fitted with return bends, coarse screens or other devices to minimize ingress of foreign material.

(D) Vent piping shall be constructed in accordance with paragraph (3)(iv)(C) of this section. Vent pipes shall be so laid as to drain toward the tank without sags or traps in which liquid can collect. They shall be located so that they will not be subjected to physical damage. The tank end of the vent pipe shall enter the tank through the top.

(E) When tank vent piping is manifolded, pipe sizes shall be such as to discharge, within the pressure limitations of the system, the vapors they may be required to handle when manifolded tanks are filled simultaneously.

(v) Tank openings other than vents.

(A) Connections for all tank openings shall be vapor or liquid tight.

(B) Openings for manual gaging, if independent of the fill pipe, shall be provided with a liquid-tight cap or cover. If inside a building, each such opening shall be protected against liquid overflow and possible vapor release by means of a spring loaded check valve or other approved device.

(C) Fill and discharge lines shall enter tanks only through the top. Fill lines shall be sloped toward the tank.

~~(D) For Class IB and Class IC liquids other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity by terminating within 6 inches (15.24 cm) of the bottom of the tank. For Category 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity by terminating within 6 inches (15.24 cm) of the bottom of the tank.~~

(E) Filling and emptying connections which are made and broken shall be located outside of buildings at a location free from any source of ignition and not less than 5 feet (1.52 m) away from any building opening. Such connection shall be closed and liquidtight when not in use. The connection shall be properly identified.

(4) Installation of tanks inside of buildings

(i) Location. Tanks shall not be permitted inside of buildings except as provided in paragraphs (e), (g), (h), or (i) of this section.

(ii) Vents. Vents for tanks inside of buildings shall be as provided in paragraphs (i)(2) (iv), (v), (vi)(b), and (3)(iv) of this section, except that emergency venting by the use of weak roof seams on tanks shall not be permitted. Vents shall discharge vapors outside the buildings.

(iii) Vent piping. Vent piping shall be constructed in accordance with paragraph (c) of this section.

(iv) Tank openings other than vents.

(A) Connections for all tank openings shall be vapor or liquidtight. Vents are covered in paragraph (i)(4)(ii) of this section.

(B) Each connection to a tank inside of buildings through which liquid can normally flow shall be provided with an internal or an external valve located as close as practical to the shell of the tank. Such valves, when external, and their connections to the tank shall be of steel except when the chemical characteristics of the liquid stored are incompatible with steel. When materials other than steel are necessary, they shall be suitable for the pressures, structural stresses, and temperatures involved, including fire exposures.

(C) ~~Flammable or combustible~~ liquid tanks located inside of buildings, except in one-story buildings designed and protected for flammable ~~or combustible~~ liquid storage, shall be provided with an automatic-closing heat-actuated valve on each withdrawal connection below the liquid level, except for connections used for emergency disposal, to prevent continued flow in the event of fire in the vicinity of the tank. This function may be incorporated in the valve required in paragraph (i)(4)(iv)(B) of this section, and if a separate valve, shall be located adjacent to the valve required in paragraph (i)(4)(iv)(B) of this section.

(D) Openings for manual gaging, if independent of the fill pipe (see paragraph (i)(4)(iv)(F) of this section), shall be provided with a vaportight cap or cover. Each such opening shall be protected against liquid overflow and possible vapor release by means of a spring loaded check valve or other approved device.

~~(E) For Class IB and Class IC liquids other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity by terminating within 6 inches (15.24 cm) of the bottom of the tank. For Category 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity by terminating within 6 inches (15.24 cm) of the bottom of the tank.~~

(F) The fill pipe inside of the tank shall be installed to avoid excessive vibration of the pipe.

(G) The inlet of the fill pipe shall be located outside of buildings at a location free from any source of ignition and not less than 5 feet (1.52 m) away from any building opening. The inlet of the fill pipe shall be closed and liquidtight when not in use. The fill connection shall be properly identified.

(H) Tanks inside buildings shall be equipped with a device, or other means shall be provided, to prevent overflow into the building.

(5) Supports, foundations, and anchorage for all tank locations

(i) General. Tank supports shall be installed on firm foundations. Tank supports shall be of concrete, masonry, or protected steel. Single wood timber supports (not cribbing) laid horizontally may be used for outside aboveground tanks if not more than 12 inches (30.48 cm) high at their lowest point.

(ii) Fire resistance. Steel supports or exposed piling shall be protected by materials having a fire resistance rating of not less than 2 hours, except that steel saddles need not be protected if less than 12 inches (30.48 cm) high at their lowest point. Water spray protection or its equivalent may be used in lieu of fire-resistive materials to protect supports.

(iii) Spheres. The design of the supporting structure for tanks such as spheres shall receive special engineering consideration.

(iv) Load distribution. Every tank shall be so supported as to prevent the excessive concentration of loads on the supporting portion of the shell.

(v) Foundations. Tanks shall rest on the ground or on foundations made of concrete, masonry, piling, or steel. Tank foundations shall be designed to minimize the possibility of uneven settling of the tank and to minimize corrosion in any part of the tank resting on the foundation.

(vi) Flood areas. Where a tank is located in an area that may be subjected to flooding, the applicable precautions outlined in this subdivision shall be observed.

(A) No aboveground vertical storage tank containing a flammable or combustible liquid shall be located so that the allowable liquid level within the tank is below the established maximum flood stage, unless the tank is provided with a guiding structure such as described in paragraphs (i)(5)(vi) (M), (N), and (O) of this section.

(B) Independent water supply facilities shall be provided at locations where there is no ample and dependable public water supply available for loading partially empty tanks with water.

(C) In addition to the preceding requirements, each tank so located that more than 70 percent, but less than 100 percent, of its allowable liquid storage capacity will be submerged at the established maximum flood stage, shall be safeguarded by one of the following methods: Tank shall be raised, or its height shall be increased, until its top extends above the maximum flood stage a distance equivalent to 30 percent or more of its allowable liquid storage capacity: Provided, however, That the submerged part of the tank shall not exceed two and one-half times the diameter. Or, as an alternative to the foregoing, adequate noncombustible structural guides, designed to permit the tank to float vertically without loss of product, shall be provided.

(D) Each horizontal tank so located that more than 70 percent of its

storage capacity will be submerged at the established flood stage, shall be anchored, attached to a foundation of concrete or of steel and concrete, of sufficient weight to provide adequate load for the tank when filled with flammable ~~or combustible~~ liquid and submerged by flood waters to the established flood stage, or adequately secured by other means.

(E) [Reserved]

(F) At locations where there is no ample and dependable water supply, or where filling of underground tanks with liquids is impracticable because of the character of their contents, their use, or for other reasons, each tank shall be safeguarded against movement when empty and submerged by high ground water or flood waters by anchoring, weighting with concrete or other approved solid loading material, or securing by other means. Each such tank shall be so constructed and installed that it will safely resist external pressures due to high ground water or flood waters.

(G) At locations where there is an ample and dependable water supply available, underground tanks containing flammable ~~or combustible~~ liquids, so installed that more than 70 percent of their storage capacity will be submerged at the maximum flood stage, shall be so anchored, weighted, or secured by other means, as to prevent movement of such tanks when filled with flammable ~~or combustible~~ liquids, and submerged by flood waters to the established flood stage.

(H) Pipe connections below the allowable liquid level in a tank shall be provided with valves or cocks located as closely as practicable to the tank shell. Such valves and their connections to tanks shall be of steel or other material suitable for use with the liquid being stored. Cast iron shall not be permitted.

(I) At locations where an independent water supply is required, it shall be entirely independent of public power and water supply. Independent source of water shall be available when flood waters reach a level not less than 10 feet (3.04 m) below the bottom of the lowest tank on a property.

(J) The self-contained power and pumping unit shall be so located or so designed that pumping into tanks may be carried on continuously throughout the rise in flood waters from a level 10 feet (3.04 m) below the lowest tank to the level of the potential flood stage.

(K) Capacity of the pumping unit shall be such that the rate of rise of water in all tanks shall be equivalent to the established potential average rate of rise of flood waters at any stage.

(L) Each independent pumping unit shall be tested periodically to insure that it is in satisfactory operating condition.

(M) Structural guides for holding floating tanks above their foundations shall be so designed that there will be no resistance to the free rise of a tank, and shall be constructed of noncombustible material.

(N) The strength of the structure shall be adequate to resist lateral movement of a tank subject to a horizontal force in any direction equivalent to not less than 25 pounds per square foot (1.05 kg m(2)) acting on the projected vertical cross-sectional area of the tank.

(O) Where tanks are situated on exposed points or bends in a shoreline where swift currents in flood waters will be present, the structures shall be designed to withstand a unit force of not less than 50 pounds per square foot (2.1 kg m(2)).

(P) The filling of a tank to be protected by water loading shall be started as soon as flood waters reach a dangerous flood stage. The rate of filling shall be at least equal to the rate of rise of the floodwaters (or the established average potential rate of rise).

(Q) Sufficient fuel to operate the water pumps shall be available at all times to insure adequate power to fill all tankage with water.

(R) All valves on connecting pipelines shall be closed and locked in closed position when water loading has been completed.

(S) Where structural guides are provided for the protection of floating tanks, all rigid connections between tanks and pipelines shall be disconnected and blanked off or blinded before the floodwaters reach the bottom of the tank, unless control valves and their connections to the tank are of a type designed to prevent breakage between the valve and the tank shell.

(T) All valves attached to tanks other than those used in connection with water loading operations shall be closed and locked.

(U) If a tank is equipped with a swing line, the swing pipe shall be raised to and secured at its highest position.

(V) Inspections. The Assistant Secretary or his designated representative shall make periodic inspections of all plants where the storage of flammable ~~or combustible~~ liquids is such as to require compliance with the foregoing requirements, in order to assure the following:

(1) That all flammable ~~or combustible~~ liquid storage tanks are in compliance with these requirements and so maintained.

(2) That detailed printed instructions of what to do in flood emergencies are properly posted.

(3) That station operators and other employees depended upon to carry out such instructions are thoroughly informed as to the location and operation of such valves and other equipment necessary to effect these requirements.

(vii) Earthquake areas. In areas subject to earthquakes, the tank supports and connections shall be designed to resist damage as a result of such shocks.

(6) Sources of ignition. In locations where flammable vapors may be present, precautions shall be taken to prevent ignition by eliminating or controlling sources of ignition. Sources of ignition may include open flames, lightning, smoking, cutting and welding, hot surfaces, frictional heat, sparks (static, electrical, and mechanical), spontaneous ignition, chemical and physical-chemical reactions, and radiant heat.

(7) Testing

(i) General. All tanks, whether shop built or field erected, shall be strength tested before they are placed in service in accordance with the applicable paragraphs of the code under which they were built. The American Society of Mechanical Engineers (ASME) code stamp, American Petroleum Institute (API) monogram, or the label of the Underwriters' Laboratories, Inc., on a tank shall be evidence of compliance with this strength test. Tanks not marked in accordance with the above codes shall be strength tested before they are placed in service in accordance with good engineering principles and reference shall be made to the sections on testing in the codes listed in paragraphs (i)(1) (iii)(A), (iv)(B), or (v)(B) of this section.

(ii) Strength. When the vertical length of the fill and vent pipes is such that when filled with liquid the static head imposed upon the bottom of the tank exceeds 10 pounds per square inch (68.94 kPa), the tank and related piping shall be tested hydrostatically to a pressure equal to the static head thus imposed.

(iii) Tightness. In addition to the strength test called for in paragraphs (i)(7) (i) and (ii) of this section, all tanks and connections shall be tested for tightness. Except for underground tanks, this tightness test shall be made at operating pressure with air, inert gas, or water prior to placing the tank in service. In the case of field-erected tanks the strength test may be considered to be the test for tank tightness. Underground tanks and piping, before being covered, enclosed, or placed in use, shall be tested for tightness hydrostatically, or with air pressure at not less than 3 pounds per square inch (20.68 kPa) and not more than 5 pounds per square inch (34.47 kPa).

(iv) Repairs. All leaks or deformations shall be corrected in an acceptable manner before the tank is placed in service. Mechanical caulking is not permitted for correcting leaks in welded tanks except pinhole leaks in the roof.

(v) Derated operations. Tanks to be operated at pressures below their design

pressure may be tested by the applicable provisions of paragraphs (i)(7) (i) or (ii) of this section, based upon the pressure developed under full emergency venting of the tank.

(j) Piping, valves, and fittings

(1) General

(i) Design. The design (including selection of materials) fabrication, assembly, test, and inspection of piping systems containing flammable ~~or combustible~~ liquids shall be suitable for the expected working pressures and structural stresses. Conformity with the applicable provisions of Pressure Piping, ANSI B31 series and the provisions of this paragraph, shall be considered prima facie evidence of compliance with the foregoing provisions.

(ii) Exceptions. This paragraph does not apply to any of the following:

(A) Tubing or casing on any oil or gas wells and any piping connected directly thereto.

(B) Motor vehicle, aircraft, boat, or portable or stationary engines.

(C) Piping within the scope of any applicable boiler and pressures vessel code.

(iii) Definitions. As used in this paragraph, piping systems consist of pipe, tubing, flanges, bolting, gaskets, valves, fittings, the pressure containing parts of other components such as expansion joints and strainers, and devices which serve such purposes as mixing, separating, snubbing, distributing, metering, or controlling flow.

(2) Materials for piping, valves, and fittings

(i) Required materials. Materials for piping, valves, or fittings shall be steel, nodular iron, or malleable iron, except as provided in paragraphs (j)(2) (ii), (iii) and (iv) of this section.

(ii) Exceptions. Materials other than steel, nodular iron, or malleable iron may be used underground, or if required by the properties of the flammable ~~or combustible~~ liquid handled. Material other than steel, nodular iron, or malleable iron shall be designed to specifications embodying principles recognized as good engineering practices for the material used.

(iii) Linings. Piping, valves, and fittings may have combustible or noncombustible linings.

(iv) Low-melting materials. When low-melting point materials such as

aluminum and brass or materials that soften on fire exposure such as plastics, or non-ductile materials such as cast iron, are necessary, special consideration shall be given to their behavior on fire exposure. If such materials are used in above ground piping systems or inside buildings, they shall be suitably protected against fire exposure or so located that any spill resulting from the failure of these materials could not unduly expose persons, important buildings or structures or can be readily controlled by remote valves.

(3) Pipe joints. Joints shall be made liquid tight. Welded or screwed joints or approved connectors shall be used. Threaded joints and connections shall be made up tight with a suitable lubricant or piping compound. Pipe joints dependent upon the friction characteristics of combustible materials for mechanical continuity of piping shall not be used inside buildings. They may be used outside of buildings above or below ground. If used above ground, the piping shall either be secured to prevent disengagement at the fitting or the piping system shall be so designed that any spill resulting from such disengagement could not unduly expose persons, important buildings or structures, and could be readily controlled by remote valves.

(4) Supports. Piping systems shall be substantially supported and protected against physical damage and excessive stresses arising from settlement, vibration, expansion, or contraction.

(5) Protection against corrosion. All piping for flammable ~~or combustible~~ liquids, both aboveground and underground, where subject to external corrosion, shall be painted or otherwise protected.

(6) Valves. Piping systems shall contain a sufficient number of valves to operate the system properly and to protect the plant. Piping systems in connection with pumps shall contain a sufficient number of valves to control properly the flow of liquid in normal operation and in the event of physical damage. Each connection to pipelines, by which equipments such as tankcars or tank vehicles discharge liquids by means of pumps into storage tanks, shall be provided with a check valve for automatic protection against backflow if the piping arrangement is such that backflow from the system is possible.

(7) Testing. All piping before being covered, enclosed, or placed in use shall be hydrostatically tested to 150 percent of the maximum anticipated pressure of the system, or pneumatically tested to 110 percent of the maximum anticipated pressure of the system, but not less than 5 pounds per square inch gage at the highest point of the system. This test shall be maintained for a sufficient time to complete visual inspection of all joints and connections, but for at least 10 minutes.

(k) Marine service stations

(1) Dispensing.

(i) The dispensing area shall be located away from other structures so as to

provide room for safe ingress and egress of craft to be fueled. Dispensing units shall in all cases be at least 20 feet (6.08 m) from any activity involving fixed sources of ignition.

(ii) Dispensing shall be by approved dispensing units with or without integral pumps and may be located on open piers, wharves, or floating docks or on shore or on piers of the solid fill type.

(iii) Dispensing nozzles shall be automatic-closing without a hold-open latch.

(2) Tanks and pumps.

(i) Tanks, and pumps not integral with the dispensing unit, shall be on shore or on a pier of the solid fill type, except as provided in paragraphs (k)(2) (ii) and (iii) of this section.

(ii) Where shore location would require excessively long supply lines to dispensers, tanks may be installed on a pier provided that applicable portions of paragraph (b) of this section relative to spacing, diking, and piping are complied with and the quantity so stored does not exceed 1,100 gallons (4,163.5 L) aggregate capacity.

(iii) Shore tanks supplying marine service stations may be located above ground, where rock ledges or high water table make underground tanks impractical.

(iv) Where tanks are at an elevation which would produce gravity head on the dispensing unit, the tank outlet shall be equipped with a pressure control valve positioned adjacent to and outside the tank block valve specified in 1926.152(c)(8) of this section, so adjusted that liquid cannot flow by gravity from the tank in case of piping or hose failure.

(3) Piping.

(1) Piping between shore tanks and dispensing units shall be as described in paragraph (k)(2)(iii) of this section, except that, where dispensing is from a floating structure, suitable lengths of oil-resistant flexible hose may be employed between the shore piping and the piping on the floating structure as made necessary by change in water level or shoreline.

Table F-19 - Electrical Equipment Hazardous Areas - Service Stations

TABLE F-19 - ELECTRICAL EQUIPMENT HAZARDOUS AREAS - SERVICE STATIONS

| Location | Class I Group D division | Extent of classified area |
|------------------------------|--------------------------------|--|
| Underground tank: | | |
| Fill opening | 1 | Any pit, box or space below grade level, any part of which is within the Division 1 or 2 classified area. |
| | 2 | Up to 18 inches (45.72 cm) above grade level within a horizontal radius of 10 feet (3.04 m) from a loose fill connection and within a horizontal radius of 5 feet (1.52 m) from a tight fill connection. |
| Vent - Discharging upward... | 1 | Within 3 feet (0.912 m) of open end of vent, extending in all directions. |
| | 2 | Area between 3 feet (0.912 m) and 5 feet (1.52 m) of open end of vent, extending in all directions. |
| Dispenser: | | |
| Pits..... | 1 | Any pit, box or space below grade level, any part of which is within the Division 1 or 2 classified area. |
| Dispenser enclosure..... | 1 | The area 4 feet (1.216 m) vertically above base within the enclosure and 18 inches (45.72 cm) horizontally in all directions. |
| Outdoor..... | 2 | Up to 18 inches (45.72 cm) above grade level within 20 feet (6.08 m) horizontally of any edge of enclosure. |
| Indoor: | | |
| With mechanical ventilation. | 2 | Up to 18 inches (45.72 cm) above grade level within 20 feet (6.08 m) horizontally of any edge of enclosure. |
| With gravity ventilation.... | 2 | Up to 18 inches (45.72 cm) above grade or floor level within 25 feet (7.6 m) horizontally of any edge of enclosure. |
| Remote pump - Outdoor..... | 1 | Any pit, box or space below grade level if any part is within a horizontal distance of 10 feet (3.04 m) from any edge of pump. |
| | 2 | Within 3 feet (0.912 m) of any edge of pump, extending |

| | | | |
|---|-----|--|--|
| Remote pump - Indoor..... | 1 | Entire area within any pit. | in all directions. Also up to 18 inches (45.72 cm) above grade level within 10 feet (3.04 m) horizontally from any edge of pump. |
| | 2 | Within 5 feet (1.52 m) of any edge of pump, extending in all directions. Also up to 3 feet (3.04 m) above floor or grade level within 25 feet (6.08 m) horizontally from any edge of pump. | |
| Lubrication or service room. | 1 | Entire area within any pit. | |
| | 2 | Area up to 18 inches (45.72 cm) above floor or grade level within entire lubrication room. | |
| Dispenser for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 ° F (37.8 ° C) | 2 | Within 3 feet (0.912 m) of any fill or dispensing point, extending in all directions. | |
| Special enclosure inside building per 1910.106(f)(1)(ii). Sales, storage and rest rooms..... | 1 | Entire enclosure. | |
| | (1) | If there is any opening to these rooms within the extent of a Division 1 area, the entire room shall be classified as Division 1. | |

(1) Ordinary.

• • • • •

(1) Ordinary.

(ii) A readily accessible valve to shut off the supply from shore shall be provided in each pipeline at or near the approach to the pier and at the shore end of each pipeline adjacent to the point where flexible hose is attached.

(iii) Piping shall be located so as to be protected from physical damage.

(iv) ~~Piping handling Class I liquids shall be grounded to control stray currents.~~ Piping handling Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be grounded to control stray currents.

(4) Definition; as used in this section: Marine service station shall mean that portion of a property where flammable ~~or combustible~~ liquids used as fuels are stored and dispensed from fixed equipment on shore, piers, wharves, or floating docks into the fuel tanks of self-propelled craft, and shall include all facilities used in connection therewith.

[44 FR 8577, Feb. 9, 1979; 44 FR 20940, Apr. 6, 1979, as amended at 51 FR 25318, July 11 1986]

1926.153 Liquefied petroleum gas (LP-Gas).

(a) Approval of equipment and systems.

(1) Each system shall have containers, valves, connectors, manifold valve assemblies, and regulators of an approved type.

(2) All cylinders shall meet the Department of Transportation specification identification requirements published in 49 CFR Part 178, Shipping Container Specifications.

(3) Definition. As used in this section, Containers - All vessels, such as tanks, cylinders, or drums, used for transportation or storing liquefied petroleum gases.

(b) Welding on LP-Gas containers. Welding is prohibited on containers.

(c) Container valves and container accessories.

(1) Valves, fittings, and accessories connected directly to the container, including primary shut off valves, shall have a rated working pressure of at least 250 p.s.i.g. and shall be of material and design suitable for LP-Gas service.

(2) Connections to containers, except safety relief connections, liquid level gauging devices, and plugged openings, shall have shutoff valves located as close to the container as practicable.

(d) Safety devices.

(1) Every container and every vaporizer shall be provided with one or more approved safety relief valves or devices. These valves shall be arranged to afford free vent to the outer air with discharge not less than 5 feet horizontally away from any opening into a building which is below such discharge.

(2) Shutoff valves shall not be installed between the safety relief device and the container, or the equipment or piping to which the safety relief device is connected, except that a shutoff valve may be used where the arrangement of this valve is such that full required capacity flow through the safety relief device is always afforded.

(3) Container safety relief devices and regulator relief vents shall be located not less than 5 feet in any direction from air openings into sealed combustion system appliances or mechanical ventilation air intakes.

(e) Dispensing.

(1) Filling of fuel containers for trucks or motor vehicles from bulk storage containers

shall be performed not less than 10 feet from the nearest masonry-walled building, or not less than 25 feet from the nearest building or other construction and, in any event, not less than 25 feet from any building opening.

(2) Filling of portable containers or containers mounted on skids from storage containers shall be performed not less than 50 feet from the nearest building.

(f) Requirements for appliances.

(1) LP-Gas consuming appliances shall be approved types.

(2) Any appliance that was originally manufactured for operation with a gaseous fuel other than LP-Gas, and is in good condition, may be used with LP-Gas only after it is properly converted, adapted, and tested for performance with LP-Gas before the appliance is placed in use.

(g) Containers and regulating equipment installed outside of buildings or structures. Containers shall be upright upon firm foundations or otherwise firmly secured. The possible effect on the outlet piping of settling shall be guarded against by a flexible connection or special fitting.
STEP

(h) Containers and equipment used inside of buildings or structures.

(1) When operational requirements make portable use of containers necessary, and their location outside of buildings or structures is impracticable, containers and equipment shall be permitted to be used inside of buildings or structures in accordance with paragraphs (h)(2) through (11) of this section.

(2) "Containers in use" means connected for use.

(3) Systems utilizing containers having a water capacity greater than 2 1/2 pounds (nominal 1 pound LP-Gas capacity) shall be equipped with excess flow valves. Such excess flow valves shall be either integral with the container valves or in the connections to the container valve outlets.

(4) Regulators shall be either directly connected to the container valves or to manifolds connected to the container valves. The regulator shall be suitable for use with LP-Gas. Manifolds and fittings connecting containers to pressure regulator inlets shall be designed for at least 250 p.s.i.g. service pressure.

(5) Valves on containers having water capacity greater than 50 pounds (nominal 20 pounds LP-Gas capacity) shall be protected from damage while in use or storage.

(6) Aluminum piping or tubing shall not be used.

(7) Hose shall be designed for a working pressure of at least 250 p.s.i.g. Design, construction, and performance of hose, and hose connections shall have their suitability determined by listing by a nationally recognized testing agency. The hose length shall be as short as practicable. Hoses shall be long enough to permit compliance with spacing provisions of paragraphs (h)(1) through (13) of this section, without kinking or straining, or causing hose to be so close to a burner as to be damaged by heat.

(8) Portable heaters, including salamanders, shall be equipped with an approved automatic device to shut off the flow of gas to the main burner, and pilot if used, in the event of flame failure. Such heaters, having inputs above 50,000 B.t.u. per hour, shall be equipped with either a pilot, which must be lighted and proved before the main burner can be turned on, or an electrical ignition system.

NOTE: The provisions of this subparagraph do not apply to portable heaters under 7,500 B.t.u. per hour input when used with containers having a maximum water capacity of 2 1/2 pounds.

(9) Container valves, connectors, regulators, manifolds, piping, and tubing shall not be used as structural supports for heaters.

(10) Containers, regulating equipment, manifolds, pipe, tubing, and hose shall be located to minimize exposure to high temperatures or physical damage.

(11) Containers having a water capacity greater than 2 1/2 pounds (nominal 1 pound LP-Gas capacity) connected for use shall stand on a firm and substantially level surface and, when necessary, shall be secured in an upright position.

(12) The maximum water capacity of individual containers shall be 245 pounds (nominal 100 pounds LP-Gas capacity).

(13) For temporary heating, heaters (other than integral heater-container units) shall be located at least 6 feet from any LP-Gas container. This shall not prohibit the use of heaters specifically designed for attachment to the container or to a supporting standard, provided they are designed and installed so as to prevent direct or radiant heat application from the heater onto the containers. Blower and radiant type heaters shall not be directed toward any LP-Gas container within 20 feet.

(14) If two or more heater-container units, of either the integral or nonintegral type, are located in an unpartitioned area on the same floor, the container or containers of each unit shall be separated from the container or containers of any other unit by at least 20 feet.

(15) When heaters are connected to containers for use in an unpartitioned area on the same floor, the total water capacity of containers, manifolded together for connection to a heater or heaters, shall not be greater than 735 pounds (nominal 300 pounds LP-Gas capacity). Such manifolds shall be separated by at least 20 feet.

(16) Storage of containers awaiting use shall be in accordance with paragraphs (j) and (k) of this section.

(i) Multiple container systems.

(1) Valves in the assembly of multiple container systems shall be arranged so that replacement of containers can be made without shutting off the flow of gas in the system. This provision is not to be construed as requiring an automatic changeover device.

(2) Heaters shall be equipped with an approved regulator in the supply line between the fuel cylinder and the heater unit. Cylinder connectors shall be provided with an excess flow valve to minimize the flow of gas in the event the fuel line becomes ruptured.

(3) Regulators and low-pressure relief devices shall be rigidly attached to the cylinder valves, cylinders, supporting standards, the building walls, or otherwise rigidly secured, and shall be so installed or protected from the elements.

(j) Storage of LPG containers. Storage of LPG within buildings is prohibited. STEP

(k) Storage outside of buildings.

(1) Storage outside of buildings, for containers awaiting use, shall be located from the nearest building or group of buildings, in accordance with the following:

TABLE F-3

| Quantity of LP-Gas stored | Distance : (feet) |
|---------------------------|----------------------|
| 500 lbs. or less..... | 0 |
| 501 to 6,000 lbs..... | 10 |
| 6,001 to 10,000 lbs..... | 20 |
| Over 10,000 lbs..... | 25 |

(2) Containers shall be in a suitable ventilated enclosure or otherwise protected against tampering. STEP

(l) Fire protection. Storage locations shall be provided with at least one approved portable fire extinguisher having a rating of not less than 20-B:C.

STEP

(m) Systems utilizing containers other than DOT containers

(1) Application. This paragraph applies specifically to systems utilizing storage containers other than those constructed in accordance with DOT specifications. Paragraph (b) of this section applies to this paragraph unless otherwise noted in paragraph (b) of this section.

(2) Design pressure and classification of storage containers. Storage containers shall be designed and classified in accordance with Table F-31.

Table F-31

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:-----:-----:-----:-----:
:      :      : Minimum design pressure of      :
:      :      : container, lb. per sq. in. gage :
:      :      :-----:-----:
:      :      :      : 1949 edition of      :
:      :      :      : ASME Code (Par. U- :
:      : For gases : 1949 and : 200, U-201); 1950, :
:      : with vapor : earlier : 1952, 1956, 1959, :
:      : press. Not : editions of : 1962, 1965, and :
:      : to exceed : ASME Code : 1968 (Division 1) :
:      : lb. per sq. : (Par. U-68, : editions of ASME :
:      : in. gage at : U-69)      : Code; All      :
: Container : 100E F. : : editions of API- :
: type      : (37.8E C.) : : ASME Code(3) :
:-----:-----:-----:-----:
: (1) 80   : (1) 80   : (1) 80   : (1) 100   :
: 100     : 100     : 100     : 125      :
: 125     : 125     : 125     : 156      :
: 150     : 150     : 150     : 187      :
: 175     : 175     : 175     : 219      :
: (2) 200 : 215     : 200     : 250      :
:-----:-----:-----:-----:

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(1) New storage containers of the 80 type have not been authorized since Dec. 31, 1947.

(2) Container type may be increased by increments of 25. The minimum design pressure of containers shall be 100% of the container type designation when constructed under 1949 or earlier editions of the ASME Code (Par. U-68 and U-69). The minimum design pressure of containers shall be 125% of the container type designation when constructed under: (1) the 1949 ASME Code (Par. U-200 and U-201), (2) 1950, 1952, 1956, 1959, 1962, 1965, and 1968

(Division 1) editions of the ASME Code, and (3) all editions of the API-ASME Code.

(3) Construction of containers under the API-ASME Code is not authorized after July 1, 1961.

(3) Containers with foundations attached (portable or semiportable containers with suitable steel "runners" or "skids" and popularly known in the industry as "skid tanks") shall be designed, installed, and used in accordance with these rules subject to the following provisions:

(i) If they are to be used at a given general location for a temporary period not to exceed 6 months they need not have fire-resisting foundations or saddles but shall have adequate ferrous metal supports.

(ii) They shall not be located with the outside bottom of the container shell more than 5 feet (1.52 m) above the surface of the ground unless fire-resisting supports are provided.

(iii) The bottom of the skids shall not be less than 2 inches (5.08 cm) or more than 12 inches (30.48 cm) below the outside bottom of the container shell.

(iv) Flanges, nozzles, valves, fittings, and the like, having communication with the interior of the container, shall be protected against physical damage.

(v) When not permanently located on fire-resisting foundations, piping connections shall be sufficiently flexible to minimize the possibility of breakage or leakage of connections if the container settles, moves, or is otherwise displaced.

(vi) Skids, or lugs for attachment of skids, shall be secured to the container in accordance with the code or rules under which the container is designed and built (with a minimum factor of safety of four) to withstand loading in any direction equal to four times the weight of the container and attachments when filled to the maximum permissible loaded weight.

(4) Field welding where necessary shall be made only on saddle plates or brackets which were applied by the manufacturer of the tank.

(n) When LP-Gas and one or more other gases are stored or used in the same area, the containers shall be marked to identify their content. Marking shall be in compliance with American National Standard Z48.1-1954, "Method of Marking Portable Compressed Gas Containers To Identify the Material Contained."

(o) Damage from vehicles. When damage to LP-Gas systems from vehicular traffic is a possibility, precautions against such damage shall be taken.

STEP

1926.154 Temporary heating devices.

(a) Ventilation.

(1) Fresh air shall be supplied in sufficient quantities to maintain the health and safety of workmen. Where natural means of fresh air supply is inadequate, mechanical ventilation shall be provided.

(2) When heaters are used in confined spaces, special care shall be taken to provide sufficient ventilation in order to ensure proper combustion, maintain the health and safety of workmen, and limit temperature rise in the area.

(b) Clearance and mounting.

(1) Temporary heating devices shall be installed to provide clearance to combustible material not less than the amount shown in Table F-4.

(2) Temporary heating devices, which are listed for installation with lesser clearances than specified in Table F-4, may be installed in accordance with their approval.

TABLE F-4

| Heating appliances | :Minimum clearance, (inches) | | |
|------------------------------------|------------------------------|-------|--------------------|
| | :Sides | :Rear | :Chimney Connector |
| Room heater, circulating type..... | 12 | 12 | 18 |
| Room heater, radiant type..... | 36 | 36 | 18 |

(3) Heaters not suitable for use on wood floors shall not be set directly upon them or other combustible materials. When such heaters are used, they shall rest on suitable heat insulating material or at least 1-inch concrete, or equivalent. The insulating material shall extend beyond the heater 2 feet or more in all directions.

(4) Heaters used in the vicinity of combustible tarpaulins, canvas, or similar coverings shall be located at least 10 feet from the coverings. The coverings shall be securely fastened to prevent ignition or upsetting of the heater due to wind action on the covering or other material.

(c) Stability. Heaters, when in use, shall be set horizontally level, unless otherwise permitted by the manufacturer's markings.

(d) Solid fuel salamanders. Solid fuel salamanders are prohibited in buildings and on scaffolds.

(e) Oil-fired heaters.

(1) Flammable liquid-fired heaters shall be equipped with a primary safety control to stop the flow of fuel in the event of flame failure. Barometric or gravity oil feed shall not be considered a primary safety control.

(2) Heaters designed for barometric or gravity oil feed shall be used only with the integral tanks.

(3) [Reserved]

(4) Heaters specifically designed and approved for use with separate supply tanks may be directly connected for gravity feed, or an automatic pump, from a supply tank.

1926.155 Definitions applicable to this subpart.

(a) "Approved", for the purpose of this subpart, means equipment that has been listed or approved by a nationally recognized testing laboratory such as Factory Mutual Engineering Corp., or Underwriters' Laboratories, Inc., or Federal agencies such as Bureau of Mines, or U.S. Coast Guard, which issue approvals for such equipment.

(b) "Closed container" means a container so sealed by means of a lid or other device that neither liquid nor vapor will escape from it at ordinary temperatures.

(c) ~~"Combustible liquids" mean any liquid having a flash point at or above 140 deg. F. (60 deg. C.), and below 200 deg. F. (93.4 deg. C.).~~ [Reserved]

(d) "Combustion" means any chemical process that involves oxidation sufficient to produce light or heat.

(e) "Fire brigade" means an organized group of employees that are knowledgeable, trained, and skilled in the safe evacuation of employees during emergency situations and in assisting in fire fighting operations.

(f) "Fire resistance" means so resistant to fire that, for specified time and under conditions of a standard heat intensity, it will not fail structurally and will not permit the side away from the fire to become hotter than a specified temperature. For purposes of this part, fire resistance shall be determined by the Standard Methods of Fire Tests of Building Construction and Materials, NFPA 251-1969.

(g) "Flammable" means capable of being easily ignited, burning intensely, or having a rapid rate of flame spread.

(h) "Flammable liquids" means any liquid having a flash point below 140 deg. F. and having a vapor pressure not exceeding 40 pounds per square inch (absolute) at 100 deg F. means any liquid having a vapor pressure not exceeding 40 pounds per square inch (absolute) at 100 °F (37.8 °C) and having a flashpoint at or below 199.4 °F (93 °C). Flammable liquids are divided into four categories as follows:

(1) Category 1 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point at or below 95 °F (35 °C).

(2) Category 2 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point above 95 °F (35 °C).

(3) Category 3 shall include liquids having flashpoints at or above 73.4 °F (23 °C) and at or below 140 °F (60 °C).

(4) Category 4 shall include liquids having flashpoints above 140 °F (60 °C) and at or below 199.4 °F (93 °C).

(i) "Flash point" of the liquid means the temperature at which it gives off vapor sufficient to form an ignitable mixture with the air near the surface of the liquid or within the vessel used as determined by appropriate test procedure and apparatus as specified below.

~~(1) The flash point of liquids having a viscosity less than 45 Saybolt Universal Second(s) at 100 deg. F. (37.8 deg. C.) and a flash point below 175 deg. F. (79.4 deg. C.) shall be determined in accordance with the Standard Method of Test for Flash Point by the Tag Closed Tester, ASTM D-56-69.~~

~~————(2) The flash point of liquids having a viscosity of 45 Saybolt Universal Second(s) or more at 175 deg. F. (79.4 deg. C.) or higher shall be determined in accordance with the Standard Method of Test for Flash Point by the Pensky Martens Closed Tester, ASTM D-93-69. The flashpoint of liquids having a viscosity less than 45 Saybolt Universal Second(s) at 100 °F (37.8 °C) and a flashpoint below 175 °F (79.4 °C) shall be determined in accordance with the Standard Method of Test for Flash Point by the Tag Closed Tester, ASTM D-56-69 (incorporated by reference; See §1926.6), or an equivalent method as defined by §1910.1200 appendix B.~~

(2) The flashpoints of liquids having a viscosity of 45 Saybolt Universal Second(s) or more at 175 °F (79.4 °C) or higher shall be determined in accordance with the Standard Method of Test for Flash Point by the Pensky Martens Closed Tester, ASTM D-93-69 (incorporated by reference; See §1926.6), or an equivalent method as defined by §1910.1200 appendix B.

(j) "Liquefied petroleum gases," "LPG" and "LP Gas" mean and include any material which is composed predominantly of any of the following hydrocarbons, or mixtures of them, such as propane, propylene, butane (normal butane or iso-butane), and butylenes.

(k) "Portable tank" means a closed container having a liquid capacity more than 60 U.S. gallons, and not intended for fixed installation.

(l) "Safety can" means an approved closed container, of not more than 5 gallons capacity, having a flash-arresting screen, spring-closing lid and spout cover and so designed that it will safely relieve internal pressure when subjected to fire exposure. STD 3-4.1A

(m) "Vapor pressure" means the pressure, measured in pounds per square inch (absolute), exerted by a volatile liquid as determined by the "Standard Method of Test for Vapor Pressure of Petroleum Products (Reid Method)." (ASTM D-323-58).

Fixed Fire Suppression Equipment

1926.156 Fixed extinguishing systems, general. [Removed]

1926.157 Fixed extinguishing systems, gaseous agent. [Removed]

1926.158 Fire detection systems. [Removed]

1926.159 Employee alarm systems. [Removed]

SUBPART Z - TOXIC AND HAZARDOUS SUBSTANCES

| | |
|-----------|---|
| 1910.1000 | Air contaminants. |
| 1910.1001 | Asbestos. |
| 1910.1002 | Coal tar pitch volatiles; interpretation of term. |
| 1910.1003 | 13 Carcinogens (4-Nitrobiphenyl, etc). |
| 1910.1004 | alpha-Naphthylamine. |
| 1910.1005 | [Reserved] |
| 1910.1006 | Methyl chloromethyl ether. |
| 1910.1007 | 3,3'-Dichlorobenzidine (and its salts). |
| 1910.1008 | bis-Chloromethyl ether. |
| 1910.1009 | beta-Naphthylamine. |
| 1910.1010 | Benzidine. |
| 1910.1011 | 4-Aminodiphenyl. |
| 1910.1012 | Ethyleneimine. |
| 1910.1013 | beta-Propiolactone. |
| 1910.1014 | 2-Acetylaminofluorene. |
| 1910.1015 | 4-Dimethylaminoazobenzene. |
| 1910.1016 | N-Nitrosodimethylamine. |
| 1910.1017 | Vinyl chloride. |
| 1910.1018 | Inorganic arsenic. |
| 1910.1020 | Access to employee exposure and medical records |
| 1910.1025 | Lead. |
| 1910.1026 | Chromium (VI) |
| 1910.1027 | Cadmium. |
| 1910.1028 | Benzene. |
| 1910.1029 | Coke oven emissions. |
| 1910.1030 | Bloodborne pathogens. |
| 1910.1043 | Cotton dust. (Not applicable in Wyoming) |
| 1910.1044 | 1,2-dibromo-3-chloropropane. |
| 1910.1045 | Acrylonitrile. |
| 1910.1047 | Ethylene oxide. |
| 1910.1048 | Formaldehyde. |
| 1910.1050 | Methylenedianline. |
| 1910.1052 | Methylene Chloride |
| 1910.1051 | 1,3-Butadiene |
| 1910.1096 | Ionizing Radiation |
| 1910.1200 | Hazard communication. |
| 1910.1450 | Occupational exposure to hazardous chemicals in laboratories. |
| 1910.1499 | Source of standards. |
| 1910.1500 | Standards organizations. |

Authority: 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-

76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), 3-2000 (65 FR 50017), 5-2002 (67 FR 65008), 5-2007 (72 FR 31160), or 4-2010 (75 FR 55355), as applicable, and 29 CFR 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act, except those substances that have exposure limits listed in Tables Z-1, Z-2, and Z-3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z-1, Z-2, and Z-3 also issued under 5 U.S.C. 553, Section 1910.1000 Tables Z-1, Z-2, and Z-3, but not under 29 CFR 1911, except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under 40 U.S.C. 3704 and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR 1911.

Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653.

Section 1910.1030 also issued under Pub. L. 106-430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 1801-1819 and 5 U.S.C. 533.

[55 FR 3327, Jan. 31, 1990; 55 FR 4999, Feb. 13, 1990; 55 FR 12819, Apr. 6, 1990; 55 FR 50686, Dec. 10, 1990; 56 FR, Dec. 6, 1991; 58 FR 21780 April 23, 1993; 58 FR 35310 & 35338, June 30, 1993; 59 FR 6169, Feb. 9, 1994; 59 FR 17479, April 13, 1994; 59 FR 36695, July 19, 1994; 59 FR 40964, Aug. 10, 1994; 59 FR 65947, Dec. 22, 1994; 60 FR 9624, Feb. 21, 1995; 60 FR 33343, June 28, 1995; 60 FR 52856, Oct. 11, 1995; 61 FR 9227, March 7, 1996; 61 FR 31427, June 20, 1996; 61 FR 43454, August, 23, 1996; 61 FR 56746, Nov. 4, 1996; 62 FR 1493, Jan. 10, 1997; 62 FR 42018, Aug. 4, 1997; 62 FR 42666, Aug. 8, 1997; 62 FR 48175, Sept. 15, 1997; 62 FR 54383, Oct. 20, 1997; 62 FR 66275, Dec. 18, 1997; 63 FR 1152, Jan. 8, 1998; 63 FR 33450, June 18, 1998; 63 FR 50729, Sept. 22, 1998; 66 FR 5324 Jan. 18, 2001; 67 FR 67965, Nov. 7, 2002; 70 FR 1141, Jan. 5, 2005; 71 FR 10373, Feb. 28, 2006; 71 FR 50188, August 24, 2006; 71 FR 63242, Oct. 30, 2006; 73 FR 75584, Dec. 12, 2008; 75 FR 12686, March 17, 2010; 76 FR 33607, June 8, 2011]

1910.1000 Air contaminants.

An employee's exposure to any substance listed in Tables Z-1-, Z-2, or Z-3 of this section shall be limited in accordance with the requirements of the following paragraphs of this section.

(a) Table Z-1

(1) Substances with limits preceded by "C" - Ceiling Values. An employee's exposure to any

substance in Table Z-1, the exposure limit of which is preceded by a "C", shall at no time exceed the exposure limit given for that substance in Table Z-1. If instantaneous monitoring is not feasible, then the ceiling shall be assessed as a 15-minute time weighted average exposure which shall not be exceeded at any time during the working day.

(2) Other substances - 8-hour Time Weighted Averages. An employee's exposure to any substance in Table Z-1, the exposure limit of which is not preceded by a "C", shall not exceed the 8-hour Time Weighted Average given for that substance in any 8-hour work shift of a 40-hour work week.

(b) Table Z-2. An employees's exposure to any substance listed in Table Z-2 shall not exceed the exposure limits specified as follows:

(1) 8-hour time weighted averages. An employee's exposure to any substance listed in Table Z-2, in any 8-hour work shift of a 40-hour work week, shall not exceed the 8-hour time weighted average limit given for that substance in Table Z-2.

(2) Acceptable ceiling concentrations. An employee's exposure to a substance listed in Table Z-2 shall not exceed at any time during an 8-hour shift the acceptable ceiling concentration limit given for the substance in the table, except for a time period, and up to a concentration not exceeding the maximum duration and concentration allowed in the column under "acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift".

(3) Example. During an 8-hour work shift, an employee may be exposed to a concentration of Substance A (with a 10 ppm TWA, 25 ppm ceiling and 50 ppm peak) above 25 ppm (but never above 50 ppm) only for a maximum period of 10 minutes. Such exposure must be compensated by exposures to concentrations less than 10 ppm so that the cumulative exposure for the entire 8-hour work shift does not exceed a weighted average of 10 ppm.

(c) Table Z-3. An employee's exposure to any substance listed in Table Z-3, in any 8-hour work shift of a 40-hour work week shall not exceed the 8-hour time weighted average limit given for that substance in the table.

(d) Computation formulae. The computation formula which shall apply to employee exposure to more than one substance for which 8-hour time weighted averages are listed in Subpart Z of 29 CFR part 1910 in order to determine whether an employee is exposed over the regulatory limit is as follows:

(1)

(i) The cumulative exposure for an 8-hour work shift shall be computed as follows:

$$(E = C(a) T(a) + C(b) T(b) + \dots C(n) T(n)+8$$

Where:

E is the equivalent exposure for the working shift.

C is the concentration during any period of time T where the concentration remains constant.

T is the duration in hours of the exposure at the concentration C.

The value of E shall not exceed the 8-hour time weighted average specified in Subpart Z of 29 CFR part 1910 for the substance involved.

(ii) To illustrate the formula prescribed in paragraph (d)(1)(i) of this section, assume that Substance A has an 8-hour time weighted average limit of 100 ppm noted in Table Z-1. Assume that an employee is subject to the following exposure:

Two hours exposure at 150 p/m

Two hours exposure at 75 p/m

Four hours exposure at 50 p/m

Substituting this information in the formula, we have

$$(2 \times 150 + 2 \times 75 + 4 \times 50) \div 8 = 81.25 \text{ ppm}$$

Since 81.25 p.p.m. is less than 100 p.p.m., the 8-hour time weighted average limit, the exposure is acceptable.

(2)

(i) in case of a mixture of air contaminants an employer shall compute the equivalent exposure as follows:

$$E(m) = (C(1) + L(1) + C(2) + L(2)) + \dots + (C(n) + L(n))$$

Where:

E(m) is the equivalent exposure for the mixture.

C is the concentration of a particular contaminant.

L is the exposure limit for that substance specified in subpart Z of 29 CFR part 1910.

The value of E(m) shall not exceed unity (1).

(ii) To illustrate the formula prescribed in paragraph (d)(2)(i) of this section, consider the following exposures:

| Substance | Actual concentration | |
|-----------|--------------------------|--------------------|
| | of 8-hour exposure (ppm) | 8 hr.TWA PEL (ppm) |
| B..... | 500..... | 1,000 |
| C..... | 45..... | 200 |
| D..... | 40..... | 200 |

Substituting in the formula, we have:

$$E(m)=500 \text{ divided by } 1,000 + 45 \text{ divided by } 200 + 40 \text{ divided by } 200$$

$$E(m)=0.500 + 0.225 + 0.200$$

$$E(m)=0.925$$

Since E(m) is less than unity (1), the exposure combination is within acceptable limits.

(e) To achieve compliance with paragraphs (a) through (d) of this section, administrative or engineering controls must first be determined and implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or any other protective measures shall be used to keep the exposure of employees to air contaminants within the limits prescribed in this section. Any equipment and/or technical measures used for this purpose must be approved for each particular use by a competent industrial hygienist or other technically qualified person. Whenever respirators are used, their use shall comply with 1910.134.

TABLE Z-1 LIMITS FOR AIR CONTAMINANTS

NOTE: Because of the length of the table, explanatory Footnotes applicable to all substances are given below as well as at the end of the table. Footnotes specific only to a limited number of substances are also shown within the table.

Footnote(1) The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

Footnote(a) Parts of vapor or gas per million parts of contaminated air by volume at 25 degrees C and 760 torr.

Footnote(b) Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

Footnote(c) The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound measured as the metal, the CAS number for the metal is given - not CAS numbers for the individual compounds.

Footnote(d) The final benzene standard in 1910.1028 applies to all occupational exposures to benzene except in some circumstances the distribution and sale of fuels, sealed containers and pipelines, coke production, oil and gas drilling and production, natural gas processing, and the percentage exclusion for liquid mixtures; for the excepted subsegments, the benzene limits in Table Z-2 apply. See 1910.1028 for specific circumstances.

Footnote(e) This 8-hour TWA applies to respirable dust as measured by a vertical elutriator cotton dust sampler or equivalent instrument. The time-weighted average applies to the cotton waste processing operations of waste recycling (sorting, blending, cleaning and willowing) and garnetting. See also 1910.1043 for cotton dust limits applicable to other sectors.

Footnote(f) All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by the Particulates Not Otherwise Regulated (PNOR) limit which is the same as the inert or nuisance dust limit of Table Z-3.

Footnote(2) See Table Z-2.

Footnote(3) See Table Z-3

Footnote(4) Varies with compound.

Footnote(5) See Table Z-2 for the exposure limits for any operations or sectors where the exposure limits in 1910.1026 are stayed or are otherwise not in effect.

TABLE Z-1. - LIMITS FOR AIR CONTAMINANTS

| Substance | CAS No. (c) | ppm (a)(1) | mg/m(3) (b)(1) | Skin designation |
|--|-------------|------------|-------------------|---------------------|
| Acetaldehyde..... | 75-07-0 | 200 | 360 | |
| Acetic acid..... | 64-19-7 | 10 | 25 | |
| Acetic anhydride..... | 108-24-7 | 5 | 20 | |
| Acetone..... | 67-64-1 | 1000 | 2400 | |
| Acetonitrile..... | 75-05-8 | 40 | 70 | |
| 2-Acetylaminofluorene; see 1910.1014..... | 53-96-3 | | | |

| | | | | | |
|--|------------|-------|-------|--|---|
| Acetylene dichloride; see 1,2-Dichloroethylene. | | | | | |
| Acetylene tetrabromide. | 79-27-6 | 1 | 14 | | |
| Acrolein..... | 107-02-8 | 0.1 | 0.25 | | |
| Acrylamide..... | 79-06-1 | | 0.3 | | X |
| Acrylonitrile; see 1910.1045..... | 107-13-1 | | | | |
| Aldrin..... | 309-00-2 | | 0.25 | | X |
| Allyl alcohol..... | 107-18-6 | 2 | 5 | | X |
| Allyl chloride..... | 107-05-1 | 1 | 3 | | |
| Allyl glycidyl ether... (AGE)..... | 106-92-3 | (C)10 | (C)45 | | |
| Allyl propyl disulfide. | 2179-59-1 | 2 | 12 | | |
| alpha-Alumina..... | 1344-28-1 | | | | |
| Total dust..... | | | 15 | | |
| Respirable fraction.. | | | 5 | | |
| Aluminum Metal (as Al). | 7429-90-5 | | | | |
| Total dust..... | | | 15 | | |
| Respirable fraction.. | | | 5 | | |
| 4-Aminodiphenyl; see 1910.1011..... | 92-67-1 | | | | |
| 2-Aminoethanol; see Ethanolamine..... | | | | | |
| 2-Aminopyridine..... | 504-29-0 | 0.5 | 2 | | |
| Ammonia..... | 7664-41-7 | 50 | 35 | | |
| Ammonium sulfamate..... | 7773-06-0 | | | | |
| Total dust..... | | | 15 | | |
| Respirable fraction.. | | | 5 | | |
| n-Amyl acetate..... | 628-63-7 | 100 | 525 | | |
| sec-Amyl acetate..... | 626-38-0 | 125 | 650 | | |
| Aniline and homologs... | 62-53-3 | 5 | 19 | | X |
| Anisidine (o-,p-isomers)..... | 29191-52-4 | | 0.5 | | X |
| Antimony and compounds (as Sb)..... | 7440-36-0 | | 0.5 | | |
| ANTU (alpha Naphthylthiourea).... | 86-88-4 | | 0.3 | | |
| Arsenic, inorganic compounds (as As); see 1910.1018..... | 7440-38-2 | | | | |
| Arsenic, organic compounds (as As).... | 7440-38-2 | | 0.5 | | |
| Arsine..... | 7784-42-1 | 0.05 | 0.2 | | |
| Asbestos; see 1910.1001..... | (4) | | | | |
| Azinphos-methyl..... | 86-50-0 | | 0.2 | | X |
| Barium, soluble compounds (as Ba).... | 7440-39-3 | | 0.5 | | |
| Barium sulfate..... | 7727-43-7 | | | | |
| Total dust..... | | | 15 | | |
| Respirable fraction.. | | | 5 | | |
| Benomyl..... | 17804-35-2 | | | | |
| Total dust..... | | | 15 | | |
| Respirable fraction.. | | | 5 | | |
| Benzene; See 1910.1028. See Table Z-2 for the limits | 71-43-2 | | | | |

| | | | | |
|--|-----------|----------|-------|---|
| applicable in the operations or sectors excluded in 1910.1028(d) | | | | |
| Benzidine; | | | | |
| See 1910.1010..... | 92-87-5 | | | |
| p-Benzoquinone; | | | | |
| see Quinone. | | | | |
| Benzo(a)pyrene; see | | | | |
| Coal tar pitch | | | | |
| volatiles..... | | | | |
| Benzoyl peroxide..... | 94-36-0 | | 5 | |
| Benzyl chloride..... | 100-44-7 | 1 | 5 | |
| Beryllium and | | | | |
| beryllium compounds | | | | |
| (as Be)..... | 7440-41-7 | | (2) | |
| Biphenyl; see Diphenyl. | | | | |
| Bismuth telluride, | | | | |
| Undoped..... | 1304-82-1 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Boron oxide..... | 1303-86-2 | | | |
| Total dust..... | | | 15 | |
| Boron trifluoride..... | 7637-07-2 | (C)1 | (C)3 | |
| Bromine..... | 7726-95-6 | 0.1 | 0.7 | |
| Bromoform..... | 75-25-2 | 0.5 | 5 | X |
| Butadiene | | | | |
| (1,3-Butadiene); See | | | | |
| 29 CFR 1910.1051; | 106-99-0 | 1 ppm/5 | | |
| 29 CFR 1910.19(1).... | | ppm STEL | | |
| Butanethiol; | | | | |
| see Butyl mercaptan. | | | | |
| 2-Butanone | | | | |
| (Methyl ethyl ketone) | 78-93-3 | 200 | 590 | |
| 2-Butoxyethanol..... | 111-76-2 | 50 | 240 | X |
| n-Butyl-acetate..... | 123-86-4 | 150 | 710 | |
| sec-Butyl acetate..... | 105-46-4 | 200 | 950 | |
| tert-Butyl-acetate..... | 540-88-5 | 200 | 950 | |
| n-Butyl alcohol..... | 71-36-3 | 100 | 300 | |
| sec-Butyl alcohol..... | 78-92-2 | 150 | 450 | |
| tert-Butyl alcohol..... | 75-65-0 | 100 | 300 | |
| Butylamine..... | 109-73-9 | (C)5 | (C)15 | X |
| tert-Butyl chromate | | | | |
| (as CrO(3))..... | 1189-85-1 | | | |
| see 1910.1026 | | | | |
| n-Butyl glycidyl ether | | | | |
| (BGE)..... | 2426-08-6 | 50 | 270 | |
| Butyl mercaptan..... | 109-79-5 | 10 | 35 | |
| p-tert-Butyltoluene.... | 98-51-1 | 10 | 60 | |
| Cadmium (as Cd); | | | | |
| see 1910.1027..... | 7440-43-9 | | | |
| Calcium Carbonate..... | 1317-65-3 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Calcium hydroxide..... | 1305-62-0 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Calcium oxide..... | 1305-78-8 | | 5 | |

| | | | | | |
|--|------------|--------|--|--------|---|
| Calcium silicate..... | 1344-95-2 | | | | |
| Total dust..... | | | | 15 | |
| Respirable fraction.. | | | | 5 | |
| Calcium sulfate..... | 7778-18-9 | | | | |
| Total dust..... | | | | 15 | |
| Respirable fraction.. | | | | 5 | |
| Camphor, synthetic..... | 76-22-2 | | | 2 | |
| Carbaryl (Sevin)..... | 63-25-2 | | | 5 | |
| Carbon black..... | 1333-86-4 | | | 3.5 | |
| Carbon dioxide..... | 124-38-9 | 5000 | | 9000 | |
| Carbon disulfide..... | 75-15-0 | | | (2) | |
| Carbon monoxide..... | 630-08-0 | 50 | | 55 | |
| Carbon tetrachloride... | 56-23-5 | | | (2) | |
| Cellulose..... | 9004-34-6 | | | | |
| Total dust..... | | | | 15 | |
| Respirable fraction.. | | | | 5 | |
| Chlordane..... | 57-74-9 | | | 0.5 | X |
| Chlorinated camphene... | 8001-35-2 | | | 0.5 | X |
| Chlorinated diphenyl oxide..... | 55720-99-5 | | | 0.5 | |
| Chlorine..... | 7782-50-5 | (C)1 | | (C)3 | |
| Chlorine dioxide..... | 10049-04-4 | 0.1 | | 0.3 | |
| Chlorine trifluoride... | 7790-91-2 | (C)0.1 | | (C)0.4 | |
| Chloroacetaldehyde..... | 107-20-0 | (C)1 | | (C)3 | |
| a-Chloroacetophenone (Phenacyl chloride).. | 532-27-4 | 0.05 | | 0.3 | |
| Chlorobenzene..... | 108-90-7 | 75 | | 350 | |
| o-Chlorobenzylidene malononitrile..... | 2698-41-1 | 0.05 | | 0.4 | |
| Chlorobromomethane..... | 74-97-5 | 200 | | 1050 | |
| 2-Chloro-1,3-butadiene; See beta-Chloroprene. | | | | | |
| Chlorodiphenyl (42% Chlorine)(PCB).. | 53469-21-9 | | | 1 | X |
| Chlorodiphenyl (54% Chlorine)(PCB).. | 11097-69-1 | | | 0.5 | X |
| 1-Chloro-2, 3-epoxypropane; See Epichlorohydrin. | | | | | |
| 2-Chloroethanol; See Ethylene chlorohydrin | | | | | |
| Chloroethylene; See Vinyl chloride. | | | | | |
| Chloroform (Trichloromethane)... | 67-66-3 | (C)50 | | (C)240 | |
| bis(Chloromethyl) ether; see 1910.1008. | 542-88-1 | | | | |
| Chloromethyl methyl ether; see 1910.1006. | 107-30-2 | | | | |
| 1-Chloro-1-nitropropane | 600-25-9 | 20 | | 100 | |
| Chloropicrin..... | 76-06-2 | 0.1 | | 0.7 | |
| beta-Chloroprene..... | 126-99-8 | 25 | | 90 | X |
| 2-Chloro-6 (trichloromethyl) pyridine..... | 1929-82-4 | | | | |
| Total dust..... | | | | 15 | |
| Respirable fraction.. | | | | 5 | |
| Chromic acid and | | | | | |

| | | | | |
|---|------------|-------|------|---|
| chromates (as CrO(3)) | (4) | | (2) | |
| Chromium (II) compounds (as Cr)..... | 7440-47-3 | | 0.5 | |
| Chromium (III) compounds (as Cr).... | 7440-47-3 | | 0.5 | |
| Chromium (VI) compounds See 1910.1026(5) | | | | |
| Chromium metal and insol. salts (as Cr).. | 7440-47-3 | | 1 | |
| Chrysene; see Coal tar pitch volatiles..... | | | | |
| Clopidol..... | 2971-90-6 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Coal dust (less than 5% SiO(2)), respirable fraction.. | | | (3) | |
| Coal dust (greater than or equal to 5% SiO(2)), respirable fraction..... | | | (3) | |
| Coal tar pitch volatiles (benzene soluble fraction), anthracene, BaP, phenanthrene, acridine, chrysene, pyrene..... | 65966-93-2 | | 0.2 | |
| Cobalt metal, dust, and fume (as Co)..... | 7440-48-4 | | 0.1 | |
| Coke oven emissions; see 1910.1029..... | | | | |
| Copper..... | 7440-50-8 | | | |
| Fume (as Cu)..... | | | 0.1 | |
| Dusts and mists (as Cu)..... | | | 1 | |
| Cotton dust (e), see 1910.1043..... | | | 1 | |
| Crag herbicide (Sesone) | 136-78-7 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Cresol, all isomers.... | 1319-77-3 | 5 | 22 | X |
| Crotonaldehyde..... | 123-73-9 | 2 | 6 | |
| | 4170-30-3 | | | |
| Cumene..... | 98-82-8 | 50 | 245 | X |
| Cyanides (as CN).... | (4) | | 5 | X |
| Cyclohexane..... | 110-82-7 | 300 | 1050 | |
| Cyclohexanol..... | 108-93-0 | 50 | 200 | |
| Cyclohexanone..... | 108-94-1 | 50 | 200 | |
| Cyclohexene..... | 110-83-8 | 300 | 1015 | |
| Cyclopentadiene..... | 542-92-7 | 75 | 200 | |
| 2,4-D (Dichlorophen- oxyacetic acid)..... | 94-75-7 | | 10 | |
| Decaborane..... | 17702-41-9 | 0.05 | 0.3 | X |
| Demeton (Systox)..... | 8065-48-3 | | 0.1 | X |
| Diacetone alcohol (4-Hydroxy-4-methyl- 2-pentanone)..... | 123-42-2 | 50 | 240 | |

| | | | | |
|---|------------|--------|--------|---|
| 1,2-Diaminoethane; see Ethylenediamine.. | | | | |
| Diazomethane..... | 334-88-3 | 0.2 | 0.4 | |
| Diborane..... | 19287-45-7 | 0.1 | 0.1 | |
| 1,2-Dibromo-3- chloropropane (DBCP); see 1910.1044..... | 96-12-8 | | | |
| 1,2-Dibromoethane; see Ethylene dibromide... | | | | |
| Dibutyl phosphate..... | 107-66-4 | 1 | 5 | |
| Dibutyl phthalate..... | 84-74-2 | | 5 | |
| o-Dichlorobenzene..... | 95-50-1 | (C)50 | (C)300 | |
| p-Dichlorobenzene..... | 106-46-7 | 75 | 450 | |
| 3,3'-Dichlorobenzidine; see 1910.1007..... | 91-94-1 | | | |
| Dichlorodifluoromethane | 75-71-8 | 1000 | 4950 | |
| 1,3-Dichloro-5, 5-dimethyl hydantoin. | 118-52-5 | | 0.2 | |
| Dichlorodiphenyltri- chloroethane (DDT)... | 50-29-3 | | 1 | X |
| 1,1-Dichloroethane..... | 75-34-3 | 100 | 400 | |
| 1,2-Dichloroethane; see Ethylene dichloride.. | | | | |
| 1,2-Dichloroethylene... | 540-59-0 | 200 | 790 | |
| Dichloroethyl ether.... | 111-44-4 | (C)15 | (C)90 | X |
| Dichloromethane; see Methylene chloride... | | | | |
| Dichloromonofluoro- methane..... | 75-43-4 | 1000 | 4200 | |
| 1,1-Dichloro-1- nitroethane..... | 594-72-9 | (C)10 | (C)60 | |
| 1,2-Dichloropropane; see Propylene dichloride. | | | | |
| Dichlorotetrafluoro- ethane..... | 76-14-2 | 1000 | 7000 | |
| Dichlorvos (DDVP)..... | 62-73-7 | | 1 | X |
| Dicyclopentadienyl iron Total dust..... | 102-54-5 | | 15 | |
| Respirable fraction.. | | | 5 | |
| Dieldrin..... | 60-57-1 | | 0.25 | X |
| Diethylamine..... | 109-89-7 | 25 | 75 | |
| 2-Diethylaminoethanol.. | 100-37-8 | 10 | 50 | X |
| Diethyl ether; see Ethyl ether..... | | | | |
| Difluorodibromomethane. | 75-61-6 | 100 | 860 | |
| Diglycidyl ether (DGE). | 2238-07-5 | (C)0.5 | (C)2.8 | |
| Dihydroxybenzene; see Hydroquinone..... | | | | |
| Diisobutyl ketone..... | 108-83-8 | 50 | 290 | |
| Diisopropylamine..... | 108-18-9 | 5 | 20 | X |
| 4-Dimethylaminoazo- benzene; see 1910.1015..... | 60-11-7 | | | |
| Dimethoxymethane; see Methylal..... | | | | |
| Dimethyl acetamide..... | 127-19-5 | 10 | 35 | X |
| Dimethylamine..... | 124-40-3 | 10 | 18 | |

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|--|------------|-------|------|---|
| Dimethylaminobenzene; see Xylidine..... | | | | |
| Dimethylaniline (N,N-Dimethylaniline) | 121-69-7 | 5 | 25 | X |
| Dimethylbenzene; see Xylene..... | | | | |
| Dimethyl-1,2-dibromo-2, 2-dichloroethyl phosphate..... | 300-76-5 | | 3 | |
| Dimethylformamide..... | 68-12-2 | 10 | 30 | X |
| 2,6-Dimethyl-4- heptanone; see Diisobutyl ketone.... | | | | |
| 1,1-Dimethylhydrazine.. | 57-14-7 | 0.5 | 1 | X |
| Dimethylphthalate..... | 131-11-3 | | 5 | |
| Dimethyl sulfate..... | 77-78-1 | 1 | 5 | X |
| Dinitrobenzene (all isomers)..... | | | 1 | X |
| (ortho)..... | 528-29-0 | | | |
| (meta)..... | 99-65-0 | | | |
| (para)..... | 100-25-4 | | | |
| Dinitro-o-cresol..... | 534-52-1 | | 0.2 | X |
| Dinitrotoluene..... | 25321-14-6 | | 1.5 | X |
| Dioxane (Diethylene dioxide).. | 123-91-1 | 100 | 360 | X |
| Diphenyl (Biphenyl).... | 92-52-4 | 0.2 | 1 | |
| Diphenylmethane diisocyanate; see Methylene bisphenyl isocyanate..... | | | | |
| Dipropylene glycol methyl ether..... | 34590-94-8 | 100 | 600 | X |
| Di-sec octyl phthalate (Di-(2-ethylhexyl) phthalate)..... | 117-81-7 | | 5 | |
| Emery..... | 12415-34-8 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Endrin..... | 72-20-8 | | 0.1 | X |
| Epichlorohydrin..... | 106-89-8 | 5 | 19 | X |
| EPN..... | 2104-64-5 | | 0.5 | X |
| 1,2-Epoxypropane; see Propylene oxide..... | | | | |
| 2,3-Epoxy-1-propanol; see Glycidol..... | | | | |
| Ethanethiol; see Ethyl mercaptan..... | | | | |
| Ethanolamine..... | 141-43-5 | 3 | 6 | |
| 2-Ethoxyethanol (Cellosolve)..... | 110-80-5 | 200 | 740 | X |
| 2-Ethoxyethyl acetate (Cellosolve acetate).. | 111-15-9 | 100 | 540 | X |
| Ethyl acetate..... | 141-78-6 | 400 | 1400 | |
| Ethyl acrylate..... | 140-88-5 | 25 | 100 | X |
| Ethyl alcohol (Ethanol) | 64-17-5 | 1000 | 1900 | |
| Ethylamine..... | 75-04-7 | 10 | 18 | |
| Ethyl amyl ketone (5-Methyl-3- | | | | |

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|--|------------|--------|-------|---|
| heptanone)..... | 541-85-5 | 25 | 130 | |
| Ethyl benzene..... | 100-41-4 | 100 | 435 | |
| Ethyl bromide..... | 74-96-4 | 200 | 890 | |
| Ethyl butyl ketone (3-Heptanone)..... | 106-35-4 | 50 | 230 | |
| Ethyl chloride..... | 75-00-3 | 1000 | 2600 | |
| Ethyl ether..... | 60-29-7 | 400 | 1200 | |
| Ethyl formate..... | 109-94-4 | 100 | 300 | |
| Ethyl mercaptan..... | 75-08-1 | (C)10 | (C)25 | |
| Ethyl silicate..... | 78-10-4 | 100 | 850 | |
| Ethylene chlorohydrin.. | 107-07-3 | 5 | 16 | X |
| Ethylenediamine..... | 107-15-3 | 10 | 25 | |
| Ethylene dibromide.... | 106-93-4 | | (2) | |
| Ethylene dichloride (1,2-Dichloroethane).. | 107-06-2 | | (2) | |
| Ethylene glycol dinitrate..... | 628-96-6 | (C)0.2 | (C)1 | X |
| Ethylene glycol methyl acetate; see Methyl cellosolve acetate... | | | | |
| Ethyleneimine; see 1910.1012..... | 151-56-4 | | | |
| Ethylene oxide; see 1910.1047..... | 75-21-8 | | | |
| Ethylidene chloride; see 1,1-Dichlorethane | | | | |
| N-Ethylmorpholine..... | 100-74-3 | 20 | 94 | X |
| Ferbam..... | 14484-64-1 | | | |
| Total dust..... | | | 15 | |
| Ferrovandium dust..... | 12604-58-9 | | 1 | |
| Fluorides (as F)..... | (4) | | 2.5 | |
| Fluorine..... | 7782-41-4 | 0.1 | 0.2 | |
| Fluorotrchloromethane (Trichloro- fluoromethane)..... | 75-69-4 | 1000 | 5600 | |
| Formaldehyde; see 1910.1048..... | 50-00-0 | | | |
| Formic acid..... | 64-18-6 | 5 | 9 | |
| Furfural..... | 98-01-1 | 5 | 20 | X |
| Furfuryl alcohol..... | 98-00-0 | 50 | 200 | |
| Grain dust (oat, wheat barley)..... | | | 10 | |
| Glycerin (mist)..... | 56-81-5 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Glycidol..... | 556-52-5 | 50 | 150 | |
| Glycol monoethyl ether; see 2-Ethoxyethanol.. | | | | |
| Graphite, natural respirable dust..... | 7782-42-5 | | (3) | |
| Graphite, synthetic.... | | | | |
| Total dust..... | | | 15 | |
| Respirable Fraction.. | | | 5 | |
| Guthion; see Azinphos methyl.. | | | | |
| Gypsum..... | 13397-24-5 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |

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| Hafnium..... | 7440-58-6 | | 0.5 | |
| Heptachlor..... | 76-44-8 | | 0.5 | X |
| Heptane (n-Heptane).... | 142-82-5 | 500 | 2000 | |
| Hexachloroethane..... | 67-72-1 | 1 | 10 | X |
| Hexachloronaphthalene.. | 1335-87-1 | | 0.2 | X |
| n-Hexane..... | 110-54-3 | 500 | 1800 | |
| 2-Hexanone (Methyl n-butyl ketone)..... | 591-78-6 | 100 | 410 | |
| Hexone (Methyl isobutyl ketone)..... | 108-10-1 | 100 | 410 | |
| sec-Hexyl acetate..... | 108-84-9 | 50 | 300 | |
| Hydrazine..... | 302-01-2 | 1 | 1.3 | X |
| Hydrogen bromide..... | 10035-10-6 | 3 | 10 | |
| Hydrogen chloride..... | 7647-01-0 | (C)5 | (C)7 | |
| Hydrogen cyanide..... | 74-90-8 | 10 | 11 | X |
| Hydrogen fluoride (as F)..... | 7664-39-3 | | (2) | |
| Hydrogen peroxide..... | 7722-84-1 | 1 | 1.4 | |
| Hydrogen selenide (as Se)..... | 7783-07-5 | 0.05 | 0.2 | |
| Hydrogen sulfide..... | 7783-06-4 | | (2) | |
| Hydroquinone..... | 123-31-9 | | 2 | |
| Iodine..... | 7553-56-2 | (C)0.1 | (C)1 | |
| Iron oxide fume..... | 1309-37-1 | | 10 | |
| Isomyl acetate..... | 123-92-2 | 100 | 525 | |
| Isomyl alcohol (primary and secondary)..... | 123-51-3 | 100 | 360 | |
| Isobutyl acetate..... | 110-19-0 | 150 | 700 | |
| Isobutyl alcohol..... | 78-83-1 | 100 | 300 | |
| Isophorone..... | 78-59-1 | 25 | 140 | |
| Isopropyl acetate..... | 108-21-4 | 250 | 950 | |
| Isopropyl alcohol..... | 67-63-0 | 400 | 980 | |
| Isopropylamine..... | 75-31-0 | 5 | 12 | |
| Isopropyl ether..... | 108-20-3 | 500 | 2100 | |
| Isopropyl glycidyl ether (IGE)..... | 4016-14-2 | 50 | 240 | |
| Kaolin..... | 1332-58-7 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Ketene..... | 463-51-4 | 0.5 | 0.9 | |
| Lead inorganic (as Pb); see 1910.1025..... | 7439-92-1 | | | |
| Limestone..... | 1317-65-3 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Lindane..... | 58-89-9 | | 0.5 | X |
| Lithium hydride..... | 7580-67-8 | | 0.025 | |
| L.P.G. (Liquified petroleum gas)..... | 68476-85-7 | 1000 | 1800 | |
| Magnesite..... | 546-93-0 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Magnesium oxide fume... Total Particulate.... | 1309-48-4 | | 15 | |
| Malathion..... | 121-75-5 | | | |
| Total dust..... | | | 15 | X |
| Maleic anhydride..... | 108-31-6 | 0.25 | 1 | |

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| Manganese compounds | | | | |
| (as Mn)..... | 7439-96-5 | | (C)5 | |
| Manganese fume (as Mn).. | 7439-96-5 | | (C)5 | |
| Marble..... | 1317-65-3 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Mercury (aryl and inorganic)(as Hg).... | 7439-97-6 | | (2) | |
| Mercury (organo) alkyl compounds (as Hg).... | 7439-97-6 | | (2) | |
| Mercury (vapor) (as Hg) | 7439-97-6 | | (2) | |
| Mesityl oxide..... | 141-79-7 | 25 | 100 | |
| Methanethiol; see Methyl mercaptan. | | | | |
| Methoxychlor..... | 72-43-5 | | | |
| Total dust..... | | | 15 | |
| 2-Methoxyethanol; (Methyl cellosolve).. | 109-86-4 | 25 | 80 | X |
| 2-Methoxyethyl acetate (Methyl cellosolve acetate)..... | 110-49-6 | 25 | 120 | X |
| Methyl acetate..... | 79-20-9 | 200 | 610 | |
| Methyl acetylene (Propyne)..... | 74-99-7 | 1000 | 1650 | |
| Methyl acetylene propadiene mixture (MAPP)..... | | 1000 | 1800 | |
| Methyl acrylate..... | 96-33-3 | 10 | 35 | X |
| Methylal (Dimethoxy-methane).. | 109-87-5 | 1000 | 3100 | |
| Methyl alcohol..... | 67-56-1 | 200 | 260 | |
| Methylamine..... | 74-89-5 | 10 | 12 | |
| Methyl amyl alcohol; see Methyl Isobutyl carbinol..... | | | | |
| Methyl n-amyl ketone... | 110-43-0 | 100 | 465 | |
| Methyl bromide..... | 74-83-9 | (C)20 | (C)80 | X |
| Methyl butyl ketone; see 2-Hexanone..... | | | | |
| Methyl cellosolve; see 2-Methoxyethanol. | | | | |
| Methyl cellosolve acetate; see 2-Methoxyethyl acetate..... | | | | |
| Methyl chloride..... | 74-87-3 | | (2) | |
| Methyl chloroform (1,1,1-Trichloroethane)..... | 71-55-6 | 350 | 1900 | |
| Methylcyclohexane..... | 108-87-2 | 500 | 2000 | |
| Methylcyclohexanol..... | 25639-42-3 | 100 | 470 | |
| o-Methylcyclohexanone.. | 583-60-8 | 100 | 460 | X |
| Methylene chloride..... | 75-09-2 | | (2) | |
| Methyl ethyl ketone (MEK); see 2-Butanone | | | | |
| Methyl formate..... | 107-31-3 | 100 | 250 | |
| Methyl hydrazine (Monomethyl | | | | |

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|--|------------|---------|---------|---|
| hydrazine)..... | 60-34-4 | (C)0.2 | (C)0.35 | X |
| Methyl iodide..... | 74-88-4 | 5 | 28 | X |
| Methyl isoamyl ketone.. | 110-12-3 | 100 | 475 | |
| Methyl isobutyl carbinol..... | 108-11-2 | 25 | 100 | X |
| Methyl isobutyl ketone; see Hexone..... | | | | |
| Methyl isocyanate..... | 624-83-9 | 0.02 | 0.05 | X |
| Methyl mercaptan..... | 74-93-1 | (C)10 | (C)20 | |
| Methyl methacrylate.... | 80-62-6 | 100 | 410 | |
| Methyl propyl ketone; see 2-Pentanone..... | | | | |
| alpha-Methyl styrene... | 98-83-9 | (C)100 | (C)480 | |
| Methylene bisphenyl isocyanate (MDI)..... | 101-68-8 | (C)0.02 | (C)0.2 | |
| Mica; see Silicates.... | | | | |
| Molybdenum (as Mo)..... | 7439-98-7 | | | |
| Soluble compounds.... | | | 5 | |
| Insoluble Compounds Total dust..... | | | 15 | |
| Monomethyl aniline.... | 100-61-8 | 2 | 9 | X |
| Monomethyl hydrazine; see Methyl hydrazine. | | | | |
| Morpholine..... | 110-91-8 | 20 | 70 | X |
| Naphtha (Coal tar)..... | 8030-30-6 | 100 | 400 | |
| Naphthalene..... | 91-20-3 | 10 | 50 | |
| alpha-Naphthylamine; see 1910.1004..... | 134-32-7 | | | |
| beta-Naphthylamine; see 1910.1009..... | 91-59-8 | | | |
| Nickel carbonyl (as Ni) | 13463-39-3 | 0.001 | 0.007 | |
| Nickel, metal and insoluble compounds (as Ni)..... | 7440-02-0 | | 1 | |
| Nickel, soluble compounds (as Ni).... | 7440-02-0 | | 1 | |
| Nicotine..... | 54-11-5 | | 0.5 | X |
| Nitric acid..... | 7697-37-2 | 2 | 5 | |
| Nitric oxide..... | 10102-43-9 | 25 | 30 | |
| p-Nitroaniline..... | 100-01-6 | 1 | 6 | X |
| Nitrobenzene..... | 98-95-3 | 1 | 5 | X |
| p-Nitrochlorobenzene... | 100-00-5 | | 1 | X |
| 4-Nitrodiphenyl; see 1910.1003..... | 92-93-3 | | | |
| Nitroethane..... | 79-24-3 | 100 | 310 | |
| Nitrogen dioxide..... | 10102-44-0 | (C)5 | (C)9 | |
| Nitrogen trifluoride... | 7783-54-2 | 10 | 29 | |
| Nitroglycerin..... | 55-63-0 | (C)0.2 | (C)2 | X |
| Nitromethane..... | 75-52-5 | 100 | 250 | |
| 1-Nitropropane..... | 108-03-2 | 25 | 90 | |
| 2-Nitropropane..... | 79-46-9 | 25 | 90 | |
| N-Nitrosodimethylamine; see 1910.1016 | | | | |
| Nitrotoluene (all isomers)..... | | 5 | 30 | X |
| o-isomer..... | 88-72-2 | | | |
| m-isomer..... | 99-08-1 | | | |
| p-isomer..... | 99-99-0 | | | |

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| Nitrotrichloromethane; see Chloropicrin..... | | | | |
| Octachloronaphthalene.. | 2234-13-1 | | 0.1 | X |
| Octane..... | 111-65-9 | 500 | 2350 | |
| Oil mist, mineral..... | 8012-95-1 | | 5 | |
| Osmium tetroxide (as Os)..... | 20816-12-0 | | 0.002 | |
| Oxalic acid..... | 144-62-7 | | 1 | |
| Oxygen difluoride..... | 7783-41-7 | 0.05 | 0.1 | |
| Ozone..... | 10028-15-6 | 0.1 | 0.2 | |
| Paraquat, respirable dust..... | 4685-14-7 | | 0.5 | X |
| | 1910-42-5 | | | |
| | 2074-50-2 | | | |
| Parathion..... | 56-38-2 | | 0.1 | X |
| Particulates not otherwise regulated (PNOR)(f)..... | | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| PCB; see Chlorodiphenyl (42% and 54% chlorine)..... | | | | |
| Pentaborane..... | 19624-22-7 | 0.005 | 0.01 | |
| Pentachloronaphthalene.. | 1321-64-8 | | 0.5 | X |
| Pentachlorophenol..... | 87-86-5 | | 0.5 | X |
| Pentaerythritol..... | 115-77-5 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Pentane..... | 109-66-0 | 1000 | 2950 | |
| 2-Pentanone (Methyl propyl ketone)..... | 107-87-9 | 200 | 700 | |
| Perchloroethylene (Tetrachloroethylene) | 127-18-4 | | (2) | |
| Perchloromethyl mercaptan..... | 594-42-3 | 0.1 | 0.8 | |
| Perchloryl fluoride.... | 7616-94-6 | 3 | 13.5 | |
| Petroleum distillates (Naphtha)(Rubber Solvent)..... | | 500 | 2000 | |
| Phenol..... | 108-95-2 | 5 | 19 | X |
| p-Phenylene diamine.... | 106-50-3 | | 0.1 | X |
| Phenyl ether, vapor.... | 101-84-8 | 1 | 7 | |
| Phenyl ether-biphenyl mixture, vapor..... | | 1 | 7 | |
| Phenylethylene; see Styrene..... | | | | |
| Phenyl glycidyl ether (PGE)..... | 122-60-1 | 10 | 60 | |
| Phenylhydrazine..... | 100-63-0 | 5 | 22 | X |
| Phosdrin (Mevinphos)... | 7786-34-7 | | 0.1 | X |
| Phosgene (Carbonyl chloride)..... | 75-44-5 | 0.1 | 0.4 | |
| Phosphine..... | 7803-51-2 | 0.3 | 0.4 | |
| Phosphoric acid..... | 7664-38-2 | | 1 | |
| Phosphorus (yellow).... | 7723-14-0 | | 0.1 | |
| Phosphorus pentachloride..... | 10026-13-8 | | 1 | |

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| Phosphorus pentasulfide | 1314-80-3 | | 1 | |
| Phosphorus trichloride. | 7719-12-2 | 0.5 | 3 | |
| Phthalic anhydride..... | 85-44-9 | 2 | 12 | |
| Picloram..... | 1918-02-1 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Picric acid..... | 88-89-1 | | 0.1 | X |
| Pindone (2-Pivalyl-1, 3-indandione)..... | 83-26-1 | | 0.1 | |
| Plaster of paris..... | 26499-65-0 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Platinum (as Pt)..... | 7440-06-4 | | | |
| Metal..... | | | | |
| Soluble Salts..... | | | 0.002 | |
| Portland cement..... | 65997-15-1 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Propane..... | 74-98-6 | 1000 | 1800 | |
| beta-Propriolactone; see 1910.1013..... | 57-57-8 | | | |
| n-Propyl acetate..... | 109-60-4 | 200 | 840 | |
| n-Propyl alcohol..... | 71-23-8 | 200 | 500 | |
| n-Propyl nitrate..... | 627-13-4 | 25 | 110 | |
| Propylene dichloride... | 78-87-5 | 75 | 350 | |
| Propylene imine..... | 75-55-8 | 2 | 5 | X |
| Propylene oxide..... | 75-56-9 | 100 | 240 | |
| Propyne; see Methyl acetylene..... | | | | |
| Pyrethrum..... | 8003-34-7 | | 5 | |
| Pyridine..... | 110-86-1 | 5 | 15 | |
| Quinone..... | 106-51-4 | 0.1 | 0.4 | |
| RDX: see Cyclonite..... | | | | |
| Rhodium (as Rh), metal fume and insoluble compounds..... | 7440-16-6 | | 0.1 | |
| Rhodium (as Rh), soluble compounds.... | 7440-16-6 | | 0.001 | |
| Ronnel..... | 299-84-3 | | 15 | |
| Rotenone..... | 83-79-4 | | 5 | |
| Rouge..... | | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Selenium compounds (as Se)..... | 7782-49-2 | | 0.2 | |
| Selenium hexafluoride (as Se)..... | 7783-79-1 | 0.05 | 0.4 | |
| Silica, amorphous, precipitated and gel. | 112926-00-8 | | (3) | |
| Silica, amorphous, diatomaceous earth, containing less than 1% crystalline silica | 61790-53-2 | | (3) | |
| Silica, crystalline cristobalite, respirable dust..... | 14464-46-1 | | (3) | |
| Silica, crystalline quartz, respirable | | | | |

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| dust..... | 14808-60-7 | | (3) | |
| Silica, crystalline tripoli (as quartz), respirable dust..... | 1317-95-9 | | (3) | |
| Silica, crystalline tridymite, respirable dust..... | 15468-32-3 | | (3) | |
| Silica, fused, respirable dust..... | 60676-86-0 | | (3) | |
| Silicates (less than 1% crystalline silica) Mica (respirable dust)..... | 12001-26-2 | | (3) | |
| Soapstone, total dust | | | (3) | |
| Soapstone, respirable dust..... | | | (3) | |
| Talc (containing asbestos): use asbestos limit: see 29 CFR 1910.1001..... | | | (3) | |
| Talc (containing no asbestos), respirable dust..... | 14807-96-6 | | (3) | |
| Tremolite, asbestiform; see 1910.1001..... | | | | |
| Silicon..... | 7440-21-3 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Silicon carbide..... | 409-21-2 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Silver, metal and soluble compounds (as Ag)..... | 7440-22-4 | | 0.01 | |
| Soapstone; see Silicates..... | | | | |
| Sodium fluoroacetate... | 62-74-8 | | 0.05 | X |
| Sodium hydroxide..... | 1310-73-2 | | 2 | |
| Starch..... | 9005-25-8 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Stibine..... | 7803-52-3 | 0.1 | 0.5 | |
| Stoddard solvent..... | 8052-41-3 | 500 | 2900 | |
| Strychnine..... | 57-24-9 | | 0.15 | |
| Styrene..... | 100-42-5 | | (2) | |
| Sucrose..... | 57-50-1 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Sulfur dioxide..... | 7446-09-5 | 5 | 13 | |
| Sulfur hexafluoride.... | 2551-62-4 | 1000 | 6000 | |
| Sulfuric acid..... | 7664-93-9 | | 1 | |
| Sulfur monochloride.... | 10025-67-9 | 1 | 6 | |
| Sulfur pentafluoride... | 5714-22-7 | 0.025 | 0.25 | |
| Sulfuryl fluoride..... | 2699-79-8 | 5 | 20 | |
| Systox; see Demeton... | | | | |
| 2,4,5-T (2,4,5-tri- chlorophenoxyacetic | | | | |

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| acid)..... | 93-76-5 | | 10 | |
| Talc; see Silicates... | | | | |
| Tantalum, metal and oxide dust..... | 7440-25-7 | | 5 | |
| TEDP (Sulfotep)..... | 3689-24-5 | | 0.2 | X |
| Tellurium and compounds (as Te).... | 13494-80-9 | | 0.1 | |
| Tellurium hexafluoride (as Te)..... | 7783-80-4 | 0.02 | 0.2 | |
| Temephos..... | 3383-96-8 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| TEPP (Tetraethyl pyrophosphaate)..... | 107-49-3 | | 0.05 | X |
| Terphenylis..... | 26140-60-3 | (C)1 | (C)9 | |
| 1,1,1,2-Tetrachloro-2, 2-difluoroethane..... | 76-11-9 | 500 | 4170 | |
| 1,1,2,2-Tetrachloro-1, 2-difluoroethane..... | 76-12-0 | 500 | 4170 | |
| 1,1,2,2-Tetrachloro- ethane..... | 79-34-5 | 5 | 35 | X |
| Tetrachoroethylene; see Perchloroethylene | | | | |
| Tetrachloromethane; see Carbon tetrachloride. | | | | |
| Tetrachloronaphthalene. | 1335-88-2 | | 2 | X |
| Tetraethyl lead (as Pb) | 78-00-2 | | 0.075 | X |
| Tetrahydrofuran..... | 109-99-9 | 200 | 590 | |
| Tetramethyl lead, (as Pb)..... | 75-74-1 | | 0.075 | X |
| Tetramethyl succinonitrile..... | 3333-52-6 | 0.5 | 3 | X |
| Tetranitromethane..... | 509-14-8 | 1 | 8 | |
| Tetryl (2,4,6-Trinitro- phenylmethyl- nitramine)..... | 479-45-8 | | 1.5 | X |
| Thallium, soluble compounds (as Tl).... | 7440-28-0 | | 0.1 | X |
| 4,4'-Thiobis(6-tert, Butyl-m-cresol)..... | 96-69-5 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Thiram..... | 137-26-8 | | 5 | |
| Tin, inorganic compounds (except oxides) (as Sn)..... | 7440-31-5 | | 2 | |
| Tin, organic compounds (as Sn)..... | 7440-31-5 | | 0.1 | |
| Titanium dioxide..... | 13463-67-7 | | | |
| Total dust..... | | | 15 | |
| Toluene..... | 108-88-3 | | (2) | |
| Toluene-2, 4-diisocyanate (TDI). | 584-84-9 | (C)0.02 | (C)0.14 | |
| o-Toluidine..... | 95-53-4 | 5 | 22 | X |
| Toxaphene; see Chlorinated camphene. | | | | |
| Tremolite; see Silicates..... | | | | |

| | | | | |
|---|------------|-------|--------|---|
| Tributyl phosphate..... | 126-73-8 | | 5 | |
| 1,1,1-Trichloroethane; see Methyl chloroform | | | | |
| 1,1,2-Trichloroethane.. | 79-00-5 | 10 | 45 | X |
| Trichloroethylene..... | 79-01-6 | | (2) | |
| Trichloromethane; see Chloroform | | | | |
| Trichloronaphthalene... | 1321-65-9 | | 5 | X |
| 1,2,3-Trichloropropane. | 96-18-4 | 50 | 300 | |
| 1,1,2-Trichloro-1,2, 2-trifluoroethane.... | 76-13-1 | 1000 | 7600 | |
| Triethylamine..... | 121-44-8 | 25 | 100 | |
| Trifluorobromomethane.. | 75-63-8 | 1000 | 6100 | |
| 2,4,6-Trinitrophenol; see Picric acid..... | | | | |
| 2,4,6-Trinitrophenyl- methyl nitramine; see Tetryl..... | | | | |
| 2,4,6-Trinitrotoluene (TNT)..... | 118-96-7 | | 1.5 | X |
| Triorthocresyl phosphate..... | 78-30-8 | | 0.1 | |
| Triphenyl phosphate.... | 115-86-6 | | 3 | |
| Turpentine..... | 8006-64-2 | 100 | 560 | |
| Uranium (as U)..... | 7440-61-1 | | | |
| Soluble compounds.... | | | 0.05 | |
| Insoluble compounds.. | | | 0.25 | |
| Vanadium..... | 1314-62-1 | | | |
| Respirable dust (as V(2)O(5))..... | | | (C)0.5 | |
| Fume (as V(2)O(5))... | | | (C)0.1 | |
| Vegetable oil mist..... | | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Vinyl benzene; see Styrene..... | | | | |
| Vinyl chloride; see 1910.1017..... | 75-01-4 | | | |
| Vinyl cyanide; see Acrylonitrile | | | | |
| Vinyl toluene..... | 25013-15-4 | 100 | 480 | |
| Warfarin..... | 81-81-2 | | 0.1 | |
| Xylenes (o-, m-, p-isomers).. | 1330-20-7 | 100 | 435 | |
| Xylidine..... | 1300-73-8 | 5 | 25 | X |
| Yttrium..... | 7440-65-5 | | 1 | |
| Zinc chloride fume.... | 7646-85-7 | | 1 | |
| Zinc oxide fume..... | 1314-13-2 | | 5 | |
| Zinc oxide..... | 1314-13-2 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Zinc stearate..... | 557-05-1 | | | |
| Total dust..... | | | 15 | |
| Respirable fraction.. | | | 5 | |
| Zirconium compounds (as Zr)..... | 7440-67-7 | | 5 | |

Footnote(1) The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

Footnote(a) Parts of vapor or gas per million parts of contaminated air by volume at 25 degrees C and 760 torr.

Footnote(b) Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

Footnote(c) The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound measured as the metal, the CAS number for the metal is given - not CAS numbers for the individual compounds.

Footnote(d) The final benzene standard in 1910.1028 applies to all occupational exposures to benzene except in some circumstances the distribution and sale of fuels, sealed containers and pipelines, coke production, oil and gas drilling and production, natural gas processing, and the percentage exclusion for liquid mixtures; for the excepted subsegments, the benzene limits in Table Z-2 apply. See 1910.1028 for specific circumstances.

Footnote(e) This 8-hour TWA applies to respirable dust as measured by a vertical elutriator cotton dust sampler or equivalent instrument. The time-weighted average applies to the cotton waste processing operations of waste recycling (sorting, blending, cleaning and willowing) and garnetting. See also 1910.1043 for cotton dust limits applicable to other sectors.

Footnote(f) All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by the Particulates Not Otherwise Regulated (PNOR) limit which is the same as the inert or nuisance dust limit of Table Z-3.

Footnote(2) See Table Z-2.

Footnote(3) See Table Z-3

Footnote(4) Varies with compound.

Footnote(5) See Table Z-2 for the exposure limits for any operations or sectors where the exposure limits in 1910.1026 are stayed or are otherwise not in effect.

[54 FR 36767, Sept. 5, 1989; 54 FR 41244, Oct. 6, 1989; 55 FR 3724, Feb. 5, 1990; 55 FR 12819, Apr 6, 1990; 55 FR 19259, May 9, 1990; 55 FR 46950, Nov. 8, 1990; 57 FR 29204, July 1, 1992; 57 FR 42388, Sept. 14, 1992; 58 FR 35340, June 30, 1993; 61 FR 56746, Nov. 4, 1996; 62 FR 42018, August 4, 1997; 71 FR 10373, Feb. 28, 2006]

TABLE Z-2

| Substance | 8-hour time weighted average | Acceptable ceiling concentration | Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift | |
|---|------------------------------|----------------------------------|--|---|
| | | | Concentration | Maximum duration |
| Benzene ^(a) (Z37.40-1969) | 10 ppm | 25 ppm | 50 ppm | 10 minutes. |
| Beryllium and beryllium compounds (Z37.29-1970) | 2 ug/m(3) | 5 ug/m(3) | 25 ug/m(3) | 30 minutes. |
| Cadmium fume ^(b) (Z37.5-1970) | 0.1 mg/m(3) | 0.3 mg/m(3) | | |
| Cadmium dust ^(b) (Z37.5-1970) | 0.2 mg/m(3) | 0.6 mg/m(3) | | |
| Carbon disulfide (Z37.3-1968) | 20 ppm | 30 ppm | 100 ppm | 30 minutes. |
| Carbon tetrachloride (Z37.17-1967) | 10 ppm | 25 ppm | 200 ppm | 5 min. in any 3 hrs. |
| Chromic acid and chromates (Z37-7-1971) (as CrO ₃) ^(c) | | 1 mg/10 m(3) | | |
| Ethylene dibromide (Z37.31-1970) | 20 ppm | 30 ppm | 50 ppm | 5 minutes. |
| Ethylene dichloride (Z37.21-1969) | 50 ppm | 100 ppm | 200 ppm | 5 min. in any 3 hrs. |
| Fluoride as dust (Z37.28-1969) | 2.5 mg/m(3) | | | |
| Formaldehyde: see 1910.1048 | | | | |
| Hydrogen fluoride (Z37.28-1969) | 3 ppm | | | |
| Hydrogen sulfide (Z37.2-1966) | | 20 ppm | 50 ppm | 10 mins. once only if no other meas. exp. occurs. |
| Mercury (Z37.8-1971) | | 1 mg/10m(3) | | |
| Methyl chloride (Z37.18-1969) | 100 ppm | 200 ppm | 300 ppm | 5 mins. in any 3 hrs. |
| Methylene Chloride: see 1910.1052 | | | | |

| | | | | |
|--------------------------------------|-------------|--------------|---------|-----------------------|
| Organo (alkyl) mercury (Z37.30-1969) | 0.01mg/m(3) | 0.04 mg/m(3) | | |
| Styrene (Z37.15-1969) | 100 ppm | 200 ppm | 600 ppm | 5 mins. in any 3 hrs. |
| Tetrachloroethylene | 100 ppm | 200 ppm | 300 ppm | 5 mins. in any 3 hrs. |
| Toluene (Z37.12-1967) | 200 ppm | 300 ppm | 500 ppm | 10 minutes |
| Trichloroethylene (Z37.19-1967) | 100 ppm | 200 ppm | 300 ppm | 5 mins. in any 2 hrs. |

Footnote^(a) This standard applies to the industry segments exempt from the 1 ppm 8-hour TWA and 5 ppm STEL of the benzene standard at 1910.1028.

Footnote^(b) This standard applies to any operations or sectors for which the Cadmium standard, 1910.1027, is stayed or otherwise not in effect.

Footnote^(c) This standard applies to any operations or sectors for which the Hexavalent Chromium standard, 1910.1026, is stayed or otherwise not in effect.

TABLE Z-3 Mineral Dusts

| Substance | mppcf ^a | mg/m ³ |
|---|--|---|
| Silica: | | |
| Crystalline | | |
| Quartz (Respirable) | 250 ^b %SiO ₂ +5 | 10 mg/m ³ ^e %SiO ₂ +2 |
| Quartz (Total Dust) | | 30 mg/m ³ %SiO ₂ +2 |
| <ul style="list-style-type: none"> ▪ Cristobalite: Use ½ the value calculated from the count or mass formulae for quartz. ▪ Tridymite: Use ½ the value calculated from the formulae for quartz. | | |
| Amorphous, including natural diatomaceous earth | 20 | 80 mg/m ³ %SiO ₂ |
| Silicates (less than 1% crystalline silica): | | |
| Mica | 20 | |

| | | |
|--|-----------------|---|
| Soapstone | 20 | |
| Talc (not containing asbestos) | 20 ^c | |
| Talc (containing asbestos) Use asbestos limit | | |
| Tremolite, asbestiform (see 29 CFR 1910.1001) | | |
| Portland cement | 50 | |
| Graphite (Natural) | 15 | |
| Coal Dust: | | |
| Respirable fraction less than 5% SiO ₂ | | 2.4 mg/m ³ ^e |
| Respirable fraction greater than 5% SiO ₂ | | 10 mg/m ³ ^e %SiO ₂ +2 |
| Inert or Nuisance Dust: ^d | | |
| Respirable fraction | 15 | 5 mg/m ³ |
| Total dust | 50 | 15 mg/m ³ |

Note -- Conversion factors - mppcf X 35.3 = million particles per cubic meter = particles per c.c.

^a Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques.

^b The percentage of crystalline silica in the formula is the amount determined from airborne samples, except in those instances in which other methods have been shown to be applicable.

^c Containing less than 1% quartz; if 1% quartz or more, use quartz limit.

^d All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by this limit, which is the same as the Particulates Not Otherwise Regulated (PNOR) limit in Table Z-1.

^e Both concentration and percent quartz for the application of this limit are to be determined from the fraction passing a size-selector with the following characteristics:

| Aerodynamic diameter (unit density sphere) | Percent passing selector |
|--|--------------------------|
| 2 | 90 |
| 2.5 | 75 |
| 3.5 | 50 |
| 5.0 | 25 |
| 10 | 0 |

The measurements under this note refer to the use of an AEC (now NRC) instrument. The respirable fraction of coal dust is determined with an MRE; the figure corresponding to that of 2.4 mg/m³ in the table for coal dust is 4.5 mg/m³.

1910.1001 Asbestos.

(a) Scope and application.

(1) This section applies to all occupational exposures to asbestos in all industries covered by the Occupational Safety and Health Act, except as provided in paragraph (a)(2) and (3) of this section.

(2) This section does not apply to construction work as defined in 29 CFR 1910.12(b). (Exposure to asbestos in construction work is covered by 29 CFR 1926.1101).

(3) This section does not apply to ship repairing, shipbuilding and shipbreaking employments and related employments as defined in 29 CFR 1915.4. (Exposure to asbestos in these employments is covered by 29 CFR 1915.1001).

(b) Definitions.

Asbestos includes chrysotile, amosite, crocidolite, tremolite asbestos, anthophyllite asbestos, actinolite asbestos, and any of these minerals that have been chemically treated and/or altered.

Asbestos-containing material (ACM) means any material containing more than 1% asbestos.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person authorized by the employer and required by work duties to be present in regulated areas.

Building/facility owner is the legal entity, including a lessee, which exercises control over management and record keeping functions relating to a building and/or facility in which activities covered by this standard take place.

Certified industrial hygienist (CIH) means one certified in the practice of industrial hygiene by the American Board of Industrial Hygiene.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Employee exposure means that exposure to airborne asbestos that would occur if the employee

were not using respiratory protective equipment.

Fiber means a particulate form of asbestos 5 micrometers or longer, with a length-to-diameter ratio of at least 3 to 1.

High-efficiency particulate air (HEPA) filter means a filter capable of trapping and retaining at least 99.97 percent of 0.3 micrometer diameter mono-disperse particles.

Homogeneous area means an area of surfacing material or thermal system insulation that is uniform in color and texture.

Industrial hygienist means a professional qualified by education, training, and experience to anticipate, recognize, evaluate and develop controls for occupational health hazards.

PACM means presumed asbestos containing material.

Presumed asbestos containing material means thermal system insulation and surfacing material found in buildings constructed no later than 1980. The designation of a material as 'PACM' may be rebutted pursuant to paragraph (j)(8) of this section.

Regulated area means an area established by the employer to demarcate areas where airborne concentrations of asbestos exceed, or there is a reasonable possibility they may exceed, the permissible exposure limits.

Surfacing ACM means surfacing material which contains more than 1% asbestos.

Surfacing material means material that is sprayed, troweled-on or otherwise applied to surfaces (such as acoustical plaster on ceilings and fireproofing materials on structural members, or other materials on surfaces for acoustical, fireproofing, and other purposes.

Thermal System Insulation (TSI) means ACM applied to pipes, fittings, boilers, breeching, tanks, ducts or other structural components to prevent heat loss or gain.

Thermal System Insulation ACM means thermal system insulation which contains more than 1% asbestos.

(c) Permissible exposure limit (PELS)-

(1) Time-weighted average limit (TWA). The employer shall ensure that no employee is exposed to an airborne concentration of asbestos in excess of 0.1 fiber per cubic centimeter of air as an eight (8)-hour time-weighted average (TWA) as determined by the method prescribed in Appendix A to this section, or by an equivalent method.

(2) Excursion limit. The employer shall ensure that no employee is exposed to an airborne concentration of asbestos in excess of 1.0 fiber per cubic centimeter of air (1 f/cc) as averaged over a sampling period of thirty (30) minutes as determined by the method prescribed in Appendix A to this section of by an equivalent method.

(d) Exposure monitoring.

(1) General.

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 30-minute short-term exposures of each employee.

(ii) Representative 8-hour TWA employee exposures shall be determined on the basis of one or more samples representing full-shift exposures for each shift for each employee in each job classification in each work area. Representative 30-minute short-term employee exposures shall be determined on the basis of one or more samples representing 30 minute exposures associated with operations that are most likely to produce exposures above the excursion limit for each shift for each job classification in each work area.

(2) Initial monitoring.

(i) Each employer who has a workplace or work operation covered by this standard, except as provided for in paragraphs (d)(2)(ii) and (d)(2)(iii) of this section, shall perform initial monitoring of employees who are, or may reasonably be expected to be exposed to airborne concentrations at or above the TWA permissible exposure limit and/or excursion limit.

(ii) Where the employer has monitored after March 31, 1992, for the TWA permissible exposure limit and/or the excursion limit, and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

(iii) Where the employer has relied upon objective data that demonstrate that asbestos is not capable of being released in airborne concentrations at or above the TWA permissible exposure limit and/or excursion limit under the expected conditions of processing, use, or handling, then no initial monitoring is required.

(3) Monitoring frequency (periodic monitoring) and patterns. After the initial determinations required by paragraph (d)(2)(i) of this section, samples shall be of such frequency and pattern as to represent with reasonable accuracy the levels of exposure of the employees. In no case shall sampling be at intervals greater than six months for employees whose exposures may reasonably be foreseen to exceed the TWA permissible exposure limit and/or excursion limit.

(4) Changes in monitoring frequency. If either the initial or the periodic monitoring required by

paragraphs (d)(2) and (d)(3) of this section statistically indicates that employee exposures are below the TWA permissible exposure limit and/or excursion limit, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(5) Additional monitoring. Notwithstanding the provisions of paragraphs (d)(2)(ii) and (d)(4) of this section, the employer shall institute the exposure monitoring required under paragraphs (d)(2)(i) and (d)(3) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures above the TWA permissible exposure limit and/or excursion limit or when the employer has any reason to suspect that a change may result in new or additional exposures above the action PEL and/or excursion limit.

(6) Method of monitoring.

(i) All samples taken to satisfy the monitoring requirements of paragraph (d) of this section shall be personal samples collected following the procedures specified in Appendix A.

(ii) All samples taken to satisfy the monitoring requirements of paragraph (d) of this section shall be evaluated using the OSHA Reference Method (ORM) specified in Appendix A of this section, or an equivalent counting method.

(iii) If an equivalent method to the ORM is used, the employer shall ensure that the method meets the following criteria:

(A) Replicate exposure data used to establish equivalency are collected in side-by-side field and laboratory comparisons; and

(B) The comparison indicates that 90% of the samples collected in the range 0.5 to 2.0 times the permissible limit have an accuracy range of plus or minus 25 percent of the ORM results at a 95% confidence level as demonstrated by a statistically valid protocol; and

(C) The equivalent method is documented and the results of the comparison testing are maintained.

(iv) To satisfy the monitoring requirements of paragraph (d) of this section, employers must use the results of monitoring analysis performed by laboratories which have instituted quality assurance programs that include the elements as prescribed in Appendix A of this section.

(7) Employee notification of monitoring results.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this sections, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location

that is accessible to affected employees.

(ii) The written notification required by paragraph (d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the TWA and/or excursion limit, wherever monitoring results indicated that the TWA and/or excursion limit had been exceeded.

(e) Regulated Areas.-

(1) Establishment. The employer shall establish regulated areas wherever airborne concentrations of asbestos and/or PACM are in excess of the TWA and/or excursion limit prescribed in paragraph (c) of this section.

(2) Demarcation. Regulated areas shall be demarcated from the rest of the workplace in any manner that minimizes the number of persons who will be exposed to asbestos.

(3) Access. Access to regulated areas shall be limited to authorized persons or to persons authorized by the Act or regulations issued pursuant thereto.

(4) Provision of respirators. Each person entering a regulated area shall be supplied with and required to use a respirator, selected in accordance with paragraph (g)(2) of this section.

(5) Prohibited activities. The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in the regulated areas.

(f) Methods of compliance.-

(1) Engineering controls and work practices.

(i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the TWA and/or excursion limit prescribed in paragraph (c) of this section, except to the extent that such controls are not feasible.

(ii) Wherever the feasible engineering controls and work practices that can be instituted are not sufficient to reduce employee exposure to or below the TWA and/or excursion limit prescribed in paragraph (c) of this section, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(iii) For the following operations, wherever feasible engineering controls and work practices that can be instituted are not sufficient to reduce the employee exposure to or below the TWA and/or excursion limit prescribed in paragraph (c) of this section, the employer shall use them to reduce employee exposure to or below 0.5 fiber per cubic centimeter of air (as an eight-hour

time-weighted average) or 2.5 fibers/cc for 30 minutes (short-term exposure) and shall supplement them by the use of any combination of respiratory protection that complies with the requirements of paragraph (g) of this section, work practices and feasible engineering controls that will reduce employee exposure to or below the TWA and to or below the excursion limit permissible prescribed in paragraph (c) of this section: Coupling cutoff in primary asbestos cement pipe manufacturing; sanding in primary and secondary asbestos cement sheet manufacturing; grinding in primary and secondary friction product manufacturing; carding and spinning in dry textile processes; and grinding and sanding in primary plastics manufacturing.

(iv) Local exhaust ventilation. Local exhaust ventilation and dust collection systems shall be designed, constructed, installed, and maintained in accordance with good practices such as those found in the American National Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, ANSI Z9.2-1979.

(v) Particular tools. All hand-operated and power-operated tools which would produce or release fibers of asbestos, such as, but not limited to, saws, scorers, abrasive wheels, and drills, shall be provided with local exhaust ventilation systems which comply with paragraph (f)(1)(iv) of this section.

(vi) Wet methods. Insofar as practicable, asbestos shall be handled, mixed, applied, removed, cut, scored, or otherwise worked in a wet state sufficient to prevent the emission of airborne fibers so as to expose employees to levels in excess of the TWA and/or excursion limit, prescribed in paragraph (c) of this section, unless the usefulness of the product would be diminished thereby.

(vii) [Reserved]

(viii) Particular products and operations. No asbestos cement, mortar, coating, grout, plaster, or similar material containing asbestos, shall be removed from bags, cartons, or other containers in which they are shipped, without being either wetted, or enclosed, or ventilated so as to prevent effectively the release of airborne fibers.

(ix) Compressed air. Compressed air shall not be used to remove asbestos or materials containing asbestos unless the compressed air is used in conjunction with a ventilation system which effectively captures the dust cloud created by the compressed air.

(x) Flooring. Sanding of asbestos-containing flooring material is prohibited.

(2) Compliance program.

(i) Where the TWA and/or excursion limit is exceeded, the employer shall establish and implement a written program to reduce employee exposure to or below the TWA and to or below the excursion limit by means of engineering and work practice controls as required by paragraph

(f)(1) of this section, and by the use of respiratory protection where required or permitted under this section.

(ii) Such programs shall be reviewed and updated as necessary to reflect significant changes in the status of the employer's compliance program.

(iii) Written programs shall be submitted upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives.

(iv) The employer shall not use employee rotation as a means of compliance with the TWA and/or excursion limit.

(3) Specific compliance methods for brake and clutch repair:

(i) Engineering controls and work practices for brake and clutch repair and service. During automotive brake and clutch inspection, disassembly, repair and assembly operations, the employer shall institute engineering controls and work practices to reduce employee exposure to materials containing asbestos using a negative pressure enclosure/HEPA vacuum system method or low pressure/wet cleaning method, which meets the detailed requirements set out in Appendix F to this section. The employer may also comply using an equivalent method which follows written procedures which the employer demonstrates can achieve results equivalent to Method A in Appendix F to this section. For facilities in which no more than 5 pair of brakes or 5 clutches are inspected, disassembled, repaired, or assembled per week, the method set forth in paragraph [D] of Appendix F to this section may be used.

(ii) The employer may also comply by using an equivalent method which follows written procedures, which the employer demonstrates can achieve equivalent exposure reductions as do the two "preferred methods." Such demonstration must include monitoring data conducted under workplace conditions closely resembling the process, type of asbestos containing materials, control method, work practices and environmental conditions which the equivalent method will be used, or objective data, which document that under all reasonably foreseeable conditions of brake and clutch repair applications, the method results in exposures which are equivalent to the methods set out in Appendix F to this section.

(g) Respiratory protection.

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work practice controls.

(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the TWA and/or excursion limit.

(iv) Emergencies.

(2) Respirator Program.

(i) The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) Employers must provide an employee with a tight-fitting, powered air-purifying respirator (PAPR) instead of a negative pressure respirator selected according to paragraph (g)(3) of this standard when the employee chooses to use a PAPR and it provides adequate protection to the employee.

(iii) No employee must be assigned to tasks requiring the use of respirators if, based on their most recent medical examination, the examining physician determines that the employee will be unable to function normally using a respirator, or that the safety or health of the employee or other employees will be impaired by the use of a respirator. Such employees must be assigned to another job or given the opportunity to transfer to a different position, the duties of which they can perform. If such a transfer position is available, the position must be with the same employer, in the same geographical area, and with the same seniority, status, and rate of pay the employee had just prior to such transfer.

(3) Respirator selection. Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering facepiece respirators for protection against asbestos fibers.

(ii) Provide HEPA filters for powered and non-powered air-purifying respirators.

(h) Protective work clothing and equipment-

(1) Provision and use. If an employee is exposed to asbestos above the TWA and/or excursion limit, or where the possibility of eye irritation exists, the employer shall provide at no cost to the employee and ensure that the employee uses appropriate protective work clothing and equipment such as, but not limited to:

(i) Coveralls or similar full-body work clothing;

(ii) Gloves, head coverings, and foot coverings; and

(iii) Face shields, vented goggles, or other appropriate protective equipment which complies with 1910.133 of this Part.

(2) Removal and storage.

(i) The employer shall ensure that employees remove work clothing contaminated with asbestos only in change rooms provided in accordance with paragraph (i)(1) of this section.

(ii) The employer shall ensure that no employee takes contaminated work clothing out of the change room, except those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(iii) Contaminated work clothing shall be placed and stored in closed containers which prevent dispersion of the asbestos outside the container.

(iv) The employer shall ensure that ~~€~~containers of contaminated protective devices or work clothing, which are to be taken out of change rooms or the workplace for cleaning, maintenance or disposal, shall bear labels in accordance with paragraph(j)(4) of this section.

(3) Cleaning and replacement.

(i) The employer shall clean, launder, repair, or replace protective clothing and equipment required by this paragraph to maintain their effectiveness. The employer shall provide clean protective clothing and equipment at least weekly to each affected employee.

(ii) The employer shall prohibit the removal of asbestos from protective clothing and equipment by blowing or shaking.

(iii) Laundering of contaminated clothing shall be done so as to prevent the release of airborne fibers of asbestos in excess of the permissible exposure limits prescribed in paragraph (c) of this section.

(iv) ~~Any employer who gives~~ The employer shall ensure that contaminated clothing is transported in sealed impermeable bags, or other closed, impermeable containers, and labeled in accordance with to another person for laundering shall inform such person of the requirement in paragraph (h)(3)(iii) (j) of this section, to effectively prevent the release of airborne fibers of asbestos in excess of the permissible exposure limits.

(v) The employer shall inform any person who launders or cleans protective clothing or

equipment contaminated with asbestos of the potentially harmful effects of exposure to asbestos.

(vi) Contaminated clothing shall be transported in sealed impermeable bags, or other closed, impermeable containers, and labeled in accordance with paragraph (j) of this section.

(i) Hygiene facilities and practices

(1) Change rooms.

(i) The employer shall provide clean change rooms for employees who work in areas where their airborne exposure to asbestos is above the TWA and/or excursion limit.

(ii) The employer shall ensure that change rooms are in accordance with 1910.141(e) of this part, and are equipped with two separate lockers or storage facilities, so separated as to prevent contamination of the employee's street clothes from his protective work clothing and equipment.

(2) Showers.

(i) The employer shall ensure that employees who work in areas where their airborne exposure is above the TWA and/or excursion limit, shower at the end of the work shift.

(ii) The employer shall provide shower facilities which comply with 1910.141(d)(3) of this part.

(iii) The employer shall ensure that employees who are required to shower pursuant to paragraph (i)(2)(i) of this section do not leave the workplace wearing any clothing or equipment worn during the work shift.

(3) Lunchrooms.

(i) The employer shall provide lunchroom facilities for employees who work in areas where their airborne exposure is above the TWA and/or excursion limit.

(ii) The employer shall ensure that lunchroom facilities have a positive pressure, filtered air supply, and are readily accessible to employees.

(iii) The employer shall ensure that employees who work in areas where their airborne exposure is above the PEL and/or excursion limit wash their hands and faces prior to eating, drinking or smoking.

(iv) The employer shall ensure that employees do not enter lunchroom facilities with protective work clothing or equipment unless surface asbestos fibers have been removed from the clothing or equipment by vacuuming or other method that removes dust without causing the

asbestos to become airborne.

(4) Smoking in work areas. The employer shall ensure that employees do not smoke in work areas where they are occupationally exposed to asbestos because of activities in that work area.

(j) Communication of hazards to employees-Introduction. This section applies to the communication of information concerning asbestos hazards in general industry to facilitate compliance with this standard. Asbestos exposure in general industry occurs in a wide variety of industrial and commercial settings. Employees who manufacture asbestos-containing products may be exposed to asbestos fibers. Employees who repair and replace automotive brakes and clutches may be exposed to asbestos fibers. In addition, employees engaged in housekeeping activities in industrial facilities with asbestos product manufacturing operations, and in public and commercial buildings with installed asbestos containing materials may be exposed to asbestos fibers. Most of these workers are covered by this general industry standard, with the exception of state or local governmental employees in non-state plan states. It should be noted that employees who perform housekeeping activities during and after construction activities are covered by the asbestos construction standard, 29 CFR 1926.1101, formerly 1926.58. However, housekeeping employees, regardless of industry designation, should know whether building components they maintain may expose them to asbestos. The same hazard communication provisions will protect employees who perform housekeeping operations in all three asbestos standards; general industry, construction, and shipyard employment. As noted in the construction standard, building owners are often the only and/or best source of information concerning the presence of previously installed asbestos containing building materials. Therefore they, along with employers of potentially exposed employees, are assigned specific information conveying and retention duties under this section.

(1) Hazard communication-general.

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for asbestos.

(ii) In classifying the hazards of asbestos at least the following hazards are to be addressed: Cancer and lung effects.

(iii) Employers shall include asbestos in the hazard communication program established to comply with the SCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of asbestos and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j)(7) of this section.

~~(4)~~(2) Installed Asbestos Containing Material. Employers and building owners are required to treat installed TSI and sprayed on and troweled-on surfacing materials as ACM in buildings constructed no later than 1980 for purposes of this standard. These materials are designated

"presumed ACM or PACM", and are defined in paragraph (b) of this section. Asphalt and vinyl flooring material installed no later than 1980 also must be treated as asbestos-containing. The employer or building owner may demonstrate that PACM and flooring material do not contain asbestos by complying with paragraph (j)(8)(iii) of this section.

~~(2)~~(3) Duties of employers and building and facility owners.

(i) Building and facility owners shall determine the presence, location and quantity of ACM and/or PACM at the work site. Employers and building and facility owners shall exercise due diligence in complying with these requirements to inform employers and employees about the presence and location of ACM and PACM.

(ii) Building and facility owners shall maintain records of all information required to be provided pursuant to this section and/or otherwise known to the building owner concerning the presence, location and quantity of ACM and PACM in the building/facility. Such records shall be kept for the duration of ownership and shall be transferred to successive owners.

(iii) Building and facility owners shall inform employers of employees, and employers shall inform employees who will perform housekeeping activities in areas which contain ACM and/or PACM of the presence and location of ACM and PACM in such areas which may be contacted during such activities.

~~(3)~~(4) Warning signs-

(i) Posting. Warning signs shall be provided and displayed at each regulated area. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective s before entering the area.

(ii) Sign specifications.

(A) The warning signs required by paragraph (j)~~(3)~~(4)(i) of this section shall bear the following information:

DANGER

ASBESTOS

MAY CAUSE CANCER AND LUNG DISEASE HAZARD

CAUSES DAMAGE TO LUNGS

AUTHORIZED PERSONNEL ONLY

(B) In addition, where the use of respirators and protective clothing is required in the regulated area under this section, the warning signs shall include the following:

WEAR ~~RESPIRATORS~~ RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA

(C) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(4)(ii)(A) of this section:

DANGER

ASBESTOS

CANCER AND LUNG DISEASE

HAZARD

AUTHORIZED PERSONNEL ONLY

(D) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(4)(ii)(B) of this section:

RESPIRATORS AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA

~~(iii)~~ [Reserved]

~~(iv)~~(iii) The employer shall ensure that employees working in and contiguous to regulated areas comprehend the warning signs required to be posted by paragraph (j)(~~3~~)(4)(i) of this section. Means to ensure employee comprehension may include the use of foreign languages, pictographs and graphics.

~~(v)~~(iv) At the entrance to mechanical rooms/areas in which employees reasonably can be expected to enter and which contain ACM and/or PACM, the building owner shall post signs which identify the material which is present, its location, and appropriate work practices which, if followed, will ensure that ACM and/or PACM will not be disturbed. The employer shall ensure, to the extent feasible, that employees who come in contact with these signs can comprehend them. Means to ensure employee comprehension may include the use of foreign languages, pictographs, graphics, and awareness training.

~~(4)~~(5) Warning labels.

(i) Labeling. Warning labels shall be affixed to all raw materials, mixtures, scrap, waste,

debris, and other products containing asbestos fibers, or to their containers. When a building owner or employer identifies previously installed ACM and/or PACM, labels or signs shall be affixed or posted so that employees will be notified of what materials contain ACM and/or PACM. The employer shall attach such labels in areas where they will clearly be noticed by employees who are likely to be exposed, such as at the entrance to mechanical room/areas. Signs required by paragraph (j)(3) of this section may be posted in lieu of labels so long as they contain information required for labeling.

(ii) Label specifications. ~~The labels shall comply with the requirements of 29 CFR 1910.1200(f) of OSHA's Hazard Communication standard, and shall~~ In addition to the requirements of paragraph (j) (1), the employer shall ensure that labels of bags or containers of protective clothing and equipment, scrap, waste, and debris containing asbestos fibers include the following information:

DANGER

CONTAINS ASBESTOS FIBERS

MAY CAUSE CANCER

CAUSE DAMAGE TO LUNGS

DO NOT BREATHE DUST

AVOID CREATING DUST

(iii) Prior to June 1, 2015, employers may include the following information on raw materials, mixtures or labels of bags or containers of protective clothing and equipment, scrap, waste, and debris containing asbestos fibers in lieu of the labeling requirements in paragraphs (j)(1)(i) and (j)(5)(ii) of this section:

DANGER

CONTAINS ASBESTOS FIBERS

AVOID CREATING DUST

CANCER AND LUNG DISEASE HAZARD

~~(5) Material safety data sheets. Employers who are manufacturers or importers of asbestos or asbestos products shall comply with the requirements regarding development of material safety data sheets as specified in 29 CFR 1910.1200(g) of OSHA's Hazard Communication standard, except as provided by paragraph (j)(6) of this section.~~

(6) The provisions for labels required by paragraph ~~(j)(4)~~ of this section or for ~~material~~ safety data sheets required by paragraph ~~(j)(5)~~ of this section do not apply where:

(i) Asbestos fibers have been modified by a bonding agent, coating, binder, or other material provided that the manufacturer can demonstrate that during any reasonably foreseeable use, handling, storage, disposal, processing, or transportation, no airborne concentrations of fibers of asbestos in excess of the TWA permissible exposure level and/or excursion limit will be released or

(ii) Asbestos is present in a product in concentrations less than 1.0%.

(7) Employee information and training.

(i) The employer shall train each employee who is exposed to airborne concentrations of asbestos at or above the PEL and/or excursion limit in accordance with the requirements of this section. The employer shall institute a training program and ensure employee participation in the program.

(ii) Training shall be provided prior to or at the time of initial assignment and at least annually thereafter.

(iii) The training program shall be conducted in a manner which the employee is able to understand. The employer shall ensure that each employee is informed of the following:

(A) The health effects associated with asbestos exposure;

(B) The relationship between smoking and exposure to asbestos producing lung cancer:

(C) The quantity, location, manner of use, release, and storage of asbestos, and the specific nature of operations which could result in exposure to asbestos;

(D) The engineering controls and work practices associated with the employee's job assignment;

(E) The specific procedures implemented to protect employees from exposure to asbestos, such as appropriate work practices, emergency and clean-up procedures, and personal protective equipment to be used;

(F) The purpose, proper use, and limitations of respirators and protective clothing, if appropriate;

(G) The purpose and a description of the medical surveillance program required by

paragraph (l) of this section;

(H) The content of this standard, including appendices.

(I) The names, addresses and phone numbers of public health organizations which provide information, materials, and/or conduct programs concerning smoking cessation. The employer may distribute the list of such organizations contained in Appendix I to this section, to comply with this requirement.

(J) The requirements for posting signs and affixing labels and the meaning of the required legends for such signs and labels.

(iv) The employer shall also provide, at no cost to employees who perform housekeeping operations in an area which contains ACM or PACM, an asbestos awareness training course, which shall at a minimum contain the following elements: health effects of asbestos, locations of ACM and PACM in the building/facility, recognition of ACM and PACM damage and deterioration, requirements in this standard relating to housekeeping, and proper response to fiber release episodes, to all employees who perform housekeeping work in areas where ACM and/or PACM is present. Each such employee shall be so trained at least once a year.

(v) Access to information and training materials.

(A) The employer shall make a copy of this standard and its appendices readily available without cost to all affected employees.

(B) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the training program to the Assistant Secretary and the Director.

(C) The employer shall inform all employees concerning the availability of self-help smoking cessation program material. Upon employee request, the employer shall distribute such material, consisting of NIH Publication No. 89-1647, or equivalent self-help material, which is approved or published by a public health organization listed in Appendix I to this section.

(8) Criteria to rebut the designation of installed material as PACM.

(i) At any time, an employer and/or building owner may demonstrate, for purposes of this standard, that PACM does not contain asbestos. Building owners and/or employers are not required to communicate information about the presence of building material for which such a demonstration pursuant to the requirements of paragraph (j)(8)(ii) of this section has been made. However, in all such cases, the information, data and analysis supporting the determination that PACM does not contain asbestos, shall be retained pursuant to paragraph (m) of this section.

(ii) An employer or owner may demonstrate that PACM does not contain asbestos by the following:

(A) Having a completed inspection conducted pursuant to the requirements of AHERA (40 CFR 763, Subpart E) which demonstrates that no ACM is present in the material; or

(B) Performing tests of the material containing PACM which demonstrate that no ACM is present in the material. Such tests shall include analysis of bulk samples collected in the manner described in 40 CFR 763.86. The tests, evaluation and sample collection shall be conducted by an accredited inspector or by a CIH. Analysis of samples shall be performed by persons or laboratories with proficiency demonstrated by current successful participation in a nationally recognized testing program such as the National Voluntary Laboratory Accreditation Program (NVLAP) or the National Institute for Standards and Technology (NIST) or the Round Robin for bulk samples administered by the American Industrial Hygiene Association (AIHA) or an equivalent nationally-recognized round robin testing program.

(iii) The employer and/or building owner may demonstrate that flooring material including associated mastic and backing does not contain asbestos, by a determination of an industrial hygienist based upon recognized analytical techniques showing that the material is not ACM.

(k) Housekeeping.

(1) All surfaces shall be maintained as free as practicable of ACM waste and debris and accompanying dust.

(2) All spills and sudden releases of material containing asbestos shall be cleaned up as soon as possible.

(3) Surfaces contaminated with asbestos may not be cleaned by the use of compressed air.

(4) Vacuuming. HEPA-filtered vacuuming equipment shall be used for vacuuming asbestos containing waste and debris. The equipment shall be used and emptied in a manner which minimizes the reentry of asbestos into the workplace.

(5) Shoveling, dry sweeping and dry clean-up of asbestos may be used only where vacuuming and/or wet cleaning are not feasible.

(6) Waste disposal. Waste, scrap, debris, bags, containers, equipment, and clothing contaminated with asbestos consigned for disposal, shall be collected, recycled and disposed of in sealed impermeable bags, or other closed, impermeable containers.

(7) Care of asbestos-containing flooring material.

(i) Sanding of asbestos-containing floor material is prohibited.

(ii) Stripping of finishes shall be conducted using low abrasion pads at speeds lower than 300 rpm and wet methods.

(iii) Burnishing or dry buffing may be performed only on asbestos-containing flooring which has sufficient finish so that the pad cannot contact the asbestos-containing material.

(8) Waste and debris and accompanying dust in an area containing accessible ACM and/or PACM or visibly deteriorated ACM, shall not be dusted or swept dry or vacuumed without using a HEPA filter.

(1) Medical surveillance

(1) General

(i) Employees covered. The employer shall institute a medical surveillance program for all employees who are or will be exposed to airborne concentrations of fibers of asbestos at or above the TWA and/or excursion limit.

(ii) Examination by a physician.

(A) The employer shall ensure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee and at a reasonable time and place.

(B) Persons other than licensed physicians, who administer the pulmonary function testing required by this section, shall complete a training course in spirometry sponsored by an appropriate academic or professional institution.

(2) Pre-placement examinations.

(i) Before an employee is assigned to an occupation exposed to airborne concentrations of asbestos fibers at or above the TWA and/or excursion limit, a pre-placement medical examination shall be provided or made available by the employer.

(ii) Such examination shall include, as a minimum, a medical and work history; a complete physical examination of all systems with emphasis on the respiratory system, the cardiovascular system and digestive tract; completion of the respiratory disease standardized questionnaire in Appendix D to this section, Part 1; a chest roentgenogram (posterior-anterior 14x17 inches); pulmonary function tests to include forced vital capacity (FVC) and forced expiratory volume at 1 second (FEV(1.0)); and any additional tests deemed appropriate by the examining physician. Interpretation and classification of chest roentgenogram shall be conducted in accordance with Appendix E to this section.

(3) Periodic examinations.

(i) Periodic medical examinations shall be made available annually.

(ii) The scope of the medical examination shall be in conformance with the protocol established in paragraph (1)(2)(ii) of this section, except that the frequency of chest roentgenogram shall be conducted in accordance with Table 1, and the abbreviated standardized questionnaire contained in, Part 2 of Appendix D to this section shall be administered to the employee

Table 1. -- Frequency of Chest Roentgenogram

| Years since first exposure | Age of employee | | |
|----------------------------|--------------------|------------------|----------------|
| | 15 to 35 | 35+ to 45 | 45+ |
| 0 to 10..... | Every 5 years..... | Every 5 years... | Every 5 years. |
| 10+..... | Every 5 years..... | Every 2 years... | Every 1 year. |

(4) Termination of employment examinations.

(i) The employer shall provide, or make available, a termination of employment medical examination for any employee who has been exposed to airborne concentrations of fibers of asbestos at or above the TWA and/or excursion limit.

(ii) The medical examination shall be in accordance with the requirements of the periodic examinations stipulated in paragraph (1)(3) of this section, and shall be given within 30 calendar days before or after the date of termination of employment.

(5) Recent examinations. No medical examination is required of any employee, if adequate records show that the employee has been examined in accordance with any of paragraphs ((1)(2) through (1)(4)) of this section within the past 1 year period. A pre- employment medical examination which was required as a condition of employment by the employer, may not be used by that employer to meet the requirements of this paragraph, unless the cost of such examination is borne by the employer.

(6) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this standard and Appendices D and E.

(ii) A description of the affected employee's duties as they relate to the employee's exposure.

(iii) The employee's representative exposure level or anticipated exposure level.

(iv) A description of any personal protective and respiratory equipment used or to be used.

(v) Information from previous medical examinations of the affected employee that is not otherwise available to the examining physician.

(7) Physician's written opinion.

(i) The employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination and shall include:

(A) The physician's opinion as to whether the employee has any detected medical conditions that would place the employee at an increased risk of material health impairment from exposure to asbestos;

(B) Any recommended limitations on the employee or upon the use of personal protective equipment such as clothing or respirators;

(C) A statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions resulting from asbestos exposure that require further explanation or treatment; and

(D) A statement that the employee has been informed by the physician of the increased risk of lung cancer attributable to the combined effect of smoking and asbestos exposure.

(ii) The employer shall instruct the physician not to reveal in the written opinion given to the employer specific findings or diagnoses unrelated to occupational exposure to asbestos.

(iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 30 days from its receipt.

(m) Recordkeeping.-

(1) Exposure measurements. NOTE: The employer may utilize the services of competent organizations such as industry trade associations and employee associations to maintain the records required by this section.

(i) The employer shall keep an accurate record of all measurements taken to monitor employee exposure to asbestos as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

- (A) The date of measurement;
- (B) The operation involving exposure to asbestos which is being monitored;
- (C) Sampling and analytical methods used and evidence of their accuracy;
- (D) Number, duration, and results of samples taken;
- (E) Type of respiratory protective devices worn, if any; and
- (F) Name, social security number and exposure of the employees whose exposure are represented.

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.1020.

(2) Objective data for exempted operations.

(i) Where the processing, use, or handling of products made from or containing asbestos is exempted from other requirements of this section under paragraph (d)(2)(iii) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

(ii) The record shall include at least the following:

- (A) The product qualifying for exemption;
- (B) The source of the objective data;
- (C) The testing protocol, results of testing, and/or analysis of the material for the release of asbestos;
- (D) A description of the operation exempted and how the data support the exemption; and
- (E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(3) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (l)(1)(i) of this section, in accordance with 29 CFR 1910.1020.

(ii) The record shall include at least the following information:

(A) The name and social security number of the employee;

(B) Physician's written opinions;

(C) Any employee medical complaints related to exposure to asbestos; and

(D) A copy of the information provided to the physician as required by paragraph (l)(6) of this section.

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

(4) Training. The employer shall maintain all employee training records for one (1) year beyond the last date of employment of that employee.

(5) Availability.

(i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying.

(ii) The employer, upon request shall make any exposure records required by paragraph (m)(1) of this section available for examination and copying to affected employees, former employees, designated representatives and the Assistant Secretary, in accordance with 29 CFR 1910.1020(a)through(e) and (g)through(i).

(iii) The employer, upon request, shall make employee medical records required by paragraph (m)(3) of this section available for examination and copying to the subject employee, to anyone having the specific written consent of the subject employee, and the Assistant Secretary, in accordance with 29 CFR 1910.1020.

(6) The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

(n) Observation of monitoring-

(1) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to asbestos conducted in accordance with paragraph (d) of this section.

(2) Observation procedures. When observation of the monitoring of employee exposure to asbestos requires entry into an area where the use of protective clothing or equipment is required, the observer shall be provided with and be required to use such clothing and equipment and shall

comply with all other applicable safety and health procedures.

(o) Appendices.

(1) Appendices A, C, D, E, and F, to this section are incorporated as part of this section and the contents of these Appendices are mandatory.

(2) Appendices B, G, H, I, and J to this section are informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

[For amendment dates see end of 1910.1001 appendices]

1910.1001 App A OSHA Reference Method - Mandatory

Appendix A to 1910.1001 - OSHA Reference Method - Mandatory

This mandatory appendix specifies the procedure for analyzing air samples for asbestos and specifies quality control procedures that must be implemented by laboratories performing the analysis. The sampling and analytical methods described below represent the elements of the available monitoring methods (such as Appendix B of their regulation, the most current version of the OSHA method ID-160, or the most current version of the NIOSH Method 7400). All employers who are required to conduct air monitoring under paragraph (d) of the standard are required to utilize analytical laboratories that use this procedure, or an equivalent method, for collecting and analyzing samples.

Sampling and Analytical Procedure

1. The sampling medium for air samples shall be mixed cellulose ester filter membranes. These shall be designated by the manufacturer as suitable for asbestos counting. See below for rejection of blanks.

2. The preferred collection device shall be the 25-mm diameter cassette with an open-faced 50-mm electrically conductive extension cowl. The 37-mm cassette may be used if necessary but only if written justification for the need to use the 37-mm filter cassette accompanies the sample results in the employee's exposure monitoring record. Do not reuse or reload cassettes for asbestos sample collection.

3. An air flow rate between 0.5 liter/min and 2.5 liters/min shall be selected for the 25-mm cassette. If the 37-mm cassette is used, an air flow rate between 1 liter/min and 2.5 liters/min shall be selected.

4. Where possible, a sufficient air volume for each air sample shall be collected to yield between 100 and 1,300 fibers per square millimeter on the membrane filter. If a filter darkens in

appearance or if loose dust is seen on the filter, a second sample shall be started.

5. Ship the samples in a rigid container with sufficient packing material to prevent dislodging the collected fibers. Packing material that has a high electrostatic charge on its surface (e.g., expanded polystyrene) cannot be used because such material can cause loss of fibers to the sides of the cassette.

6. Calibrate each personal sampling pump before and after use with a representative filter cassette installed between the pump and the calibration devices.

7. Personal samples shall be taken in the "breathing zone" of the employee (i.e., attached to or near the collar or lapel near the worker's face).

8. Fiber counts shall be made by positive phase contrast using a microscope with an 8 to 10 X eyepiece and a 40 to 45 X objective for a total magnification of approximately 400 X and a numerical aperture of 0.65 to 0.75. The microscope shall also be fitted with a green or blue filter.

9. The microscope shall be fitted with a Walton-Beckett eyepiece graticule calibrated for a field diameter of 100 micrometers (+/-2 micrometers).

10. The phase-shift detection limit of the microscope shall be about 3 degrees measured using the HSE phase shift test slide as outlined below.

a. Place the test slide on the microscope stage and center it under the phase objective.

b. Bring the blocks of grooved lines into focus.

NOTE: The slide consists of seven sets of grooved lines (ca. 20 grooves to each block) in descending order of visibility from sets 1 to 7, seven being the least visible. The requirements for asbestos counting are that the microscope optics must resolve the grooved lines in set 3 completely, although they may appear somewhat faint, and that the grooved lines in sets 6 and 7 must be invisible. Sets 4 and 5 must be at least partially visible but may vary slightly in visibility between microscopes. A microscope that fails to meet these requirements has either too low or too high a resolution to be used for asbestos counting.

c. If the image deteriorates, clean and adjust the microscope optics. If the problem persists, consult the microscope manufacturer.

11. Each set of samples taken will include 10% field blanks or a minimum of 2 field blanks. These blanks must come from the same lot as the filters used for sample collection. The field blank results shall be averaged and subtracted from the analytical results before reporting. A set consists of any sample or group of samples for which an evaluation for this standard must be made. Any samples represented by a field blank having a fiber count in excess of the detection

limit of the method being used shall be rejected.

12. The samples shall be mounted by the acetone/triacetin method or a method with an equivalent index of refraction and similar clarity.

13. Observe the following counting rules.

a. Count only fibers equal to or longer than 5 micrometers. Measure the length of curved fibers along the curve.

b. In the absence of other information, count all particles as asbestos that have a length-to-width ratio (aspect ratio) of 3:1 or greater.

c. Fibers lying entirely within the boundary of the Walton-Beckett graticule field shall receive a count of 1. Fibers crossing the boundary once, having one end within the circle, shall receive the count of one half (1/2). Do not count any fiber that crosses the graticule boundary more than once. Reject and do not count any other fibers even though they may be visible outside the graticule area.

d. Count bundles of fibers as one fiber unless individual fibers can be identified by observing both ends of an individual fiber.

e. Count enough graticule fields to yield 100 fibers. Count a minimum of 20 fields; stop counting at 100 fields regardless of fiber count.

14. Blind recounts shall be conducted at the rate of 10 percent.

Quality Control Procedures

1. Intralaboratory program. Each laboratory and/or each company with more than one microscopist counting slides shall establish a statistically designed quality assurance program involving blind recounts and comparisons between microscopists to monitor the variability of counting by each microscopist and between microscopists. In a company with more than one laboratory, the program shall include all laboratories and shall also evaluate the laboratory-to-laboratory variability.

2.a. Interlaboratory program. Each laboratory analyzing asbestos samples for compliance determination shall implement an interlaboratory quality assurance program that as a minimum includes participation of at least two other independent laboratories. Each laboratory shall participate in round robin testing at least once every 6 months with at least all the other laboratories in its interlaboratory quality assurance group. Each laboratory shall submit slides typical of its own work load for use in this program. The round robin shall be designed and results analyzed using appropriate statistical methodology.

2.b. All laboratories should also participate in a national sample testing scheme such as the Proficiency Analytical Testing Program (PAT), or the Asbestos Registry sponsored by the American Industrial Hygiene Association (AIHA).

3. All individuals performing asbestos analysis must have taken the NIOSH course for sampling and evaluating airborne asbestos dust or an equivalent course.

4. When the use of different microscopes contributes to differences between counters and laboratories, the effect of the different microscope shall be evaluated and the microscope shall be replaced, as necessary.

5. Current results of these quality assurance programs shall be posted in each laboratory to keep the microscopists informed.

Appendix B to 1910.1001-Detailed Procedures for Asbestos Sampling and Analysis-Non-mandatory

Matrix:

OSHA Permissible Exposure Limits:

| | |
|-----------------------------------|--------------|
| Time Weighted Average..... | 0.1 fiber/cc |
| Excursion Level (30 minutes)..... | 1.0 fiber/cc |

Collection Procedure:

A known volume of air is drawn through a 25-mm diameter cassette containing a mixed-cellulose ester filter. The cassette must be equipped with an electrically conductive 50-mm extension cowl. The sampling time and rate are chosen to give a fiber density of between 100 to 1,300 fibers/mm(2) on the filter.

| | |
|--------------------------------|--------------------------------------|
| Recommended Sampling Rate..... | 0.5 to 5.0 liters/ minute (L/min) |
|--------------------------------|--------------------------------------|

Recommended Air Volumes:

| | |
|--------------|---------|
| Minimum..... | 25 L |
| Maximum..... | 2,400 L |

Analytical Procedure: A portion of the sample filter is cleared and prepared for asbestos fiber counting by Phase Contrast Microscopy (PCM) at 400X.

Commercial manufacturers and products mentioned in this method are for descriptive use only and do not constitute endorsements by USDOL-OSHA. Similar products from other sources can be substituted.

1. Introduction

This method describes the collection of airborne asbestos fibers using calibrated sampling pumps with mixed-cellulose ester (MCE) filters and analysis by phase contrast microscopy (PCM). Some terms used are unique to this method and are defined below:

Asbestos: A term for naturally occurring fibrous minerals. Asbestos includes chrysotile, crocidolite, amosite (cummingtonite-grunerite asbestos), tremolite asbestos, actinolite asbestos, anthophyllite asbestos, and any of these minerals that have been chemically treated and/or altered. The precise chemical formulation of each species will vary with the location from which it was mined. Nominal compositions are listed:

| | |
|----------------------|---|
| Chrysotile | $Mg_3Si_2O_5(OH)_4$ |
| Crocidolite | $Na_2 Fe^{2+}_2 Fe^{3+}_2 Si_8O_{22}(OH)_2$ |
| Amosite | $(Mg,Fe)_7 Si_8O_{22}(OH)_2$ |
| Tremolite-actinolite | $Ca_2(Mg,Fe)_5 Si_8O_{22}(OH)_2$ |
| Anthophyllite | $(Mg,Fe)_7 Si_8O_{22}(OH)_2$ |

Asbestos Fiber: A fiber of asbestos which meets the criteria specified below for a fiber.

Aspect Ratio: The ratio of the length of a fiber to its diameter (e.g. 3:1, 5:1 aspect ratios).

Cleavage Fragments: Mineral particles formed by comminution of minerals, especially those characterized by parallel sides and a moderate aspect ratio (usually less than 20:1).

Detection Limit: The number of fibers necessary to be 95% certain that the result is greater than zero.

Differential Counting: The term applied to the practice of excluding certain kinds of fibers from the fiber count because they do not appear to be asbestos.

Fiber: A particle that is 5 μm or longer, with a length-to-width ratio of 3 to 1 or longer.

Field: The area within the graticule circle that is superimposed on the microscope image.

Set: The samples which are taken, submitted to the laboratory, analyzed, and for which, interim or final result reports are generated.

Tremolite, Anthophyllite, and Actinolite: The non-asbestos form of these minerals which meet the definition of a fiber. It includes any of these minerals that have been chemically treated and/or altered.

Walton-Beckett Graticule: An eyepiece graticule specifically designed for asbestos fiber counting. It consists of a circle with a projected diameter of $100 \pm 2 \mu\text{m}$ (area of about 0.00785 mm^2) with a crosshair having tic-marks at $3\text{-}\mu\text{m}$ intervals in one direction and $5\text{-}\mu\text{m}$ in the orthogonal direction. There are marks around the periphery of the circle to demonstrate the proper sizes and shapes of fibers. This design is reproduced in Figure 1. The disk is placed in one of the microscope eyepieces so that the design is superimposed on the field of view.

1.1. History

Early surveys to determine asbestos exposures were conducted using impinger counts of total dust with the counts expressed as million particles per cubic foot. The British Asbestos Research Council recommended filter membrane counting in 1969. In July 1969, the Bureau of Occupational Safety and Health published a filter membrane method for counting asbestos fibers in the United States. This method was refined by NIOSH and published as P & CAM 239. On May 29, 1971, OSHA specified filter membrane sampling with phase contrast counting for evaluation of asbestos exposures at work sites in the United States. The use of this technique was again required by OSHA in 1986. Phase contrast microscopy has continued to be the method of choice for the measurement of occupational exposure to asbestos.

1.2. Principle

Air is drawn through a MCE filter to capture airborne asbestos fibers. A wedge shaped portion of the filter is removed, placed on a glass microscope slide and made transparent. A measured area (field) is viewed by PCM. All the fibers meeting a defined criteria for asbestos are counted and considered a measure of the airborne asbestos concentration.

1.3. Advantages and Disadvantages

There are four main advantages of PCM over other methods:

- (1) The technique is specific for fibers. Phase contrast is a fiber counting technique which excludes non-fibrous particles from the analysis.
- (2) The technique is inexpensive and does not require specialized knowledge to carry out the analysis for total fiber counts.
- (3) The analysis is quick and can be performed on-site for rapid determination of air concentrations of asbestos fibers.
- (4) The technique has continuity with historical epidemiological studies so that estimates of expected disease can be inferred from long-term determinations of asbestos exposures.

The main disadvantage of PCM is that it does not positively identify asbestos fibers. Other fibers which are not asbestos may be included in the count unless differential counting is performed. This requires a great deal of experience to adequately differentiate asbestos from non-asbestos fibers. Positive identification of asbestos must be performed by polarized light or electron microscopy techniques. A further disadvantage of PCM is that the smallest visible fibers are about 0.2 μm in diameter while the finest asbestos fibers may be as small as 0.02 μm in diameter. For some exposures, substantially more fibers may be present than are actually counted.

1.4. Workplace Exposure

Asbestos is used by the construction industry in such products as shingles, floor tiles, asbestos cement, roofing felts, insulation and acoustical products. Non-construction uses include brakes, clutch facings, paper, paints, plastics, and fabrics. One of the most significant exposures in the workplace is the removal and encapsulation of asbestos in schools, public buildings, and homes. Many workers have the potential to be exposed to asbestos during these operations.

About 95% of the asbestos in commercial use in the United States is chrysotile. Crocidolite and amosite make up most of the remainder. Anthophyllite and tremolite or actinolite are likely to be encountered as contaminants in various industrial products.

1.5. Physical Properties

Asbestos fiber possesses a high tensile strength along its axis, is chemically inert, non-combustible, and heat resistant. It has a high electrical resistance and good sound absorbing properties. It can be weaved into cables, fabrics or other textiles, and also matted into asbestos papers, felts, or mats.

2. Range and Detection Limit

2.1. The ideal counting range on the filter is 100 to 1,300 fibers/mm². With a Walton-Beckett graticule this range is equivalent to 0.8 to 10 fibers/field. Using NIOSH counting statistics, a count of 0.8 fibers/field would give an approximate coefficient of variation (CV) of 0.13.

2.2. The detection limit for this method is 4.0 fibers per 100 fields or 5.5 fibers/mm². This was determined using an equation to estimate the maximum CV possible at a specific concentration (95% confidence) and a Lower Control Limit of zero. The CV value was then used to determine a corresponding concentration from historical CV vs fiber relationships. As an example:

$$\text{Lower Control Limit (95\% Confidence)} = AC - 1.645(CV)(AC)$$

Where:

AC = Estimate of the airborne fiber concentration (fibers/cc) Setting the Lower Control Limit = 0

and solving for CV:

$$0 = AC - 1.645(CV)(AC)$$

$$CV = 0.61$$

This value was compared with CV vs. count curves. The count at which CV = 0.61 for Leidel-Busch counting statistics or for an OSHA Salt Lake Technical Center (OSHA-SLTC) CV curve (see Appendix A for further information) was 4.4 fibers or 3.9 fibers per 100 fields, respectively. Although a lower detection limit of 4 fibers per 100 fields is supported by the OSHA-SLTC data, both data sets support the 4.5 fibers per 100 fields value.

3. Method Performance-Precision and Accuracy

Precision is dependent upon the total number of fibers counted and the uniformity of the fiber distribution on the filter. A general rule is to count at least 20 and not more than 100 fields. The count is discontinued when 100 fibers are counted, provided that 20 fields have already been counted. Counting more than 100 fibers results in only a small gain in precision. As the total count drops below 10 fibers, an accelerated loss of precision is noted.

At this time, there is no known method to determine the absolute accuracy of the asbestos analysis. Results of samples prepared through the Proficiency Analytical Testing (PAT) Program and analyzed by the OSHA-SLTC showed no significant bias when compared to PAT reference values. The PAT samples were analyzed from 1987 to 1989 (N=36) and the concentration range was from 120 to 1,300 fibers/mm².

4. Interferences

Fibrous substances, if present, may interfere with asbestos analysis.

Some common fibers are:

- fiberglass
- anhydrite
- plant fibers
- perlite veins
- gypsum
- some synthetic fibers
- membrane structures
- sponge spicules
- diatoms
- microorganisms
- wollastonite

The use of electron microscopy or optical tests such as polarized light, and dispersion staining may be used to differentiate these materials from asbestos when necessary.

5. Sampling

5.1. Equipment

5.1.1. Sample assembly (The assembly is shown in Figure 3). Conductive filter holder consisting of a 25-mm diameter, 3-piece cassette having a 50-mm long electrically conductive extension cowl. Backup pad, 25-mm, cellulose. Membrane filter, mixed-cellulose ester (MCE), 25-mm, plain, white, 0.4- to 1.2- μm pore size.

Notes: (a) Do not re-use cassettes.

(b) Fully conductive cassettes are required to reduce fiber loss to the sides of the cassette due to electrostatic attraction.

(c) Purchase filters which have been selected by the manufacturer for asbestos counting or analyze representative filters for fiber background before use. Discard the filter lot if more than 4 fibers/100 fields are found.

(d) To decrease the possibility of contamination, the sampling system (filter-backup pad-cassette) for asbestos is usually preassembled by the manufacturer.

(e) Other cassettes, such as the Bell-mouth, may be used within the limits of their validation.

5.1.2. Gel bands for sealing cassettes.

5.1.3. Sampling pump.

Each pump must be a battery operated, self-contained unit small enough to be placed on the monitored employee and not interfere with the work being performed. The pump must be capable of sampling at the collection rate for the required sampling time.

5.1.4. Flexible tubing, 6-mm bore.

5.1.5. Pump calibration.

Stopwatch and bubble tube/burette or electronic meter.

5.2. Sampling Procedure

5.2.1. Seal the point where the base and cowl of each cassette meet with a gel band or tape.

5.2.2. Charge the pumps completely before beginning.

5.2.3. Connect each pump to a calibration cassette with an appropriate length of 6-mm bore plastic tubing. Do not use luer connectors-the type of cassette specified above has built-in adapters.

5.2.4. Select an appropriate flow rate for the situation being monitored. The sampling flow rate must be between 0.5 and 5.0 L/min for personal sampling and is commonly set between 1 and 2 L/min. Always choose a flow rate that will not produce overloaded filters.

5.2.5. Calibrate each sampling pump before and after sampling with a calibration cassette in-line (Note: This calibration cassette should be from the same lot of cassettes used for sampling). Use a primary standard (e.g. bubble burette) to calibrate each pump. If possible, calibrate at the sampling site.

Note: If sampling site calibration is not possible, environmental influences may affect the flow rate. The extent is dependent on the type of pump used. Consult with the pump manufacturer to determine dependence on environmental influences. If the pump is affected by temperature and pressure changes, correct the flow rate using the formula shown in the section "Sampling Pump Flow Rate Corrections" at the end of this appendix".

5.2.6. Connect each pump to the base of each sampling cassette with flexible tubing. Remove the end cap of each cassette and take each air sample open face. Assure that each sample cassette is held open side down in the employee's breathing zone during sampling. The distance from the nose/mouth of the employee to the cassette should be about 10 cm. Secure the cassette on the collar or lapel of the employee using spring clips or other similar devices.

5.2.7. A suggested minimum air volume when sampling to determine TWA compliance is 25 L. For Excursion Limit (30 min sampling time) evaluations, a minimum air volume of 48 L is recommended.

5.2.8. The most significant problem when sampling for asbestos is overloading the filter with non-asbestos dust. Suggested maximum air sample volumes for specific environments are:

| Environment | Air vol. (L) |
|---|-----------------|
| Asbestos removal operations (visible dust)..... | 100 |
| Asbestos removal operations (little dust)..... | 240 |
| Office environments..... | 400 to 2,400 |

Caution: Do not overload the filter with dust. High levels of non-fibrous dust particles may

obscure fibers on the filter and lower the count or make counting impossible. If more than about 25 to 30% of the field area is obscured with dust, the result may be biased low. Smaller air volumes may be necessary when there is excessive non-asbestos dust in the air.

While sampling, observe the filter with a small flashlight. If there is a visible layer of dust on the filter, stop sampling, remove and seal the cassette, and replace with a new sampling assembly. The total dust loading should not exceed 1 mg.

5.2.9. Blank samples are used to determine if any contamination has occurred during sample handling. Prepare two blanks for the first 1 to 20 samples. For sets containing greater than 20 samples, prepare blanks as 10% of the samples. Handle blank samples in the same manner as air samples with one exception: Do not draw any air through the blank samples. Open the blank cassette in the place where the sample cassettes are mounted on the employee. Hold it open for about 30 seconds. Close and seal the cassette appropriately. Store blanks for shipment with the sample cassettes.

5.2.10. Immediately after sampling, close and seal each cassette with the base and plastic plugs. Do not touch or puncture the filter membrane as this will invalidate the analysis.

5.2.11. Attach and secure a sample seal around each sample cassette in such a way as to assure that the end cap and base plugs cannot be removed without destroying the seal. Tape the ends of the seal together since the seal is not long enough to be wrapped end-to-end. Also wrap tape around the cassette at each joint to keep the seal secure.

5.3. Sample Shipment

5.3.1. Send the samples to the laboratory with paperwork requesting asbestos analysis. List any known fibrous interferences present during sampling on the paperwork. Also, note the workplace operation(s) sampled.

5.3.2. Secure and handle the samples in such that they will not rattle during shipment nor be exposed to static electricity. Do not ship samples in expanded polystyrene peanuts, vermiculite, paper shreds, or excelsior. Tape sample cassettes to sheet bubbles and place in a container that will cushion the samples in such a manner that they will not rattle.

5.3.3. To avoid the possibility of sample contamination, always ship bulk samples in separate mailing containers.

6. Analysis

6.1. Safety Precautions

6.1.1. Acetone is extremely flammable and precautions must be taken not to ignite it. Avoid

using large containers or quantities of acetone. Transfer the solvent in a ventilated laboratory hood. Do not use acetone near any open flame. For generation of acetone vapor, use a spark free heat source.

6.1.2. Any asbestos spills should be cleaned up immediately to prevent dispersal of fibers. Prudence should be exercised to avoid contamination of laboratory facilities or exposure of personnel to asbestos. Asbestos spills should be cleaned up with wet methods and/or a High Efficiency Particulate-Air (HEPA) filtered vacuum.

Caution: Do not use a vacuum without a HEPA filter-It will disperse fine asbestos fibers in the air.

6.2. Equipment

6.2.1. Phase contrast microscope with binocular or trinocular head.

6.2.2. Widefield or Huygenian 10X eyepieces (Note: The eyepiece containing the graticule must be a focusing eyepiece. Use a 40X phase objective with a numerical aperture of 0.65 to 0.75).

6.2.3. Kohler illumination (if possible) with green or blue filter.

6.2.4. Walton-Beckett Graticule, type G-22 with $100 \nabla 2 \mu\text{m}$ projected diameter.

6.2.5. Mechanical stage.

A rotating mechanical stage is convenient for use with polarized light.

6.2.6. Phase telescope.

6.2.7. Stage micrometer with 0.01-mm subdivisions.

6.2.8. Phase-shift test slide, mark II (Available from PTR optics Ltd., and also McCrone).

6.2.9. Pre-cleaned glass slides, 25 mm X 75 mm. One end can be frosted for convenience in writing sample numbers, etc., or paste-on labels can be used.

6.2.10. Cover glass $\nabla 1 \ 2$.

6.2.11. Scalpel ($\nabla 10$, curved blade).

6.2.12. Fine tipped forceps.

6.2.13. Aluminum block for clearing filter (see Appendix D and Figure 4).

6.2.14. Automatic adjustable pipette, 100- to 500- μ L.

6.2.15. Micropipette, 5 μ L.

6.3. Reagents

6.3.1. Acetone (HPLC grade).

6.3.2. Triacetin (glycerol triacetate).

6.3.3. Lacquer or nail polish.

6.4. Standard Preparation

A way to prepare standard asbestos samples of known concentration has not been developed. It is possible to prepare replicate samples of nearly equal concentration. This has been performed through the PAT program. These asbestos samples are distributed by the AIHA to participating laboratories.

Since only about one-fourth of a 25-mm sample membrane is required for an asbestos count, any PAT sample can serve as a "standard" for replicate counting.

6.5. Sample Mounting

Note: See Safety Precautions in Section 6.1. before proceeding. The objective is to produce samples with a smooth (non-grainy) background in a medium with a refractive index of approximately 1.46. The technique below collapses the filter for easier focusing and produces permanent mounts which are useful for quality control and interlaboratory comparison.

An aluminum block or similar device is required for sample preparation.

6.5.1. Heat the aluminum block to about 70E C. The hot block should not be used on any surface that can be damaged by either the heat or from exposure to acetone.

6.5.2. Ensure that the glass slides and cover glasses are free of dust and fibers.

6.5.3. Remove the top plug to prevent a vacuum when the cassette is opened. Clean the outside of the cassette if necessary. Cut the seal and/or tape on the cassette with a razor blade. Very carefully separate the base from the extension cowl, leaving the filter and backup pad in the base.

6.5.4. With a rocking motion cut a triangular wedge from the filter using the scalpel. This wedge should be one-sixth to one-fourth of the filter. Grasp the filter wedge with the forceps on the perimeter of the filter which was clamped between the cassette pieces. DO NOT TOUCH the

filter with your finger. Place the filter on the glass slide sample side up. Static electricity will usually keep the filter on the slide until it is cleared.

6.5.5. Place the tip of the micropipette containing about 200 μL acetone into the aluminum block. Insert the glass slide into the receiving slot in the aluminum block. Inject the acetone into the block with slow, steady pressure on the plunger while holding the pipette firmly in place. Wait 3 to 5 seconds for the filter to clear, then remove the pipette and slide from the aluminum block.

6.5.6. Immediately (less than 30 seconds) place 2.5 to 3.5 μL of triacetin on the filter (Note: Waiting longer than 30 seconds will result in increased index of refraction and decreased contrast between the fibers and the preparation. This may also lead to separation of the cover slip from the slide).

6.5.7. Lower a cover slip gently onto the filter at a slight angle to reduce the possibility of forming air bubbles. If more than 30 seconds have elapsed between acetone exposure and triacetin application, glue the edges of the cover slip to the slide with lacquer or nail polish.

6.5.8. If clearing is slow, warm the slide for 15 min on a hot plate having a surface temperature of about 50 EC to hasten clearing. The top of the hot block can be used if the slide is not heated too long.

6.5.9. Counting may proceed immediately after clearing and mounting are completed.

6.6. Sample Analysis

Completely align the microscope according to the manufacturer's instructions. Then, align the microscope using the following general alignment routine at the beginning of every counting session and more often if necessary.

6.6.1. Alignment

(1) Clean all optical surfaces. Even a small amount of dirt can significantly degrade the image.

(2) Rough focus the objective on a sample.

(3) Close down the field iris so that it is visible in the field of view. Focus the image of the iris with the condenser focus. Center the image of the iris in the field of view.

(4) Install the phase telescope and focus on the phase rings. Critically center the rings. Misalignment of the rings results in astigmatism which will degrade the image.

(5) Place the phase-shift test slide on the microscope stage and focus on the lines. The analyst must see line set 3 and should see at least parts of 4 and 5 but, not see line set 6 or 6. A microscope/microscopist combination which does not pass this test may not be used.

6.6.2. Counting Fibers

(1) Place the prepared sample slide on the mechanical stage of the microscope. Position the center of the wedge under the objective lens and focus upon the sample.

(2) Start counting from one end of the wedge and progress along a radial line to the other end (count in either direction from perimeter to wedge tip). Select fields randomly, without looking into the eyepieces, by slightly advancing the slide in one direction with the mechanical stage control.

(3) Continually scan over a range of focal planes (generally the upper 10 to 15 μm of the filter surface) with the fine focus control during each field count. Spend at least 5 to 15 seconds per field.

(4) Most samples

will contain asbestos fibers with fiber diameters less than 1 μm . Look carefully for faint fiber images. The small diameter fibers will be very hard to see. However, they are an important contribution to the total count.

(5) Count only fibers equal to or longer than 5 μm . Measure the length of curved fibers along the curve.

(6) Count fibers which have a length to width ratio of 3:1 or greater.

(7) Count all the fibers in at least 20 fields. Continue counting until either 100 fibers are counted or 100 fields have been viewed; whichever occurs first. Count all the fibers in the final field.

(8) Fibers lying entirely within the boundary of the Walton-Beckett graticule field shall receive a count of 1. Fibers crossing the boundary once, having one end within the circle shall receive a count of 2. Do not count any fiber that crosses the graticule boundary more than once. Reject and do not count any other fibers even though they may be visible outside the graticule area. If a fiber touches the circle, it is considered to cross the line.

(9) Count bundles of fibers as one fiber unless individual fibers can be clearly identified and each individual fiber is clearly not connected to another counted fiber. See Figure 1 for counting conventions.

(10) Record the number of fibers in each field in a consistent way such that filter non-uniformity can be assessed.

(11) Regularly check phase ring alignment.

(12) When an agglomerate (mass of material) covers more than 25% of the field of view, reject the field and select another. Do not include it in the number of fields counted.

(13) Perform a "blind recount" of 1 in every 10 filter wedges (slides). Re-label the slides using a person other than the original counter.

6.7. Fiber Identification

As previously mentioned in Section 1.3., PCM does not provide positive confirmation of asbestos fibers. Alternate differential counting techniques should be used if discrimination is desirable. Differential counting may include primary discrimination based on morphology, polarized light analysis of fibers, or modification of PCM data by Scanning Electron or Transmission Electron Microscopy.

A great deal of experience is required to routinely and correctly perform differential counting. It is discouraged unless it is legally necessary. Then, only if a fiber is obviously not asbestos should it be excluded from the count. Further discussion of this technique can be found in reference 8.10.

If there is a question whether a fiber is asbestos or not, follow the rule:

"WHEN IN DOUBT, COUNT."

6.8. Analytical Recommendations-Quality Control System

6.8.1. All individuals performing asbestos analysis must have taken the NIOSH course for sampling and evaluating airborne asbestos or an equivalent course.

6.8.2. Each laboratory engaged in asbestos counting shall set up a slide trading arrangement with at least two other laboratories in order to compare performance and eliminate inbreeding of error. The slide exchange occurs at least semiannually. The round robin results shall be posted where all analysts can view individual analyst's results.

6.8.3. Each laboratory engaged in asbestos counting shall participate in the Proficiency Analytical Testing Program, the Asbestos Analyst Registry or equivalent.

6.8.4. Each analyst shall select and count prepared slides from a "slide bank". These are quality assurance counts. The slide bank shall be prepared using uniformly distributed samples taken from the workload. Fiber densities should cover the entire range routinely analyzed by the laboratory. These slides are counted blind by all counters to establish an original standard deviation. This historical distribution is compared with the quality assurance counts. A counter must have 95% of all quality control samples counted within three standard deviations of the

historical mean. This count is then integrated into a new historical mean and standard deviation for the slide.

The analyses done by the counters to establish the slide bank may be used for an interim quality control program if the data are treated in a proper statistical fashion.

7. CALCULATIONS

7.1. Calculate the estimated airborne asbestos fiber concentration on the filter sample using the following formula:

where:

AC=Airborne fiber concentration

$$AC = \frac{\left[\left(\frac{FB}{FL} \right) - \left(\frac{BFB}{BFL} \right) \right] \times ECA}{1000 \times FR \times T \times MFA}$$

FB=Total number of fibers greater than 5 µm counted

FL=Total number of fields counted on the filter

BFB=Total number of fibers greater than 5 µm counted in the blank

BFL=Total number of fields counted on the blank

ECA=Effective collecting area of filter (385 mm² nominal for a 25-mm filter.)

FR=Pump flow rate (L/min)

MFA=Microscope count field area (mm²). This is 0.00785 mm² for a Walton-Beckett Graticule.

T=Sample collection time (min)

1,000=Conversion of L to cc

Note: The collection area of a filter is seldom equal to 385 mm². It is appropriate for laboratories to routinely monitor the exact diameter using an inside micrometer. The collection

area is calculated according to the formula:

$$\text{Area}=\pi(d/2)^2$$

7.2. Short-cut Calculation

Since a given analyst always has the same interpupillary distance, the number of fields per filter for a particular analyst will remain constant for a given size filter. The field size for that analyst is constant (i.e. the analyst is using an assigned microscope and is not changing the reticle).

For example, if the exposed area of the filter is always 385 mm² and the size of the field is always 0.00785 mm², the number of fields per filter will always be 49,000. In addition it is necessary to convert liters of air to cc. These three constants can then be combined such that $ECA/(1,000 \times MFA)=49$. The previous equation simplifies to:

$$AC = \frac{\left(\frac{FB}{FL}\right) - \left(\frac{BFB}{BFL}\right) \times 49}{FR \times T}$$

7.3. Recount Calculations

As mentioned in 13 of Section 6.6.2., a "blind recount" of 10% of the slides is performed. In all cases, differences will be observed between the first and second counts of the same filter wedge. Most of these differences will be due to chance alone, that is, due to the random variability (precision) of the count method. Statistical recount criteria enables one to decide whether observed differences can be explained due to chance alone or are probably due to systematic differences between analysts, microscopes, or other biasing factors.

The following recount criterion is for a pair of counts that estimate AC in fibers/cc. The criterion is given at the type-I error level. That is, there is 5% maximum risk that we will reject a pair of counts for the reason that one might be biased, when the large observed difference is really due to chance.

Reject a pair of counts if:

$$\left| \sqrt{AC_2} - \sqrt{AC_1} \right| > 2.78 \times \left(\sqrt{AC_{AVG}} \right) \times CV_{FB}$$

Where:

AC1=lower estimated airborne fiber concentration

AC2=higher estimated airborne fiber concentration

ACavg=average of the two concentration estimates

CVFB=CV for the average of the two concentration estimates

If a pair of counts are rejected by this criterion then, recount the rest of the filters in the submitted set. Apply the test and reject any other pairs failing the test. Rejection shall include a memo to the industrial hygienist stating that the sample failed a statistical test for homogeneity and the true air concentration may be significantly different than the reported value.

7.4. Reporting Results

Report results to the industrial hygienist as fibers/cc. Use two significant figures. If multiple analyses are performed on a sample, an average of the results is to be reported unless any of the results can be rejected for cause.

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Quality Control

The OSHA asbestos regulations require each laboratory to establish a quality control program. The following is presented as an example of how the OSHA-SLTC constructed its internal CV curve as part of meeting this requirement. Data is from 395 samples collected during OSHA compliance inspections and analyzed from October 1980 through April 1986.

Each sample was counted by 2 to 5 different counters independently of one another. The standard deviation and the CV statistic was calculated for each sample. This data was then plotted on a graph of CV vs. fibers/mm². A least squares regression was performed using the following equation:

$$CV = \text{antilog}_{10} [A(\log_{10}(x))^2 + B(\log_{10}(x)) + C]$$

where:

x = the number of fibers/mm²

Application of least squares gave:

$$A = 0.182205$$

B=-0.973343

C=0.327499

Using these values, the equation becomes:

CV=antilog10 [0.182205(log10 (x))²-0.973343(log10 (x))+0.327499]

Sampling Pump Flow Rate Corrections

This correction is used if a difference greater than 5% in ambient temperature and/or pressure is noted between calibration and sampling sites and the pump does not compensate for the differences.

$$Q_{\text{act}} = Q_{\text{cal}} \times \sqrt{\left(\frac{P_{\text{cal}}}{P_{\text{act}}}\right) \times \left(\frac{T_{\text{act}}}{T_{\text{cal}}}\right)}$$

Where

Q_{act}=actual flow rate

Q_{cal}=calibrated flow rate (if a rotameter was used, the rotameter value)

P_{cal}=uncorrected air pressure at calibration

P_{act}=uncorrected air pressure at sampling site

T_{act}=temperature at sampling site (K)

T_{cal}=temperature at calibration (K)

Walton-Beckett Graticule

When ordering the Graticule for asbestos counting, specify the exact disc diameter needed to fit the ocular of the microscope and the diameter (mm) of the circular counting area. Instructions for measuring the dimensions necessary are listed:

- (1) Insert any available graticule into the focusing eyepiece and focus so that the graticule lines are sharp and clear.
- (2) Align the microscope.
- (3) Place a stage micrometer on the microscope object stage and focus the microscope on the graduated lines.
- (4) Measure the magnified grid length, PL (μm), using the stage micrometer.
- (5) Remove the graticule from the microscope and measure its actual grid length, AL (mm). This can be accomplished by using a mechanical stage fitted with verniers, or a jeweler's loupe with a direct reading scale.
- (6) Let $D=100 \mu\text{m}$. Calculate the circle diameter, d_c (mm), for the Walton-Beckett graticule and specify the diameter when making a purchase:

$$d(c) = \frac{AL \times D}{PL}$$

Example: If $PL=108 \mu\text{m}$, $AL=2.93 \text{ mm}$ and $D=100 \mu\text{m}$, then,

$$d(c) = \frac{2.93 \times 100}{108} = 2.71\text{mm}$$

(7) Each eyepiece-objective-reticle combination on the microscope must be calibrated. Should any of the three be changed (by zoom adjustment, disassembly, replacement, etc.), the combination must be recalibrated. Calibration may change if interpupillary distance is changed. Measure the field diameter, D (acceptable range: $100\sqrt{2} \mu\text{m}$) with a stage micrometer upon receipt of the graticule from the manufacturer. Determine the field area (mm^2).

Field Area= $n(D/2)^2$

If $D=100 \mu\text{m}=0.1 \text{ mm}$, then

Field Area=(0.1 mm/2)²=0.00785 mm²

The Graticule is available from: Graticules Ltd., Morley Road, Tonbridge TN9 IRN, Kent, England (Telephone 011-44-732-359061). Also available from PTR Optics Ltd., 145 Newton Street, Waltham, MA 02154 [telephone (617) 891-6000] or McCrone Accessories and Components, 2506 S. Michigan Ave., Chicago, IL 60616 [phone (312)-842-7100]. The graticule is custom made for each microscope.

Counts for the Fibers in the Figure

| Structure No. | Count | Explanation |
|---------------|-------|--|
| 1 to 6..... | 1 | Single fibers all contained within the circle. |
| 7..... | 1/2 | Fiber crosses circle once. |
| 8..... | 0 | Fiber too short. |
| 9..... | 2 | Two crossing fibers. |
| 10..... | 0 | Fiber outside graticule. |
| 11..... | 0 | Fiber crosses graticule twice. |
| 12..... | 1/2 | Although split, fiber only crosses once. |

1910.1001 App C Qualitative and quantitative fit testing procedures - Mandatory

Appendix C to 1910.1001 - [Reserved]

1910.1001 App D Medical questionnaires; Mandatory

Appendix D to 1910.1001 - Medical questionnaires; Mandatory

This mandatory appendix contains the medical questionnaires that must be administered to all employees who are exposed to asbestos above the permissible exposure limit, and who will therefore be included in their employer's medical surveillance program. Part 1 of the appendix contains the Initial Medical Questionnaire, which must be obtained for all new hires who will be covered by the medical surveillance requirements. Part 2 includes the abbreviated Periodical Medical Questionnaire, which must be administered to all employees who are provided periodic medical examinations under the medical surveillance provisions of the standard.

(For Medical Questionnaire, see printed copy.)

1910.1001 App E Interpretation and classification of chest roentgenograms - Mandatory

Appendix E to 1910.1001 - Interpretation and classification of chest roentgenograms - Mandatory

(a) Chest roentgenograms shall be interpreted and classified in accordance with a professionally accepted Classification system and recorded on an interpretation form following the format of the CDC/NIOSH (M) 2.8 form. As a minimum, the content within the bold lines of this form (items 1 through 4) shall be included. This form is not to be submitted to NIOSH.

(b) Roentgenograms shall be interpreted and classified only by a B-reader, a board eligible/certified radiologist, or an experienced physician with known expertise in pneumoconioses.

(c) All interpreters, whenever interpreting chest roentgenograms made under this section, shall have immediately available for reference a complete set of the ILO-U/C International Classification of Radiographs for Pneumoconioses, 1980.

Appendix F to 1910.1001-Work Practices and Engineering Controls for Automotive Brake and Clutch Inspection, Disassembly, Repair and Assembly-Mandatory

This mandatory appendix specifies engineering controls and work practices that must be implemented by the employer during automotive brake and clutch inspection, disassembly, repair, and assembly operations. Proper use of these engineering controls and work practices by trained employees will reduce employees' asbestos exposure below the permissible exposure level during clutch and brake inspection, disassembly, repair, and assembly operations. The employer shall institute engineering controls and work practices using either the method set forth in paragraph [A] or paragraph [B] of this appendix, or any other method which the employer can demonstrate to be equivalent in terms of reducing employee exposure to asbestos as defined and which meets the requirements described in paragraph [C] of this appendix, for those facilities in which no more than 5 pairs of brakes or 5 clutches are inspected, disassembled, reassembled and/or repaired per week, the method set forth in paragraph [D] of this appendix may be used:

[A] Negative Pressure Enclosure/HEPA Vacuum System Method

(1) The brake and clutch inspection, disassembly, repair, and assembly operations shall be enclosed to cover and contain the clutch or brake assembly and to prevent the release of asbestos fibers into the worker's breathing zone.

(2) The enclosure shall be sealed tightly and thoroughly inspected for leaks before work begins on brake and clutch inspection, disassembly, repair, and assembly.

(3) The enclosure shall be such that the worker can clearly see the operation and shall provide impermeable sleeves through which the worker can handle the brake and clutch inspection, disassembly, repair and assembly. The integrity of the sleeves and ports shall be examined before

work begins.

(4) A HEPA-filtered vacuum shall be employed to maintain the enclosure under negative pressure throughout the operation. Compressed-air may be used to remove asbestos fibers or particles from the enclosure.

(5) The HEPA vacuum shall be used first to loosen the asbestos containing residue from the brake and clutch parts and then to evacuate the loosened asbestos containing material from the enclosure and capture the material in the vacuum filter.

(6) The vacuum's filter, when full, shall be first wetted with a fine mist of water, then removed and placed immediately in an impermeable container, labeled according to paragraph (j)(4) of this section and disposed of according to paragraph (k) of this section.

(7) Any spills or releases of asbestos containing waste material from inside of the enclosure or vacuum hose or vacuum filter shall be immediately cleaned up and disposed of according to paragraph (k) of this section.

[B] Low Pressure/Wet Cleaning Method

(1) A catch basin shall be placed under the brake assembly, positioned to avoid splashes and spills.

(2) The reservoir shall contain water containing an organic solvent or wetting agent. The flow of liquid shall be controlled such that the brake assembly is gently flooded to prevent the asbestos-containing brake dust from becoming airborne.

(3) The aqueous solution shall be allowed to flow between the brake drum and brake support before the drum is removed.

(4) After removing the brake drum, the wheel hub and back of the brake assembly shall be thoroughly wetted to suppress dust.

(5) The brake support plate, brake shoes and brake components used to attach the brake shoes shall be thoroughly washed before removing the old shoes.

(6) In systems using filters, the filters, when full, shall be first wetted with a fine mist of water, then removed and placed immediately in an impermeable container, labeled according to paragraph (j)(4) of this section and disposed of according to paragraph (k) of this section.

(7) Any spills of asbestos-containing aqueous solution or any asbestos-containing waste material shall be cleaned up immediately and disposed of according to paragraph (k) of this section.

(8) The use of dry brushing during low pressure/wet cleaning operations is prohibited.

[C] Equivalent Methods

An equivalent method is one which has sufficient written detail so that it can be reproduced and has been demonstrated that the exposures resulting from the equivalent method are equal to or less than the exposures which would result from the use of the method described in paragraph [A] of this appendix. For purposes of making this comparison, the employer shall assume that exposures resulting from the use of the method described in paragraph [A] of this appendix shall not exceed 0.016 f/cc, as measured by the OSHA reference method and as averaged over at least 18 personal samples.

[D] Wet Method.

(1) A spray bottle, hose nozzle, or other implement capable of delivering a fine mist of water or amended water or other delivery system capable of delivering water at low pressure, shall be used to first thoroughly wet the brake and clutch parts. Brake and clutch components shall then be wiped clean with a cloth.

(2) The cloth shall be placed in an impermeable container, labelled according to paragraph (j)(4) of this section and then disposed of according to paragraph (k) of this section, or the cloth shall be laundered in a way to prevent the release of asbestos fibers in excess of 0.1 fiber per cubic centimeter of air.

(3) Any spills of solvent or any asbestos containing waste material shall be cleaned up immediately according to paragraph (k) of this standard.

(4) The use of dry brushing during the wet method operations is prohibited.

1910.1001 App G Substance technical information for asbestos - Non-Mandatory

Appendix G to 1910.1001 - Substance technical information for asbestos - Non-Mandatory

I. Substance Identification

A. Substance: "Asbestos" is the name of a class of magnesium-silicate minerals that occur in fibrous form. Minerals that are included in this group are chrysotile, crocidolite, amosite, tremolite asbestos, anthophyllite asbestos, and actinolite asbestos.

B. Asbestos is used in the manufacture of heat-resistant clothing, automotive brake and clutch linings, and a variety of building materials including floor tiles, roofing felts, ceiling tiles, asbestos-cement pipe and sheet, and fire-resistant drywall. Asbestos is also present in pipe and boiler insulation materials, and in sprayed-on materials located on beams, in crawlspaces, and

between walls.

C. The potential for a product containing asbestos to release breathable fibers depends on its degree of friability. Friable means that the material can be crumbled with hand pressure and is therefore likely to emit fibers. The fibrous or fluffy sprayed-on materials used for fireproofing, insulation, or sound proofing are considered to be friable, and they readily release airborne fibers if disturbed. Materials such as vinyl-asbestos floor tile or roofing felts are considered nonfriable and generally do not emit airborne fibers unless subjected to sanding or sawing operations. Asbestos-cement pipe or sheet can emit airborne fibers if the materials are cut or sawed, or if they are broken during demolition operations.

D. Permissible exposure: Exposure to airborne asbestos fibers may not exceed 0.2 fibers per cubic centimeter of air (0.1 f/cc) averaged over the 8-hour workday.

II. Health Hazard Data

A. Asbestos can cause disabling respiratory disease and various types of cancers if the fibers are inhaled. Inhaling or ingesting fibers from contaminated clothing or skin can also result in these diseases. The symptoms of these diseases generally do not appear for 20 or more years after initial exposure.

B. Exposure to asbestos has been shown to cause lung cancer, mesothelioma, and cancer of the stomach and colon. Mesothelioma is a rare cancer of the thin membrane lining of the chest and abdomen. Symptoms of mesothelioma include shortness of breath, pain in the walls of the chest, and/or abdominal pain.

III. Respirators and Protective Clothing

A. Respirators: You are required to wear a respirator when performing tasks that result in asbestos exposure that exceeds the permissible exposure limit (PEL) of 0.1 f/cc. These conditions can occur while your employer is in the process of installing engineering controls to reduce asbestos exposure, or where engineering controls are not feasible to reduce asbestos exposure. Air-purifying respirators equipped with a high-efficiency particulate air (HEPA) filter can be used where airborne asbestos fiber concentrations do not exceed 1 f/cc; otherwise, air-supplied, positive-pressure, full facepiece respirators must be used. Disposable respirators or dust masks are not permitted to be used for asbestos work. For effective protection, respirators must fit your face and head snugly. Your employer is required to conduct fit tests when you are first assigned a respirator and every 6 months thereafter. Respirators should not be loosened or removed in work situations where their use is required.

B. Protective clothing: You are required to wear protective clothing in work areas where asbestos fiber concentrations exceed the permissible exposure limit.

IV. Disposal Procedures and Cleanup

A. Wastes that are generated by processes where asbestos are present include:

1. Empty asbestos shipping containers.
2. Process wastes such as cuttings, trimmings, or reject material.
3. Housekeeping waste from sweeping or vacuuming.
4. Asbestos fireproofing or insulating material that is removed from buildings.
5. Building products that contain asbestos removed during building renovation or demolition.
6. Contaminated disposable protective clothing.

B. Empty shipping bags can be flattened under exhaust hoods and packed into airtight containers for disposal. Empty shipping drums are difficult to clean and should be sealed.

C. Vacuum bags or disposable paper filters should not be cleaned, but should be sprayed with a fine water mist and placed into a labeled waste container.

D. Process waste and housekeeping waste should be wetted with water or a mixture of water and surfactant prior to packaging in disposable containers.

E. Material containing asbestos that is removed from buildings must be disposed of in leak-tight 6-mil thick plastic bags, plastic-lined cardboard containers, or plastic-lined metal containers. These wastes, which are removed while wet, should be sealed in containers before they dry out to minimize the release of asbestos fibers during handling.

V. Access to Information

A. Each year, your employer is required to inform you of the information contained in this standard and appendices for asbestos. In addition, your employer must instruct you in the proper work practices for handling materials containing asbestos and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to asbestos. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure, and, if you are exposed above the permissible limit, he or she is required to inform you of the actions that are being taken to reduce your exposure to within the permissible limit.

C. Your employer is required to keep records of your exposures and medical examinations. These exposure records must be kept for at least thirty (30) years. Medical records must be kept for the

period of your employment plus thirty (30) years.

D. Your employer is required to release your exposure and medical records to your physician or designated representative upon your written request.

1910.1001 App H Medical surveillance guidelines for asbesto - Non-Mandatory

Appendix H to 1910.1001 - Medical surveillance guidelines for asbesto - Non-Mandatory

I. Route of Entry Inhalation, Ingestion

II. Toxicology

Clinical evidence of the adverse effects associated with exposure to asbestos is present in the form of several well-conducted epidemiological studies of occupationally exposed workers, family contacts of workers, and persons living near asbestos mines. These studies have shown a definite association between exposure to asbestos and an increased incidence of lung cancer, pleural and peritoneal mesothelioma, gastrointestinal cancer, and asbestosis. The latter is a disabling fibrotic lung disease that is caused only by exposure to asbestos. Exposure to asbestos has also been associated with an increased incidence of esophageal, kidney, laryngeal, pharyngeal, and buccal cavity cancers. As with other known chronic occupational diseases, disease associated with asbestos generally appears about 20 years following the first occurrence of exposure: There are no known acute effects associated with exposure to asbestos. Epidemiological studies indicate that the risk of lung cancer among exposed workers who smoke cigarettes is greatly increased over the risk of lung cancer among non-exposed smokers or exposed nonsmokers. These studies suggest that cessation of smoking will reduce the risk of lung cancer for a person exposed to asbestos but will not reduce it to the same level of risk as that existing for an exposed worker who has never smoked.

III. Signs and Symptoms of Exposure-Related Disease

The signs and symptoms of lung cancer or gastrointestinal cancer induced by exposure to asbestos are not unique, except that a chest X-ray of an exposed patient with lung cancer may show pleural plaques, pleural calcification, or pleural fibrosis. Symptoms characteristic of mesothelioma include shortness of breath, pain in the walls of the chest, or abdominal pain. Mesothelioma has a much longer latency period compared with lung cancer (40 years versus 15-20 years), and mesothelioma is therefore more likely to be found among workers who were first exposed to asbestos at an early age. Mesothelioma is always fatal.

Asbestosis is pulmonary fibrosis caused by the accumulation of asbestos fibers in the lungs. Symptoms include shortness of breath, coughing, fatigue, and vague feelings of sickness. When the fibrosis worsens, shortness of breath occurs even at rest. The diagnosis of asbestosis is based on a history of exposure to asbestos, the presence of characteristic radiologic changes,

end-inspiratory crackles (rales), and other clinical features of fibrosing lung disease. Pleural plaques and thickening are observed on X-rays taken during the early stages of the disease. Asbestosis is often a progressive disease even in the absence of continued exposure, although this appears to be a highly individualized characteristic. In severe cases, death may be caused by respiratory or cardiac failure.

IV. Surveillance and Preventive Considerations

The employer is required to institute a medical surveillance program for all employees who are or will be exposed to asbestos at or above the permissible exposure limit (0.1 fiber per cubic centimeter of air). Adequate screening tests to determine an employee's potential for developing serious chronic diseases, such as cancer, from exposure to asbestos do not presently exist. However, some tests, particularly chest X-rays and pulmonary function tests, may indicate that an employee has been overexposed to asbestos increasing his or her risk of developing exposure-related chronic diseases. It is important for the physician to become familiar with the operating conditions in which occupational exposure to asbestos is likely to occur. This is particularly important in evaluating medical and work histories and in conducting physical examinations. When an active employee has been identified as having been overexposed to asbestos measures taken by the employer to eliminate or mitigate further exposure should also lower the risk of serious long-term consequences.

The employer is required to institute a medical surveillance program for all employees who are or will be exposed to asbestos at or above the permissible exposure limit (0.1 fiber per cubic centimeter of air). All examinations and procedures must be performed by or under the supervision of a licensed physician, at a reasonable time and place, and at no cost to the employee. Although broad latitude is given to the physician in prescribing specific tests to be included in the medical surveillance program, OSHA requires inclusion of the following elements in the routine examination:

- (i) Medical and work histories with special emphasis directed to symptoms of the respiratory system, cardiovascular system, and digestive tract.
- (ii) Completion of the respiratory disease questionnaire contained in Appendix D.
- (iii) A physical examination including a chest roentgenogram and pulmonary function test that includes measurement of the employee's forced vital capacity (FVC) and forced expiratory volume at one second (FEV1).
- (iv) Any laboratory or other test that the examining physician deems by sound medical practice to be necessary.

The employer is required to make the prescribed tests available at least annually to those employees covered; more often than specified if recommended by the examining physician; and upon termination of employment.

The employer is required to provide the physician with the following information: A copy of this standard and appendices; a description of the employee's duties as they relate to asbestos exposure; the employee's representative level of exposure to asbestos a description of any personal protective and respiratory equipment used; and information from previous medical examinations of the affected employee that is not otherwise available to the physician. Making this information available to the physician will aid in the evaluation of the employee's health in relation to assigned duties and fitness to wear personal protective equipment, if required.

The employer is required to obtain a written opinion from the examining physician containing the results of the medical examination; the physician's opinion as to whether the employee has any detected medical conditions that would place the employee at an increased risk of exposure-related disease; any recommended limitations on the employee or on the use of personal protective equipment; and a statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions related to asbestos exposure that require further explanation or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to exposure to asbestos and a copy of the opinion must be provided to the affected employee.

1910.1001 App I Smoking Cessation Program Information For Asbestos - Non-Mandatory.
* [The following - Appendix I to 1910.1001 added by FR 3731, Feb. 5, 1990]

Appendix I to 1910.1001 - Smoking Cessation Program Information For Asbestos - Non-Mandatory.

The following organizations provide smoking cessation information and program material.

1. The National Cancer Institute operates a toll-free Cancer Information Service (CIS) with trained personnel to help you. Call 1-800-4-CANCER to reach the CIS office serving your area, or write: Office of Cancer Communications, National Cancer Institute, National Institutes of Health, Building 31, Room 10A24, Bethesda, Maryland 20892.

2. American Cancer Society, 3340 Peachtree Road, NE, Atlanta, Georgia 30062, (404)320-3333.

The American Cancer Society (ACS) is a voluntary organization composed of 58 divisions and 3,100 local units. Through "The Great American Smokeout" in November, the annual Cancer Crusade in April, and numerous educational materials. ACS helps people learn about the health hazards of smoking and become successful ex-smokers.

3. American Heart Association, 7320 Greenville Avenue, Dallas, Texas 75231, (214)750-5300.

The American Heart Association(AHA) is a voluntary organization with 130,000 members

(physicians, scientists, and laypersons) in 55 state and regional groups. AHA produces a variety of publications and audio-visual materials about the effects of smoking on the heart. AHA also has developed a guidebook for incorporating a weight-control component into smoking cessation programs.

4. American Lung Association, 1740 Broadway, New York, New York 10019, (212)245-8000.

A voluntary organization of 7,500 members (physicians, nurses, and laypersons), the American Lung Association (ALA) conducts numerous public information programs about the health effect of smoking. ALA has 59 state and 85 local units. The organization actively supports legislation and information campaigns for smokers who want to quit, for example, through "Freedom From Smoking," a self-help smoking cessation program.

5. Office on Smoking and Health, U.S. Department of Health and Human Services, 5600 Fishers Lane, Park Building, Room 110, Rockville, Maryland 20857.

The Office on Smoking and Health (OSH) is the Department of Health and Human Services' lead agency in smoking control. OSH has sponsored distribution of publications on smoking-related topics, such as free flyers on relapse after initial quitting, helping a friend or family member quit smoking, the health hazards of smoking, and the effects of parental smoking on teenagers. In Hawaii, on Oahu call 524-1234 (call collect from neighboring islands).

Spanish-speaking staff members are available during daytime hours to callers from the following areas: California, Florida, Georgia, Illinois, New Jersey (area code 210), New York, and Texas. Consult your local telephone directory for listings of local chapters.

Appendix J to 1910.1001-Polarized Light Microscopy of Asbestos-Non-Mandatory

* [The following - Appendix J to 1910.1001 added by FR 40964, Oct. 10, 1994]

Method number: ID-191

Matrix: Bulk

Collection Procedure

Collect approximately 1 to 2 grams of each type of material and place into separate 20 mL scintillation vials.

Analytical Procedure

A portion of each separate phase is analyzed by gross examination, phase-polar examination, and central stop dispersion microscopy.

Commercial manufacturers and products mentioned in this method are for descriptive use only and do not constitute endorsements by USDOL-OSHA. Similar products from other sources may be substituted.

1. Introduction

This method describes the collection and analysis of asbestos bulk materials by light microscopy techniques including phase- polar illumination and central-stop dispersion microscopy. Some terms unique to asbestos analysis are defined below:

Amphibole: A family of minerals whose crystals are formed by long, thin units which have two thin ribbons of double chain silicate with a brucite ribbon in between. The shape of each unit is similar to an "I beam". Minerals important in asbestos analysis include cummingtonite-grunerite, crocidolite, tremolite-actinolite and anthophyllite.

Asbestos: A term for naturally occurring fibrous minerals. Asbestos includes chrysotile, cummingtonite-grunerite asbestos (amosite), anthophyllite asbestos, tremolite asbestos, crocidolite, actinolite asbestos and any of these minerals which have been chemically treated or altered. The precise chemical formulation of each species varies with the location from which it was mined. Nominal compositions are listed:

Chrysotile $Mg_3Si_2O_5(OH)_4$

Crocidolite (Riebeckite asbestos) $Na_2Fe^{3+}_2Fe^{2+}_3Si_8O_{22}(OH)_2$

Cummingtonite-Grunerite asbestos (Amosite) $(Mg,Fe)_7Si_8O_{22}(OH)_2$

Tremolite-Actinolite asbestos $Ca_2(Mg,Fe)_5Si_8O_{22}(OH)_2$

Anthophyllite asbestos $(Mg,Fe)_7Si_8O_{22}(OH)_2$

Asbestos Fiber: A fiber of asbestos meeting the criteria for a fiber. (See section 3.5.)

Aspect Ratio: The ratio of the length of a fiber to its diameter usually defined as "length : width", e.g. 3:1.

Brucite: A sheet mineral with the composition $Mg(OH)_2$.

Central Stop Dispersion Staining (microscope): This is a dark field microscope technique that images particles using only light refracted by the particle, excluding light that travels through the particle unrefracted. This is usually accomplished with a McCrone objective or other arrangement which places a circular stop with apparent aperture equal to the objective aperture in

the back focal plane of the microscope.

Cleavage Fragments: Mineral particles formed by the comminution of minerals, especially those characterized by relatively parallel sides and moderate aspect ratio.

Differential Counting: The term applied to the practice of excluding certain kinds of fibers from a phase contrast asbestos count because they are not asbestos.

Fiber: A particle longer than or equal to 5 μm with a length to width ratio greater than or equal to 3:1. This may include cleavage fragments. (see section 3.5 of this appendix).

Phase Contrast: Contrast obtained in the microscope by causing light scattered by small particles to destructively interfere with unscattered light, thereby enhancing the visibility of very small particles and particles with very low intrinsic contrast.

Phase Contrast Microscope: A microscope configured with a phase mask pair to create phase contrast. The technique which uses this is called Phase Contrast Microscopy (PCM).

Phase-Polar Analysis: This is the use of polarized light in a phase contrast microscope. It is used to see the same size fibers that are visible in air filter analysis. Although fibers finer than 1 μm are visible, analysis of these is inferred from analysis of larger bundles that are usually present.

Phase-Polar Microscope: The phase-polar microscope is a phase contrast microscope which has an analyzer, a polarizer, a first order red plate and a rotating phase condenser all in place so that the polarized light image is enhanced by phase contrast.

Sealing Encapsulant: This is a product which can be applied, preferably by spraying, onto an asbestos surface which will seal the surface so that fibers cannot be released.

Serpentine: A mineral family consisting of minerals with the general composition $\text{Mg}_3(\text{Si}_2\text{O}_5(\text{OH})_4)$ having the magnesium in brucite layer over a silicate layer. Minerals important in asbestos analysis included in this family are chrysotile, lizardite, antigorite.

1.1. History

Light microscopy has been used for well over 100 years for the determination of mineral species. This analysis is carried out using specialized polarizing microscopes as well as bright field microscopes. The identification of minerals is an on-going process with many new minerals described each year. The first recorded use of asbestos was in Finland about 2500 B.C. where the material was used in the mud wattle for the wooden huts the people lived in as well as strengthening for pottery. Adverse health aspects of the mineral were noted nearly 2000 years ago when Pliny the Younger wrote about the poor health of slaves in the asbestos mines. Although known to be injurious for centuries, the first modern references to its toxicity were by the British

Labor Inspectorate when it banned asbestos dust from the workplace in 1898. Asbestosis cases were described in the literature after the turn of the century. Cancer was first suspected in the mid 1930's and a causal link to mesothelioma was made in 1965. Because of the public concern for worker and public safety with the use of this material, several different types of analysis were applied to the determination of asbestos content. Light microscopy requires a great deal of experience and craft. Attempts were made to apply less subjective methods to the analysis. X-ray diffraction was partially successful in determining the mineral types but was unable to separate out the fibrous portions from the non-fibrous portions. Also, the minimum detection limit for asbestos analysis by X-ray diffraction (XRD) is about 1%. Differential Thermal Analysis (DTA) was no more successful. These provide useful corroborating information when the presence of asbestos has been shown by microscopy; however, neither can determine the difference between fibrous and non-fibrous minerals when both habits are present. The same is true of Infrared Absorption (IR).

When electron microscopy was applied to asbestos analysis, hundreds of fibers were discovered present too small to be visible in any light microscope. There are two different types of electron microscope used for asbestos analysis: Scanning Electron Microscope (SEM) and Transmission Electron Microscope (TEM). Scanning Electron Microscopy is useful

in identifying minerals. The SEM can provide two of the three pieces of information required to identify fibers by electron microscopy: morphology and chemistry. The third is structure as determined by Selected Area Electron Diffraction-SAED which is performed in the TEM. Although the resolution of the SEM is sufficient for very fine fibers to be seen, accuracy of chemical analysis that can be performed on the fibers varies with fiber diameter in fibers of less than 0.2 μm diameter. The TEM is a powerful tool to identify fibers too small to be resolved by light microscopy and should be used in conjunction with this method when necessary. The TEM can provide all three pieces of information required for fiber identification. Most fibers thicker than 1 μm can adequately be defined in the light microscope. The light microscope remains as the best instrument for the determination of mineral type. This is because the minerals under investigation were first described analytically with the light microscope. It is inexpensive and gives positive identification for most samples analyzed. Further, when optical techniques are inadequate, there is ample indication that alternative techniques should be used for complete identification of the sample.

1.2. Principle

Minerals consist of atoms that may be arranged in random order or in a regular arrangement. Amorphous materials have atoms in random order while crystalline materials have long range order. Many materials are transparent to light, at least for small particles or for thin sections. The properties of these materials can be investigated by the effect that the material has on light passing through it. The six asbestos minerals are all crystalline with particular properties that have been identified and cataloged. These six minerals are anisotropic. They have a regular array of atoms, but the arrangement is not the same in all directions. Each major direction of the crystal

presents a different regularity. Light photons travelling in each of these main directions will encounter different electrical neighborhoods, affecting the path and time of travel. The techniques outlined in this method use the fact that light traveling through fibers or crystals in different directions will behave differently, but predictably. The behavior of the light as it travels through a crystal can be measured and compared with known or determined values to identify the mineral species. Usually, Polarized Light Microscopy (PLM) is performed with strain-free objectives on a bright-field microscope platform. This would limit the resolution of the microscope to about 0.4 μm . Because OSHA requires the counting and identification of fibers visible in phase contrast, the phase contrast platform is used to visualize the fibers with the polarizing elements added into the light path. Polarized light methods cannot identify fibers finer than about 1 μm in diameter even though they are visible. The finest fibers are usually identified by inference from the presence of larger, identifiable fiber bundles. When fibers are present, but not identifiable by light microscopy, use either SEM or TEM to determine the fiber identity.

1.3. Advantages and Disadvantages

The advantages of light microscopy are:

- (a) Basic identification of the materials was first performed by light microscopy and gross analysis. This provides a large base of published information against which to check analysis and analytical technique.
- (b) The analysis is specific to fibers. The minerals present can exist in asbestiform, fibrous, prismatic, or massive varieties all at the same time. Therefore, bulk methods of analysis such as X-ray diffraction, IR analysis, DTA, etc. are inappropriate where the material is not known to be fibrous.
- (c) The analysis is quick, requires little preparation time, and can be performed on-site if a suitably equipped microscope is available.

The disadvantages are:

- (a) Even using phase-polar illumination, not all the fibers present may be seen. This is a problem for very low asbestos concentrations where agglomerations or large bundles of fibers may not be present to allow identification by inference.
- (b) The method requires a great degree of sophistication on the part of the microscopist. An analyst is only as useful as his mental catalog of images. Therefore, a microscopist's accuracy is enhanced by experience. The mineralogical training of the analyst is very important. It is the basis on which subjective decisions are made.
- (c) The method uses only a tiny amount of material for analysis. This may lead to sampling bias and false results (high or low). This is especially true if the sample is severely inhomogeneous.

(d) Fibers may be bound in a matrix and not distinguishable as fibers so identification cannot be made.

1.4. Method Performance

1.4.1. This method can be used for determination of asbestos content from 0 to 100% asbestos. The detection limit has not been adequately determined, although for selected samples, the limit is very low, depending on the number of particles examined. For mostly homogeneous, finely divided samples, with no difficult fibrous interferences, the detection limit is below 1%. For inhomogeneous samples (most samples), the detection limit remains undefined. NIST has conducted proficiency testing of laboratories on a national scale. Although each round is reported statistically with an average, control limits, etc., the results indicate a difficulty in establishing precision especially in the low concentration range. It is suspected that there is significant bias in the low range especially near 1%. EPA tried to remedy this by requiring a mandatory point counting scheme for samples less than 10%. The point counting procedure is tedious, and may introduce significant biases of its own. It has not been incorporated into this method.

1.4.2. The precision and accuracy of the quantitation tests performed in this method are unknown. Concentrations are easier to determine in commercial products where asbestos was deliberately added because the amount is usually more than a few percent. An analyst's results can be "calibrated" against the known amounts added by the manufacturer. For geological samples, the degree of homogeneity affects the precision.

1.4.3. The performance of the method is analyst dependent. The analyst must choose carefully and not necessarily randomly the portions for analysis to assure that detection of asbestos occurs when it is present. For this reason, the analyst must have adequate training in sample preparation, and experience in the location and identification of asbestos in samples. This is usually accomplished through substantial on-the-job training as well as formal education in mineralogy and microscopy.

1.5. Interferences

Any material which is long, thin, and small enough to be viewed under the microscope can be considered an interference for asbestos. There are literally hundreds of interferences in workplaces. The techniques described in this method are normally sufficient to eliminate the interferences. An analyst's success in eliminating the interferences depends on proper training.

Asbestos minerals belong to two mineral families: the serpentines and the amphiboles. In the serpentine family, the only common fibrous mineral is chrysotile. Occasionally, the mineral antigorite occurs in a fibril habit with morphology similar to the amphiboles. The amphibole minerals consist of a score of different minerals of which only five are regulated by federal standard: amosite, crocidolite, anthophyllite asbestos, tremolite asbestos and actinolite asbestos.

These are the only amphibole minerals that have been commercially exploited for their fibrous properties; however, the rest can and do occur occasionally in asbestiform habit.

In addition to the related mineral interferences, other minerals common in building material may present a problem for some microscopists: gypsum, anhydrite, brucite, quartz fibers, talc fibers or ribbons, wollastonite, perlite, attapulgite, etc. Other fibrous materials commonly present in workplaces are: fiberglass, mineral wool, ceramic wool, refractory ceramic fibers, kevlar, nomex, synthetic fibers, graphite or carbon fibers, cellulose (paper or wood) fibers, metal fibers, etc.

Matrix embedding material can sometimes be a negative interference. The analyst may not be able to easily extract the fibers from the matrix in order to use the method. Where possible, remove the matrix before the analysis, taking careful note of the loss of weight. Some common matrix materials are: vinyl, rubber, tar, paint, plant fiber, cement, and epoxy. A further negative interference is that the asbestos fibers themselves may be either too small to be seen in Phase Contrast Microscopy (PCM) or of a very low fibrous quality, having the appearance of plant fibers. The analyst's ability to deal with these materials increases with experience.

1.6. Uses and Occupational Exposure

Asbestos is ubiquitous in the environment. More than 40% of the land area of the United States is composed of minerals which may contain asbestos. Fortunately, the actual formation of great amounts of asbestos is relatively rare. Nonetheless, there are locations in which environmental exposure can be severe such as in the Serpentine Hills of California.

There are thousands of uses for asbestos in industry and the home. Asbestos abatement workers are the most current segment of the population to have occupational exposure to great amounts of asbestos. If the material is undisturbed, there is no exposure. Exposure occurs when the asbestos-containing material is abraded or otherwise disturbed during maintenance operations or some other activity. Approximately 95% of the asbestos in place in the United States is chrysotile.

Amosite and crocidolite make up nearly all the difference. Tremolite and anthophyllite make up a very small percentage. Tremolite is found in extremely small amounts in certain chrysotile deposits. Actinolite exposure is probably greatest from environmental sources, but has been identified in vermiculite containing, sprayed-on insulating materials which may have been certified as asbestos-free.

1.7. Physical and Chemical Properties

The nominal chemical compositions for the asbestos minerals were given in Section 1. Compared to cleavage fragments of the same minerals, asbestiform fibers possess a high tensile strength along the fiber axis. They are chemically inert, non-combustible, and heat resistant. Except for chrysotile, they are insoluble in Hydrochloric acid (HCl). Chrysotile is slightly soluble in HCl.

Asbestos has high electrical resistance and good sound absorbing characteristics. It can be woven into cables, fabrics or other textiles, or matted into papers, felts, and mats.

1.8. Toxicology (This Section is for Information Only and Should Not Be Taken as OSHA Policy)

Possible physiologic results of respiratory exposure to asbestos are mesothelioma of the pleura or peritoneum, interstitial fibrosis, asbestosis, pneumoconiosis, or respiratory cancer. The possible consequences of asbestos exposure are detailed in the NIOSH Criteria Document or in the OSHA Asbestos Standards 29 CFR 1910.1001 and 29 CFR 1926.1101 and 29 CFR 1915.1001.

2. Sampling Procedure

2.1. Equipment for Sampling

- (a) Tube or cork borer sampling device
- (b) Knife
- (c) 20 mL scintillation vial or similar vial
- (d) Sealing encapsulant

2.2. Safety Precautions

Asbestos is a known carcinogen. Take care when sampling. While in an asbestos-containing atmosphere, a properly selected and fit-tested respirator should be worn. Take samples in a manner to cause the least amount of dust. Follow these general guidelines:

- (a) Do not make unnecessary dust.
- (b) Take only a small amount (1 to 2 g).
- (c) Tightly close the sample container.
- (d) Use encapsulant to seal the spot where the sample was taken, if necessary.

2.3. Sampling Procedure

Samples of any suspect material should be taken from an inconspicuous place. Where the material is to remain, seal the sampling wound with an encapsulant to eliminate the potential for exposure from the sample site. Microscopy requires only a few milligrams of material. The amount that will fill a 20 mL scintillation vial is more than adequate. Be sure to collect samples from all layers and phases of material. If possible, make separate samples of each different phase

of the material. This will aid in determining the actual hazard. **DO NOT USE ENVELOPES, PLASTIC OR PAPER BAGS OF ANY KIND TO COLLECT SAMPLES.** The use of plastic bags presents a contamination hazard to laboratory personnel and to other samples. When these containers are opened, a bellows effect blows fibers out of the container onto everything, including the person opening the container.

If a cork-borer type sampler is available, push the tube through the material all the way, so that all layers of material are sampled. Some samplers are intended to be disposable. These should be capped and sent to the laboratory. If a non-disposable cork borer is used, empty the contents into a scintillation vial and send to the laboratory. Vigorously and completely clean the cork borer between samples.

2.4 Shipment

Samples packed in glass vials must not touch or they might break in shipment.

(a) Seal the samples with a sample seal over the end to guard against tampering and to identify the sample.

(b) Package the bulk samples in separate packages from the air samples. They may cross-contaminate each other and will invalidate the results of the air samples.

(c) Include identifying paperwork with the samples, but not in contact with the suspected asbestos.

(d) To maintain sample accountability, ship the samples by certified mail, overnight express, or hand carry them to the laboratory.

3. Analysis

The analysis of asbestos samples can be divided into two major parts: sample preparation and microscopy. Because of the different asbestos uses that may be encountered by the analyst, each sample may need different preparations. The choices are outlined below. There are several different tests that are performed to identify the asbestos species and determine the percentage. They will be explained below.

3.1. Safety

(a) Do not create unnecessary dust. Handle the samples in HEPA-filter equipped hoods. If samples are received in bags, envelopes or other inappropriate container, open them only in a hood having a face velocity at or greater than 100 fpm. Transfer a small amount to a scintillation vial and only handle the smaller amount.

- (b) Open samples in a hood, never in the open lab area.
- (c) Index of refraction oils can be toxic. Take care not to get this material on the skin. Wash immediately with soap and water if this happens.
- (d) Samples that have been heated in the muffle furnace or the drying oven may be hot. Handle them with tongs until they are cool enough to handle.
- (e) Some of the solvents used, such as THF (tetrahydrofuran), are toxic and should only be handled in an appropriate fume hood and according to instructions given in the Material Safety Data Sheet (MSDS).

3.2. Equipment

- (a) Phase contrast microscope with 10x, 16x and 40x objectives, 10x wide-field eyepieces, G-22 Walton-Beckett graticule, Whipple disk, polarizer, analyzer and first order red or gypsum plate, 100 Watt illuminator, rotating position condenser with oversize phase rings, central stop dispersion objective, Kohler illumination and a rotating mechanical stage.
- (b) Stereo microscope with reflected light illumination, transmitted light illumination, polarizer, analyzer and first order red or gypsum plate, and rotating stage.
- (c) Negative pressure hood for the stereo microscope
- (d) Muffle furnace capable of 600 EC
- (e) Drying oven capable of 50-150 EC
- (f) Aluminum specimen pans
- (g) Tongs for handling samples in the furnace
- (h) High dispersion index of refraction oils (Special for dispersion staining.)

n = 1.550

n = 1.585

n = 1.590

n = 1.605

n = 1.620

n = 1.670

n = 1.680

n = 1.690

(i) A set of index of refraction oils from about n=1.350 to n=2.000 in n=0.005 increments. (Standard for Becke line analysis.)

(j) Glass slides with painted or frosted ends 1x3 inches 1mm thick, precleaned.

(k) Cover Slips 22x22 mm, ∇ 1 2

(l) Paper clips or dissection needles

(m) Hand grinder

(n) Scalpel with both ∇ 10 and ∇ 11 blades

(o) 0.1 molar HCl

(p) Decalcifying solution (Baxter Scientific Products) Ethylenediaminetetraacetic Acid,

Tetrasodium....0.7 g/l

Sodium Potassium Tartrate....8.0 mg/liter

Hydrochloric Acid99.2 g/liter

Sodium Tartrate0.14 g/liter

(q) Tetrahydrofuran (THF)

(r) Hotplate capable of 60 EC

(s) Balance

(t) Hacksaw blade

(u) Ruby mortar and pestle

3.3. Sample Pre-Preparation

Sample preparation begins with pre-preparation which may include chemical reduction of the matrix, heating the sample to dryness or heating in the muffle furnace. The end result is a sample which has been reduced to a powder that is sufficiently fine to fit under the cover slip. Analyze different phases of samples separately, e.g., tile and the tile mastic should be analyzed separately as the mastic may contain asbestos while the tile may not.

(a) Wet samples

Samples with a high water content will not give the proper dispersion colors and must be dried prior to sample mounting. Remove the lid of the scintillation vial, place the bottle in the drying oven and heat at 100 EC to dryness (usually about 2 h). Samples which are not submitted to the lab in glass must be removed and placed in glass vials or aluminum weighing pans before placing them in the drying oven.

(b) Samples With Organic Interference-Muffle Furnace

These may include samples with tar as a matrix, vinyl asbestos tile, or any other organic that can be reduced by heating. Remove the sample from the vial and weigh in a balance to determine the weight of the submitted portion. Place the sample in a muffle furnace at 500 EC for 1 to 2 h or until all obvious organic material has been removed. Retrieve, cool and weigh again to determine the weight loss on ignition. This is necessary to determine the asbestos content of the submitted sample, because the analyst will be looking at a reduced sample.

Note: Heating above 600 EC will cause the sample to undergo a structural change which, given sufficient time, will convert the chrysotile to forsterite. Heating even at lower temperatures for 1 to 2 h may have a measurable effect on the optical properties of the minerals. If the analyst is unsure of what to expect, a sample of standard asbestos should be heated to the same temperature for the same length of time so that it can be examined for the proper interpretation.

(c) Samples With Organic Interference-THF

Vinyl asbestos tile is the most common material treated with this solvent, although, substances containing tar will sometimes yield to this treatment. Select a portion of the material and then grind it up if possible. Weigh the sample and place it in a test tube. Add sufficient THF to dissolve the organic matrix. This is usually about 4 to 5 mL. Remember, THF is highly flammable. Filter the remaining material through a tared silver membrane, dry and weigh to determine how much is left after the solvent extraction. Further process the sample to remove carbonate or mount directly.

(d) Samples With Carbonate Interference

Carbonate material is often found on fibers and sometimes must be removed in order to perform

dispersion microscopy. Weigh out a portion of the material and place it in a test tube. Add a sufficient amount of 0.1 M HCl or decalcifying solution in the tube to react all the carbonate as evidenced by gas formation; i.e., when the gas bubbles stop, add a little more solution. If no more gas forms, the reaction is complete. Filter the material out through a tared silver membrane, dry and weigh to determine the weight lost.

3.4. Sample Preparation

Samples must be prepared so that accurate determination can be made of the asbestos type and amount present. The following s are carried out in the low-flow hood (a low-flow hood has less than 50 fpm flow):

(1) If the sample has large lumps, is hard, or cannot be made to lie under a cover slip, the grain size must be reduced. Place a small amount between two slides and grind the material between them or grind a small amount in a clean mortar and pestle. The choice of whether to use an alumina, ruby, or diamond mortar depends on the hardness of the material. Impact damage can alter the asbestos mineral if too much mechanical shock occurs. (Freezer mills can completely destroy the observable crystallinity of asbestos and should not be used). For some samples, a portion of material can be shaved off with a scalpel, ground off with a hand grinder or hack saw blade.

The preparation tools should either be disposable or cleaned thoroughly. Use vigorous scrubbing to loosen the fibers during the washing. Rinse the implements with copious amounts of water and air-dry in a dust-free environment.

(2) If the sample is powder or has been reduced as in (1) above, it is ready to mount. Place a glass slide on a piece of optical tissue and write the identification on the painted or frosted end. Place two drops of index of refraction medium $n=1.550$ on the slide. (The medium $n=1.550$ is chosen because it is the matching index for chrysotile. Dip the end of a clean paper-clip or dissecting needle into the droplet of refraction medium on the slide to moisten it. Then dip the probe into the powder sample. Transfer what sticks on the probe to the slide. The material on the end of the probe should have a diameter of about 3 mm for a good mount. If the material is very fine, less sample may be appropriate. For non-powder samples such as fiber mats, forceps should be used to transfer a small amount of material to the slide. Stir the material in the medium on the slide, spreading it out and making the preparation as uniform as possible. Place a cover-slip on the preparation by gently lowering onto the slide and allowing it to fall "trapdoor" fashion on the preparation to push out any bubbles. Press gently on the cover slip to even out the distribution of particulate on the slide. If there is insufficient mounting oil on the slide, one or two drops may be placed near the edge of the coverslip on the slide. Capillary action will draw the necessary amount of liquid into the preparation. Remove excess oil with the point of a laboratory wiper.

Treat at least two different areas of each phase in this fashion. Choose representative areas of the sample. It may be useful to select particular areas or fibers for analysis. This is useful to identify asbestos in severely inhomogeneous samples.

When it is determined that amphiboles may be present, repeat the above process using the appropriate high-dispersion oils until an identification is made or all six asbestos minerals have been ruled out. Note that percent determination must be done in the index medium 1.550 because amphiboles tend to disappear in their matching mediums.

3.5. Analytical Procedure

Note: This method presumes some knowledge of mineralogy and optical petrography.

The analysis consists of three parts: The determination of whether there is asbestos present, what type is present and the determination of how much is present. The general flow of the analysis is:

- (1) Gross examination.
- (2) Examination under polarized light on the stereo microscope.
- (3) Examination by phase-polar illumination on the compound phase microscope.
- (4) Determination of species by dispersion stain. Examination by Becke line analysis may also be used; however, this is usually more cumbersome for asbestos determination.
- (5) Difficult samples may need to be analyzed by SEM or TEM, or the results from those techniques combined with light microscopy for a definitive identification. Identification of a particle as asbestos requires that it be asbestiform. Description of particles should follow the suggestion of Campbell. (Figure 1)

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See Illustration

BILLING CODE 4510-26-C

For the purpose of regulation, the mineral must be one of the six minerals covered and must be in the asbestos growth habit. Large specimen samples of asbestos generally have the gross appearance of wood. Fibers are easily parted from it. Asbestos fibers are very long compared with their widths. The fibers have a very high tensile strength as demonstrated by bending without breaking. Asbestos fibers exist in bundles that are easily parted, show longitudinal fine structure and may be tufted at the ends showing "bundle of sticks" morphology. In the microscope some of these properties may not be observable. Amphiboles do not always show striations along their length even when they are asbestos. Neither will they always show tufting. They generally do not show a curved nature except for very long fibers. Asbestos and asbestiform minerals are usually characterized in groups by extremely high aspect ratios (greater than 100:1).

While aspect ratio analysis is useful for characterizing populations of fibers, it cannot be used to identify individual fibers of intermediate to short aspect ratio. Observation of many fibers is often necessary to determine whether a sample consists of "cleavage fragments" or of asbestos fibers.

Most cleavage fragments of the asbestos minerals are easily distinguishable from true asbestos fibers. This is because true cleavage fragments usually have larger diameters than 1 μm . Internal structure of particles larger than this usually shows them to have no internal fibrillar structure. In addition, cleavage fragments of the monoclinic amphiboles show inclined extinction under crossed polars with no compensator. Asbestos fibers usually show extinction at zero degrees or ambiguous extinction if any at all. Morphologically, the larger cleavage fragments are obvious by their blunt or ped ends showing prismatic habit. Also, they tend to be acicular rather than filiform.

Where the particles are less than 1 μm in diameter and have an aspect ratio greater than or equal to 3:1, it is recommended that the sample be analyzed by SEM or TEM if there is any question whether the fibers are cleavage fragments or asbestiform particles.

Care must be taken when analyzing by electron microscopy because the interferences are different from those in light microscopy and may structurally be very similar to asbestos. The classic interference is between anthophyllite and biopyribole or intermediate fiber. Use the same morphological clues for electron microscopy as are used for light microscopy, e.g. fibril splitting, internal longitudinal striation, fraying, curvature, etc.

(1) Gross examination:

Examine the sample, preferably in the glass vial. Determine the presence of any obvious fibrous component. Estimate a percentage based on previous experience and current observation. Determine whether any pre- preparation is necessary. Determine the number of phases present. This may be carried out or augmented by observation at 6 to 40x under a stereo microscope.

(2) After performing any necessary pre-preparation, prepare slides of each phase as described above. Two preparations of the same phase in the same index medium can be made side-by-side on the same glass for convenience. Examine with the polarizing stereo microscope. Estimate the percentage of asbestos based on the amount of birefringent fiber present.

(3) Examine the slides on the phase-polar microscopes at magnifications of 160 and 400x. Note the morphology of the fibers. Long, thin, very straight fibers with little curvature are indicative of fibers from the amphibole family. Curved, wavy fibers are usually indicative of chrysotile. Estimate the percentage of asbestos on the phase-polar microscope under conditions of crossed polars and a gypsum plate. Fibers smaller than 1.0 μm in thickness must be identified by inference to the presence of larger, identifiable fibers and morphology. If no larger fibers are visible, electron microscopy should be performed. At this point, only a tentative identification can be made. Full identification must be made with dispersion microscopy. Details of the tests

are included in the appendices.

(4) Once fibers have been determined to be present, they must be identified. Adjust the microscope for dispersion mode and observe the fibers. The microscope has a rotating stage, one polarizing element, and a system for generating dark-field dispersion microscopy (see Section 4.6. of this appendix). Align a fiber with its length parallel to the polarizer and note the color of the Becke lines. Rotate the stage to bring the fiber length perpendicular to the polarizer and note the color. Repeat this process for every fiber or fiber bundle examined. The colors must be consistent with the colors generated by standard asbestos reference materials for a positive identification. In $n=1.550$, amphiboles will generally show a yellow to straw-yellow color indicating that the fiber indices of refraction are higher than the liquid. If long, thin fibers are noted and the colors are yellow, prepare further slides as above in the suggested matching liquids listed below:

| Type of asbestos | Index of refraction |
|------------------|-------------------------|
| Chrysotile | $n=1.550$. |
| Amosite | $n=1.670$ r 1.680 . |
| Crocidolite | $n=1.690$. |
| Anthophyllite | $n=1.605$ nd 1.620 . |
| Tremolite | $n=1.605$ and 1.620 . |
| Actinolite | $n=1.620$. |

Where more than one liquid is suggested, the first is preferred; however, in some cases this liquid will not give good dispersion color. Take care to avoid interferences in the other liquid; e.g., wollastonite in $n=1.620$ will give the same colors as tremolite. In $n=1.605$ wollastonite will appear yellow in all directions. Wollastonite may be determined under crossed polars as it will change from blue to yellow as it is rotated along its fiber axis by tapping on the cover slip. Asbestos minerals will not change in this way.

Determination of the angle of extinction may, when present, aid in the determination of anthophyllite from tremolite. True asbestos fibers usually have 0E extinction or ambiguous extinction, while cleavage fragments have more definite extinction.

Continue analysis until both preparations have been examined and all present species of asbestos are identified. If there are no fibers present, or there is less than 0.1% present, end the analysis with the minimum number of slides (2).

(5) Some fibers have a coating on them which makes dispersion microscopy very difficult or impossible. Becke line analysis or electron microscopy may be performed in those cases. Determine the percentage by light microscopy. TEM analysis tends to overestimate the actual percentage present.

(6) Percentage determination is an estimate of occluded area, tempered by gross observation. Gross observation information is used to make sure that the high magnification microscopy does not greatly over- or under- estimate the amount of fiber present. This part of the analysis requires a great deal of experience. Satisfactory models for asbestos content analysis have not yet been developed, although some models based on metallurgical grain-size determination have found some utility. Estimation is more easily handled in situations where the grain sizes visible at about 160x are about the same and the sample is relatively homogeneous.

View all of the area under the cover slip to make the percentage determination. View the fields while moving the stage, paying attention to the clumps of material. These are not usually the best areas to perform dispersion microscopy because of the interference from other materials. But, they are the areas most likely to represent the accurate percentage in the sample. Small amounts of asbestos require slower scanning and more frequent analysis of individual fields.

Report the area occluded by asbestos as the concentration. This estimate does not generally take into consideration the difference in density of the different species present in the sample. For most samples this is adequate. Simulation studies with similar materials must be carried out to apply microvisual estimation for that purpose and is beyond the scope of this procedure.

(7) Where successive concentrations have been made by chemical or physical means, the amount reported is the percentage of the material in the "as submitted" or original state. The percentage determined by microscopy is multiplied by the fractions remaining after pre-preparations to give the percentage in the original sample. For example:

1. 60% remains after heating at 550 EC for 1 h. 2. 30% of the residue of 1 remains after dissolution of carbonate in 0.1 m HCl.

3. Microvisual estimation determines that 5% of the sample is chrysotile asbestos.

The reported result is:

$R = (\text{Microvisual result in percent}) \times (\text{Fraction remaining after 2}) \times (\text{Fraction remaining of original sample after 1})$

$$R = (5) \times (.30) \times (.60) = 0.9\%$$

(8) Report the percent and type of asbestos present. For samples where asbestos was identified, but is less than 1.0%, report "Asbestos present, less than 1.0%." There must have been at least two observed fibers or fiber bundles in the two preparations to be reported as present. For samples where asbestos was not seen, report as "None Detected."

4. Auxiliary Information

Because of the subjective nature of asbestos analysis, certain concepts and procedures need to be discussed in more depth. This information will help the analyst understand why some of the procedures are carried out the way they are.

4.1. Light

Light is electromagnetic energy. It travels from its source in packets called quanta. It is instructive to consider light as a plane wave. The light has a direction of travel. Perpendicular to this and mutually perpendicular to each other, are two vector components. One is the magnetic vector and the other is the electric vector. We shall only be concerned with the electric vector. In this description, the interaction of the vector and the mineral will describe all the observable phenomena. From a light source such a microscope illuminator, light travels in all different direction from the filament.

In any given direction away from the filament, the electric vector is perpendicular to the direction of travel of a light ray. While perpendicular, its orientation is random about the travel axis. If the electric vectors from all the light rays were lined up by passing the light through a filter that would only let light rays with electric vectors oriented in one direction pass, the light would then be POLARIZED.

Polarized light interacts with matter in the direction of the electric vector. This is the polarization direction. Using this property it is possible to use polarized light to probe different materials and identify them by how they interact with light.

The speed of light in a vacuum is a constant at about 2.99×10^8 m/s. When light travels in different materials such as air, water, minerals or oil, it does not travel at this speed. It travels slower. This slowing is a function of both the material through which the light is traveling and the wavelength or frequency of the light. In general, the more dense the material, the slower the light travels. Also, generally, the higher the frequency, the slower the light will travel. The ratio of the speed of light in a vacuum to that in a material is called the index of refraction (n). It is usually measured at 589 nm (the sodium D line). If white light (light containing all the visible wavelengths) travels through a material, rays of longer wavelengths will travel faster than those of shorter wavelengths, this separation is called dispersion. Dispersion is used as an identifier of materials as described in Section 4.6.

4.2. Material Properties

Materials are either amorphous or crystalline. The difference between these two descriptions depends on the positions of the atoms in them. The atoms in amorphous materials are randomly arranged with no long range order. An example of an amorphous material is glass. The atoms in crystalline materials, on the other hand, are in regular arrays and have long range order. Most of the atoms can be found in highly predictable locations. Examples of crystalline material are salt, gold, and the asbestos minerals.

It is beyond the scope of this method to describe the different types of crystalline materials that can be found, or the full description of the classes into which they can fall. However, some general crystallography is provided below to give a foundation to the procedures described.

With the exception of anthophyllite, all the asbestos minerals belong to the monoclinic crystal type. The unit cell is the basic repeating unit of the crystal and for monoclinic crystals can be described as having three unequal sides, two 90° angles and one angle not equal to 90°. The orthorhombic group, of which anthophyllite is a member has three unequal sides and three 90° angles. The unequal sides are a consequence of the complexity of fitting the different atoms into the unit cell. Although the atoms are in a regular array, that array is not symmetrical in all directions. There is long range order in the three major directions of the crystal. However, the order is different in each of the three directions. This has the effect that the index of refraction is different in each of the three directions. Using polarized light, we can investigate the index of refraction in each of the directions and identify the mineral or material under investigation. The indices α , β , and γ are used to identify the lowest, middle, and highest index of refraction respectively. The x direction, associated with α is called the fast axis. Conversely, the z direction is associated with γ and is the slow direction. Crocidolite has α along the fiber length making it "length-fast". The remainder of the asbestos minerals have the γ axis along the fiber length. They are called "length-slow". This orientation to fiber length is used to aid in the identification of asbestos.

4.3. Polarized Light Technique

Polarized light microscopy as described in this section uses the phase-polar microscope described in Section 3.2. A phase contrast microscope is fitted with two polarizing elements, one below and one above the sample. The polarizers have their polarization directions at right angles to each other. Depending on the tests performed, there may be a compensator between these two polarizing elements. Light emerging from a polarizing element has its electric vector pointing in the polarization direction of the element. The light will not be subsequently transmitted through a second element set at a right angle to the first element. Unless the light is altered as it passes from one element to the other, there is no transmission of light.

4.4. Angle of Extinction

Crystals which have different crystal regularity in two or three main directions are said to be anisotropic. They have a different index of refraction in each of the main directions. When such a crystal is inserted between the crossed polars, the field of view is no longer dark but shows the crystal in color. The color depends on the properties of the crystal. The light acts as if it travels through the crystal along the optical axes. If a crystal optical axis were lined up along one of the polarizing directions (either the polarizer or the analyzer) the light would appear to travel only in that direction, and it would blink out or go dark. The difference in degrees between the fiber direction and the angle at which it blinks out is called the angle of extinction. When this angle

can be measured, it is useful in identifying the mineral. The procedure for measuring the angle of extinction is to first identify the polarization direction in the microscope. A commercial alignment slide can be used to establish the polarization directions or use anthophyllite or another suitable mineral. This mineral has a zero degree angle of extinction and will go dark to extinction as it aligns with the polarization directions. When a fiber of anthophyllite has gone to extinction, align the eyepiece reticle or graticule with the fiber so that there is a visual cue as to the direction of polarization in the field of view. Tape or otherwise secure the eyepiece in this position so it will not shift.

After the polarization direction has been identified in the field of view, move the particle of interest to the center of the field of view and align it with the polarization direction. For fibers, align the fiber along this direction. Note the angular reading of the rotating stage. Looking at the particle, rotate the stage until the fiber goes dark or "blinks out". Again note the reading of the stage. The difference in the first reading and the second is an angle of extinction.

The angle measured may vary as the orientation of the fiber changes about its long axis. Tables of mineralogical data usually report the maximum angle of extinction. Asbestos forming minerals, when they exhibit an angle of extinction, usually do show an angle of extinction close to the reported maximum, or as appropriate depending on the substitution chemistry.

4.5. Crossed Polars with Compensator

When the optical axes of a crystal are not lined up along one of the polarizing directions (either the polarizer or the analyzer) part of the light travels along one axis and part travels along the other visible axis. This is characteristic of birefringent materials.

The color depends on the difference of the two visible indices of refraction and the thickness of the crystal. The maximum difference available is the difference between n_α and the n_γ axes. This maximum difference is usually tabulated as the birefringence of the crystal.

For this test, align the fiber at 45E to the polarization directions in order to maximize the contribution to each of the optical axes. The colors seen are called retardation colors. They arise from the recombination of light which has traveled through the two separate directions of the crystal. One of the rays is retarded behind the other since the light in that direction travels slower. On recombination, some of the colors which make up white light are enhanced by constructive interference and some are suppressed by destructive interference. The result is a color dependent on the difference between the indices and the thickness of the crystal. The proper colors, thicknesses, and retardations are shown on a Michel-Levy chart. The three items, retardation, thickness and birefringence are related by the following relationship:

$$R = t(n_\gamma - n_\alpha)$$

R=retardation, t=crystal thickness in μm , and

n_{α} , n_{γ} =indices of refraction.

Examination of the equation for asbestos minerals reveals that the visible colors for almost all common asbestos minerals and fiber sizes are shades of gray and black. The eye is relatively poor at discriminating different shades of gray. It is very good at discriminating different colors. In order to compensate for the low retardation, a compensator is added to the light train between the polarization elements. The compensator used for this test is a gypsum plate of known thickness and birefringence. Such a compensator when oriented at 45° to the polarizer direction, provides a retardation of 530 nm of the 530 nm wavelength color. This enhances the red color and gives the background a characteristic red to red-magenta color. If this "full-wave" compensator is in place when the asbestos preparation is inserted into the light train, the colors seen on the fibers are quite different. Gypsum, like asbestos has a fast axis and a slow axis. When a fiber is aligned with its fast axis in the same direction as the fast axis of the gypsum plate, the ray vibrating in the slow direction is retarded by both the asbestos and the gypsum. This results in a higher retardation than would be present for either of the two minerals. The color seen is a second order blue. When the fiber is rotated 90° using the rotating stage, the slow direction of the fiber is now aligned with the fast direction of the gypsum and the fast direction of the fiber is aligned with the slow direction of the gypsum. Thus, one ray vibrates faster in the fast direction of the gypsum, and slower in the slow direction of the fiber; the other ray will vibrate slower in the slow direction of the gypsum and faster in the fast direction of the fiber. In this case, the effect is subtractive and the color seen is a first order yellow. As long as the fiber thickness does not add appreciably to the color, the same basic colors will be seen for all asbestos types except crocidolite. In crocidolite the colors will be weaker, may be in the opposite directions, and will be altered by the blue absorption color natural to crocidolite. Hundreds of other materials will give the same colors as asbestos, and therefore, this test is not definitive for asbestos. The test is useful in discriminating against fiberglass or other amorphous fibers such as some synthetic fibers. Certain synthetic fibers will show retardation colors different than asbestos; however, there are some forms of polyethylene and aramid which will show morphology and retardation colors similar to asbestos minerals. This test must be supplemented with a positive identification test when birefringent fibers are present which can not be excluded by morphology. This test is relatively ineffective for use on fibers less than 1 μm in diameter. For positive confirmation TEM or SEM should be used if no larger bundles or fibers are visible.

4.6. Dispersion Staining

Dispersion microscopy or dispersion staining is the method of choice for the identification of asbestos in bulk materials. Becke line analysis is used by some laboratories and yields the same results as does dispersion staining for asbestos and can be used in lieu of dispersion staining. Dispersion staining is performed on the same platform as the phase-polar analysis with the analyzer and compensator removed. One polarizing element remains to define the direction of the light so that the different indices of refraction of the fibers may be separately determined. Dispersion microscopy is a dark-field technique when used for asbestos. Particles are imaged

with scattered light. Light which is unscattered is blocked from reaching the eye either by the back field image mask in a McCrone objective or a back field image mask in the phase condenser. The most convenient method is to use the rotating phase condenser to move an oversized phase ring into place. The ideal size for this ring is for the central disk to be just larger than the objective entry aperture as viewed in the back focal plane. The larger the disk, the less scattered light reaches the eye. This will have the effect of diminishing the intensity of dispersion color and will shift the actual color seen. The colors seen vary even on microscopes from the same manufacturer. This is due to the different bands of wavelength exclusion by different mask sizes. The mask may either reside in the condenser or in the objective back focal plane. It is imperative that the analyst determine by experimentation with asbestos standards what the appropriate colors should be for each asbestos type. The colors depend also on the temperature of the preparation and the exact chemistry of the asbestos. Therefore, some slight differences from the standards should be allowed. This is not a serious problem for commercial asbestos uses. This technique is used for identification of the indices of refraction for fibers by recognition of color. There is no direct numerical readout of the index of refraction. Correlation of color to actual index of refraction is possible by referral to published conversion tables. This is not necessary for the analysis of asbestos. Recognition of appropriate colors along with the proper morphology are deemed sufficient to identify the commercial asbestos minerals. Other techniques including SEM, TEM, and XRD may be required to provide additional information in order to identify other types of asbestos.

Make a preparation in the suspected matching high dispersion oil, e.g., $n=1.550$ for chrysotile. Perform the preliminary tests to determine whether the fibers are birefringent or not. Take note of the morphological character. Wavy fibers are indicative of chrysotile while long, straight, thin, frayed fibers are indicative of amphibole asbestos. This can aid in the selection of the appropriate matching oil. The microscope is set up and the polarization direction is noted as in Section 4.4. Align a fiber with the polarization direction. Note the color. This is the color parallel to the polarizer. Then rotate the fiber rotating the stage 90° so that the polarization direction is across the fiber. This is the perpendicular position. Again note the color. Both colors must be consistent with standard asbestos minerals in the correct direction for a positive identification of asbestos. If only one of the colors is correct while the other is not, the identification is not positive. If the colors in both directions are bluish-white, the analyst has chosen a matching index oil which is higher than the correct matching oil, e.g. the analyst has used $n=1.620$ where chrysotile is present. The next lower oil (Section 3.5.) should be used to prepare another specimen. If the color in both directions is yellow-white to straw-yellow-white, this indicates that the index of the oil is lower than the index of the fiber, e.g. the preparation is in $n=1.550$ while anthophyllite is present. Select the next higher oil (Section 3.5.) and prepare another slide. Continue in this fashion until a positive identification of all asbestos species present has been made or all possible asbestos species have been ruled out by negative results in this test. Certain plant fibers can have similar dispersion colors as asbestos. Take care to note and evaluate the morphology of the fibers or remove the plant fibers in pre- preparation. Coating material on the fibers such as carbonate or vinyl may destroy the dispersion color. Usually, there will be some outcropping of fiber which will show the colors sufficient for identification. When this is not the case, treat the sample as described in Section 3.3. and then perform dispersion staining. Some samples will yield to Becke

line analysis if they are coated or electron microscopy can be used for identification.

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Shipyards

[51 FR 22733, June 20, 1986, as amended at 51 FR 37004, Oct. 17, 1986; 52 FR 17754, 17755, May 12, 1987; 53 FR 35625, September 14, 1988; 54 FR 24334, June 7, 1989; 54 FR 30704, July 21, 1989; 54 FR 52027, Dec. 20, 1989; 55 FR 3731, Feb. 5, 1990; 57 FR 24310, June 8, 1992; as amended at 59 fr 40964, August 10, 1994; 60 FR 9624, February 21, 1995; 60 FR 33343, June 28, 1995]

1910.1002 Coal tar pitch volatiles; interpretation of term.

As used in 1910.1000 (Table Z-1), coal tar pitch volatiles include the fused polycyclic hydrocarbons which volatilize from the distillation residues of coal, petroleum (excluding asphalt), wood, and other organic matter. Asphalt (CAS 8052-42-4, and CAS 64742-93-4) is not covered under the "coal tar pitch volatiles" standard.

[48 FR 2768, Jan. 21, 1983]

1910.1003 13 Carcinogens (4-nitrobiphenyl, etc.).

(a) Scope and application.

(1) This section applies to any area in which the 13 carcinogens addressed by this section are manufactured, processed, repackaged, released, handled, or stored, but shall not apply to trans-shipment in sealed containers, except for the labeling requirements under paragraphs (e) (2), (3), and (4) of this section. The 13 carcinogens are the following:

4-Nitrobiphenyl, Chemical Abstracts Service Register Number (CAS No.) 92933;
alpha-Naphthylamine, CAS No. 134327;
methyl chloromethylether, AS No. 107302;
3,3'-Dichlorobenzidine (and its salts) CAS No. 91941;
bis-Chloromethyl ether, CAS No. 542881;
beta-Naphthylamine, CAS No. 91598;
Benzidine, CAS No. 92875;
4-Aminodiphenyl, CAS No. 92671;
Ethyleneimine, CAS No. 151564;
beta-Propiolactone, CAS No. 57578;
2-Acetylaminofluorene, CAS No. 53963;
4-Dimethylaminoazo-benezene, CAS No. 60117; and
N-Nitrosodimethylamine, CAS No. 62759.

(2) This section shall not apply to the following:

(i) Solid or liquid mixtures containing less than 0.1 percent by weight or volume of 4-Nitrobiphenyl; methyl chloromethyl ether; bis-chloromethyl ether; beta-Naphthylamine; benzidine or 4-Aminodiphenyl; and

(ii) Solid or liquid mixtures containing less than 1.0 percent by weight or volume of alpha-Naphthylamine; 3,3'-Dichlorobenzidine (and its salts); Ethyleneimine; beta-Propiolactone; 2-Acetylaminofluorene; 4-Dimethylaminoazobenzene, or N-Nitrosodimethylamine.

(b) Definitions. For the purposes of this section:

(1) "Absolute filter" is one capable of retaining 99.97 percent of a mono disperse aerosol of 0.3 um particles.

(2) "Authorized employee" means an employee whose duties require him to be in the regulated area and who has been specifically assigned by the employer.

(3) "Clean change room" means a room where employees put on clean clothing and/or protective equipment in an environment free of the 13 carcinogens addressed by this section. The clean change room shall be contiguous to and have an entry from a shower room, when the shower room facilities are otherwise required in this section.

(4) "Closed system" means an operation involving a carcinogen addressed by this section where containment prevents the release of the material into regulated areas, non-regulated areas, or the external environment.

(5) "Decontamination" means the inactivation of a carcinogen addressed by this section or its safe disposal.

(6) "Director" means the Director, National Institute for Occupational Safety and Health, or any person directed by him or the Secretary of Health and Human Services to act for the Director.

(7) "Disposal" means the safe removal of the carcinogens addressed by this section from the work environment.

(8) "Emergency" means an unforeseen circumstance or set of circumstances resulting in the release of a carcinogen addressed by this section that may result in exposure to or contact with the material.

(9) "External environment" means any environment external to regulated and nonregulated areas.

(10) "Isolated system" means a fully enclosed structure other than the vessel of containment of a carcinogen addressed by this section that is impervious to the passage of the material and would prevent the entry of the carcinogen addressed by this section into regulated areas, nonregulated areas, or the external environment, should leakage or spillage from the vessel of containment occur.

(11) "Laboratory type hood" is a device enclosed on three sides and the top and bottom, designed and maintained so as to draw air inward at an average linear face velocity of 150 feet per minute with a minimum of 125 feet per minute; designed, constructed, and maintained in such a way that an operation involving a carcinogen addressed by this section within the hood does not require the insertion of any portion of any employee's body other than his hands and arms.

(12) "Nonregulated area" means any area under the control of the employer where entry and exit is neither restricted nor controlled.

(13) "Open-vessel system" means an operation involving a carcinogen addressed in this section in an open vessel, which is not in an isolated system, a laboratory type hood, nor in any other

system affording equivalent protection against the entry of the material into regulated areas, non-regulated areas, or the external environment.

(14) "Protective clothing" means clothing designed to protect an employee against contact with or exposure to a carcinogen addressed by this section.

(15) "Regulated area" means an area where entry and exit is restricted and controlled.

(c) "Requirements for areas containing a carcinogen addressed by this section." A regulated area shall be established by an employer where a carcinogen addressed by this section is manufactured, processed, used, repackaged, released, handled or stored. All such areas shall be controlled in accordance with the requirements for the following category or categories describing the operation involved:

(1) Isolated systems. Employees working with a carcinogen addressed by this section within an isolated system such as a "glove box" shall wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.

(2) Closed system operation.

(i) Within regulated areas where the carcinogens addressed by this section are stored in sealed containers, or contained in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens addressed by this section are contained within, access shall be restricted to authorized employees only.

(ii) Employees exposed to 4-Nitrobiphenyl; alpha-Naphthylamine; 3,3'-Dichlorobenzidine (and its salts); beta-Naphthylamine; benzidine; 4-Aminodiphenyl; 2-Acetylaminofluorene; 4-Dimethylaminoazo-benzene; and N-Nitrosodimethylamine shall be required to wash hands, forearms, face and neck upon each exit from the regulated areas, close to the point of exit and before engaging in other activities.

(3) Open vessel system operations. Open vessel system operations as defined in paragraph (b)(13) of this section are prohibited.

(4) Transfer from a closed system, charging or discharging point operations, or otherwise opening a closed system. In operations involving "laboratory type hoods," or in locations where the carcinogens addressed by this section are contained in an otherwise "closed system," but is transferred, charged, or discharged into other normally closed containers, the provisions of this paragraph shall apply.

(i) Access shall be restricted to authorized employees only;

(ii) Each operation shall be provided with continuous local exhaust ventilation so that air

movement is always from ordinary work areas to the operation. Exhaust air shall not be discharged to regulated areas, nonregulated areas or the external environment unless decontaminated. Clean makeup air shall be introduced in sufficient volume to maintain the correct operation of the local exhaust system.

(iii) Employees shall be provided with, and required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area.

(iv) Employers must provide each employee engaged in handling operations involving the carcinogens 4-Nitrobiphenyl, alpha-Naphthylamine, 3,3'-Dichlorobenzidine (and its salts), beta-Naphthylamine, Benzidine, 4-Aminodiphenyl, 2-Acetylaminofluorene, 4-Dimethylaminoazobenzene, and N-Nitrosodimethylamine, addressed by this section, with, and ensure that each of these employees wears and uses, a NIOSH-certified air-purifying, half-mask respirator with particulate filters. Employers also must provide each employee engaged in handling operations involving the carcinogens methyl chloromethyl ether, bis-Chloromethyl ether, Ethyleneimine, and beta-Propiolactone, addressed by this section, with, and ensure that each of these employees wears and uses any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode, or any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained positive-pressure breathing apparatus. Employers may substitute a respirator affording employees higher levels of protection than these respirators.

(v) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified, as required under paragraphs (e) (2), (3), and (4) of this section.

(vi) Drinking fountains are prohibited in the regulated area.

(vii) Employees shall be required to wash hands, forearms, face and neck on each exit from the regulated area, close to the point of exit, and before engaging in other activities and employees exposed to 4-Nitrobiphenyl; alpha-Naphthylamine; 3,3'-Dichlorobenzidine (and its salts); beta-Naphthylamine; Benzidine; 4-Aminodiphenyl; 2-Acetylaminofluorene; 4-Dimethylaminoazobenzene; and N-Nitrosodimethylamine shall be required to shower after the last exit of the day.

(5) Maintenance and decontamination activities. In cleanup of leaks or spills, maintenance or repair operations on contaminated systems or equipment, or any operations involving work in an area where direct contact with a carcinogen addressed by this section could result, each authorized employee entering that area shall:

(i) Be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood in accordance with 1910.134.

(ii) Be decontaminated before removing the protective garments and hood;

(iii) Be required to shower upon removing the protective garments and hood.

(d) General regulated area requirements.

(1) Respirator program. The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b), (c), (d) (except (d)(1)(iii) and (iv), and (d)(3)), and (e) through (m), which covers each employee required by this section to use a respirator.

(2) Emergencies. In an emergency, immediate measures including, but not limited to, the requirements of paragraphs (d)(2) (i) through (v) of this section shall be implemented.

(i) The potentially affected area shall be evacuated as soon as the emergency has been determined.

(ii) Hazardous conditions created by the emergency shall be eliminated and the potentially affected area shall be decontaminated prior to the resumption of normal operations.

(iii) Special medical surveillance by a physician shall be instituted within 24 hours for employees present in the potentially affected area at the time of the emergency. A report of the medical surveillance and any treatment shall be included in the incident report, in accordance with paragraph (f)(2) of this section.

(iv) Where an employee has a known contact with a carcinogen addressed by this section, such employee shall be required to shower as soon as possible, unless contraindicated by physical injuries.

(v) An incident report on the emergency shall be reported as provided in paragraph (f)(2) of this section.

(vi) Emergency deluge showers and eyewash fountains supplied with running potable water shall be located near, within sight of, and on the same level with locations where a direct exposure to Ethyleneimine or beta-Propiolactone only would be most likely as a result of equipment failure or improper work practice.

(3) Hygiene facilities and practices.

(i) Storage or consumption of food, storage or use of containers of beverages, storage or application of cosmetics, smoking, storage of smoking materials, tobacco products or other

products for chewing, or the chewing of such products, are prohibited in regulated areas.

(ii) Where employees are required by this section to wash, washing facilities shall be provided in accordance with 1910.141(d) (1) and (2) (ii) through (vii).

(iii) Where employees are required by this section to shower, shower facilities shall be provided in accordance with 1910.141(d)(3).

(iv) Where employees wear protective clothing and equipment, clean change rooms shall be provided for the number of such employees required to change clothes, in accordance with 1910.14 (e).

(v) Where toilets are in regulated areas, such toilets shall be in a separate room.

(4) Contamination control.

(i) Except for outdoor systems, regulated areas shall be maintained under pressure negative with respect to nonregulated areas. Local exhaust ventilation may be used to satisfy this requirement. Clean makeup air in equal volume shall replace air removed.

(ii) Any equipment, material, or other item taken into or removed from a regulated area shall be done so in a manner that does not cause contamination in nonregulated areas or the external environment.

(iii) Decontamination procedures shall be established and implemented to remove carcinogens addressed by this section from the surfaces of materials, equipment and the decontamination facility.

(iv) Dry sweeping and dry mopping are prohibited for 4-Nitrobiphenyl; alpha-Naphthylamine; 3,3'-Dichlorobenzidine (and its salts); beta-Naphthylamine; Benzidine; 4-Aminodiphenyl; 2-Acetylaminofluorene; 4-Dimethylaminoazo-benzene and N-Nitrosodimethylamine.

(e) Communication of hazards

(1) Hazard communication

(i) Chemical manufacturers, importers distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for each carcinogen listed in paragraph (e)(1)(iv) of this section.

(ii) In classifying the hazards of carcinogens listed in paragraph (e)(1)(iv) of this section, at least the hazards listed in paragraph (e)(1)(iv) are to be addressed.

(iii) Employers shall include the carcinogens listed in paragraph (e)(1)(iv) of this section in the hazard communication program established to comply with HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of carcinogens listed in paragraph (e)(4) of this section.

(iv) List of Carcinogens:

(A) 4-Nitrobiphenyl: Cancer

(B) alpha-Naphthylamine: Cancer; skin irritation; and acute toxicity effects.

(C) methyl chloromethyl ether: Cancer; skin, eye, and respiratory effects; acute toxicity effects; and flammability.

(D) 3,3'-Dichlorobenzidine (and its salts): Cancer and skin sensitization.

(E) bis-Chloromethyl ether: Cancer; skin, eye, and respiratory tract effects; acute toxicity effects; and flammability.

(F) beta-Naphthylamine: Cancer and acute toxicity effects.

(G) Benzidines: Cancer and acute toxicity effects.

(H) 4-Aminodiphenyl: Cancer.

(I) Ethyleneimine: Cancer; mutagenicity; skin and eye effects; liver effects; kidney effects; acute toxicity effects; flammability.

(J) beta-Propiolactone: Cancer; skin irritation; eye effects; and acute toxicity effects.

(K) 2-Acetylaminofluorene: Cancer.

(L) 4-Dimethylaminoazo-benzene: Cancer; skin effects; and respiratory tract irritation.

(M) N-Nitrosodimethylamine: Cancer; liver effects; and acute toxicity effects.

(e)(2) Signs, information and training

(1) Signs:

(i) The employer shall post signs at Entrances to regulated areas shall be posted with signs bearing the legend:

DANGER

(CHEMICAL IDENTIFICATION)

MAY CAUSE CANCER

~~CANCER-SUSPECT AGENT~~

AUTHORIZED PERSONNEL ONLY

(ii) ~~The employer shall post signs at Entrances to regulated areas containing operations covered in paragraph (c)(5) of this section, shall be posted with~~ The signs shall bearing the legend:

DANGER

(CHEMICAL IDENTIFICATION)

MAY CAUSE CANCER

WEAR AIR-SUPPLIED HOODS,

IMPERVIOUS SUITS, AND PROTECTIVE
EQUIPMENT IN THIS AREA

~~CANCER-SUSPECT AGENT EXPOSED IN THIS AREA~~

~~IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD-
REQUIRED AT ALL TIMES~~

AUTHORIZED PERSONNEL ONLY

(iii) ~~Appropriate signs and instructions shall be posted at the entrance to, and exit from, regulated areas, informing employees of the procedures that must be followed in entering and leaving a regulated area. Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(2)(ii) of this section:~~

CANCER-SUSPECT AGENT EXPOSED IN THIS AREA

AUTHORIZED PERSONNEL ONLY

(iv) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(2)(ii) of this section:

CANCER- SUSPECT AGENT EXPOSED IN THIS AREA

IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD
REQUIRED AT ALL TIMES

AUTHORIZED PERSONNEL ONLY

(v) Appropriate signs and instructions shall be posted at the entrance to, and exit from, regulated areas, informing employees of the procedures that must be followed in entering and leaving a regulated area.

(2) Container contents identification.

(i) Containers of 4-Nitrobiphenyl and containers required under paragraphs (c)(4)(v) and (c)(6)(vii)(b), and (c)(6)(viii)(b) of this section which are accessible only to, and handled only by, authorized employees, or by other employees trained in accordance with paragraph (e)(5) of this section, may have contents identification limited to a generic or proprietary name, or other proprietary identification, of the carcinogen and percent.

(ii) Containers of a carcinogen addressed by this section and containers required under paragraphs (c)(4)(v), (c)(6)(vii)(b) and (viii)(b) of this section which are accessible to, or handled by employees other than authorized employees or employees trained in accordance with paragraph (e)(5) of this section shall have contents identification which includes the full chemical name and Chemical Abstracts Service Registry number as listed in paragraph (a)(1) of this section.

(iii) Containers shall have the warning words "CANCER-SUSPECT AGENT" displayed immediately under or adjacent to the contents identification.

(iv) Containers whose contents are carcinogens addressed by this section with corrosive or irritating properties shall have label statements warning of such hazards, noting, if appropriate, particularly sensitive or affected portions of the body.

(3) Lettering. Lettering on signs and instructions required by paragraph (e)(1) shall be a minimum letter height of 2 inches. Labels on containers required under this section shall not be less than 1/2 the size of the largest lettering on the package, and not less than 8 point type in any instance. Provided, That no such required lettering need be more than 1 inch in height.

(4) Prohibited statements. No statement shall appear on or near any required sign, label, or instruction which contradicts or detracts from the effect of any required warning, information or instruction.

(5) Training and indoctrination.

(i) Each employee prior to being authorized to enter a regulated area, shall receive a training

and indoctrination program including, but not necessarily limited to:

- (a) The nature of the carcinogenic hazards of a carcinogen addressed by this section, including local and systemic toxicity;
- (b) The specific nature of the operation involving a carcinogen addressed by this section that could result in exposure;
- (c) The purpose for and application of the medical surveillance program, including, as appropriate, methods of self-examination;
- (d) The purpose for and application of decontamination practices and purposes;
- (e) The purpose for and significance of emergency practices and procedures;
- (f) The employee's specific role in emergency procedures;
- (g) Specific information to aid the employee in recognition and evaluation of conditions and situations which may result in the release of a carcinogen addressed by this section;
- (h) The purpose for and application of specific first aid procedures and practices;
- (i) A review of this section at the employee's first training and indoctrination program and annually thereafter.
- (ii) Specific emergency procedures shall be prescribed, and posted, and employees shall be familiarized with their terms, and rehearsed in their application.
- (iii) All materials relating to the program shall be provided upon request to authorized representatives of the Assistant Secretary and the Director.
- (f) [Reserved]
- (g) Medical surveillance. At no cost to the employee, a program of medical surveillance shall be established and implemented for employees considered for assignment to enter regulated areas, and for authorized employees.
- (1) Examinations.
 - (i) Before an employee is assigned to enter a regulated area, a preassignment physical examination by a physician shall be provided. The examination shall include the personal history of the employee, family and occupational background, including genetic and environmental factors.
 - (ii) Authorized employees shall be provided periodic physical examinations, not less often

than annually, following the preassignment examination.

(iii) In all physical examinations, the examining physician shall consider whether there exist conditions of increased risk, including reduced immunological competence, those undergoing treatment with steroids or cytotoxic agents, pregnancy and cigarette smoking.

(2) Records.

(i) Employers of employees examined pursuant to this paragraph shall cause to be maintained complete and accurate records of all such medical examinations. Records shall be maintained for the duration of the employee's employment.

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a)-(e) and (g)-(i). These records shall also be provided upon request to the Director.

(iii) Any physician who conducts a medical examination required by this paragraph shall furnish to the employer a statement of the employee's suitability for employment in the specific exposure.

[39 FR 23502, June 27, 1974. Redesignated at 40 FR 23072, May 28, 1975, and amended at 41 FR 35184, Aug. 20, 1976; 43 FR 49751, Oct. 24, 1978; 45 FR 35281, May 23, 1980; 49 FR 18295, Apr. 30, 1984; 58 FR 35310, June 30, 1993; 61 FR 5507, Feb. 13, 1996; 61 FR 9227, March 7, 1996; 61 FR 31427, June 20, 1996]

1910.1004 See 1910.1003, 13 carcinogens.

1910.1005 [Reserved]

1910.1006 See 1910.1003, 13 carcinogens.

1910.1007 See 1910.1003, 13 carcinogens.

1910.1008 See 1910.1003, 13 carcinogens.

1910.1009 See 1910.1003, 13 carcinogens.

1910.1010 See 1910.1003, 13 carcinogens.

1910.1011 See 1910.1003, 13 carcinogens.

1910.1012 See 1910.1003, 13 carcinogens.

1910.1013 See 1910.1003, 13 carcinogens.

1910.1014 See 1910.1003, 13 carcinogens.

1910.1015 See 1910.1003, 13 carcinogens.

1910.1016 See 1910.1003, 13 carcinogens.

1910.1017 Vinyl chloride.

(a) Scope and application.

(1) This section includes requirements for the control of employee exposure to vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75014.

(2) This section applies to the manufacture, reaction, packaging, repackaging, storage, handling or use of vinyl chloride or polyvinyl chloride, but does not apply to the handling or use of fabricated products made of polyvinyl chloride.

(3) This section applies to the transportation of vinyl chloride or polyvinyl chloride except to the extent that the Department of Transportation may regulate the hazards covered by this section.

(b) Definitions.

(1) "Action level" means a concentration of vinyl chloride of 0.5 ppm averaged over an 8-hour work day.

(2) "Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or his designee.

(3) "Authorized person" means any person specifically authorized by the employer whose duties require him to enter a regulated area or any person entering such an area as a designated representative of employees for the purpose of exercising an opportunity to observe monitoring and measuring procedures.

(4) "Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or his designee.

(5) "Emergency" means any occurrence such as, but not limited to, equipment failure, or operation of a relief device which is likely to, or does, result in massive release of vinyl chloride.

(6) "Fabricated product" means a product made wholly or partly from polyvinyl chloride, and which does not require further processing at temperatures, and for times, sufficient to cause mass

melting of the polyvinyl chloride resulting in the release of vinyl chloride.

(7) "Hazardous operation" means any operation, procedure, or activity where a release of either vinyl chloride liquid or gas might be expected as a consequence of the operation or because of an accident in the operation, which would result in an employee exposure in excess of the permissible exposure limit.

(8) "OSHA Area Director" means the Director for the Occupational Safety and Health Administration Area Office having jurisdiction over the geographic area in which the employer's establishment is located.

(9) "Polyvinyl chloride" means polyvinyl chloride homopolymer or copolymer before such is converted to a fabricated product.

(10) "Vinyl chloride" means vinyl chloride monomer.

(c) Permissible exposure limit.

(1) No employee may be exposed to vinyl chloride at concentrations greater than 1 ppm averaged over any 8-hour period, and

(2) No employee may be exposed to vinyl chloride at concentrations greater than 5 ppm averaged over any period not exceeding 15 minutes.

(3) No employee may be exposed to vinyl chloride by direct contact with liquid vinyl chloride.

(d) Monitoring.

(1) A program of initial monitoring and measurement shall be undertaken in each establishment to determine if there is any employee exposed, without regard to the use of respirators, in excess of the action level.

(2) Where a determination conducted under paragraph (d)(1) of this section shows any employee exposures, without regard to the use of respirators, in excess of the action level, a program for determining exposures for each such employee shall be established. Such a program:

(i) Must be repeated at least quarterly for any employee exposed, without regard to the use of respirators, in excess of the permissible exposure limit.

(ii) Must be repeated not less than every 6 months for any employee exposed without regard to the use of respirators, at or above the action level.

(iii) May be discontinued for any employee only when at least two consecutive monitoring

determinations, made not less than 5 working days apart, show exposures for that employee at or below the action level.

(3) Whenever there has been a production, process or control change which may result in an increase in the release of vinyl chloride, or the employer has any other reason to suspect that any employee may be exposed in excess of the action level, a determination of employee exposure under paragraph (d)(1) of this section shall be performed.

(4) The method of monitoring and measurement shall have an accuracy (with a confidence level of 95 percent) of not less than plus or minus 50 percent from 0.25 through 0.5 ppm, plus or minus 35 percent from over 0.5 ppm through 1.0 ppm, and plus or minus 25 percent over 1.0 ppm. (Methods meeting these accuracy requirements are available in the "NIOSH Manual of Analytical Methods").

(5) Employees or their designated representatives shall be afforded reasonable opportunity to observe the monitoring and measuring required by this paragraph.

(e) Regulated area.

(1) A regulated area shall be established where:

(i) Vinyl chloride or polyvinyl chloride is manufactured, reacted, repackaged, stored, handled or used; and

(ii) Vinyl chloride concentrations are in excess of the permissible exposure limit.

(2) Access to regulated areas shall be limited to authorized persons.

(f) Methods of compliance. Employee exposures to vinyl chloride shall be controlled to at or below the permissible exposure limit provided in paragraph (c) of this section by engineering, work practice, and personal protective controls as follows:

(1) Feasible engineering and work practice controls shall immediately be used to reduce exposures to at or below the permissible exposure limit.

(2) Wherever feasible engineering and work practice controls which can be instituted immediately are not sufficient to reduce exposures to at or below the permissible exposure limit, they shall nonetheless be used to reduce exposures to the lowest practicable level, and shall be supplemented by respiratory protection in accordance with paragraph (g) of this section. A program shall be established and implemented to reduce exposures to at or below the permissible exposure limit, or to the greatest extent feasible, solely by means of engineering and work practice controls, as soon as feasible.

(3) Such plans shall be updated at least annually.

(g) Respiratory protection.

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph.

(2) Respirator program. The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d) (1)(iii), and (d)(3)(iii)(B)(1) and (2)), and (f) through (m), which covers each employee required by this section to use a respirator.

(3) Respirator Selection.

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide an organic vapor cartridge that has a service life of at least one hour when using a chemical cartridge respirator at vinyl chloride concentrations up to 10 ppm.

(C) Select a canister that has a service life of at least four hours when using a powered air-purifying respirator having a hood, helmet, or full or half facepiece, or a gas mask with a front-or back-mounted canister, at vinyl chloride concentrations up to 25 ppm.

(ii) When air-purifying respirators are used:

(A) Air-purifying canisters or cartridges must be replaced prior to the expiration of their service life or the end of the shift in which the expiration of their service life or the end of the shift in which they are first used, whichever occurs first.

(B) A continuous-monitoring and alarm system must be provided when concentrations of vinyl chloride would reasonably exceed the allowable concentrations for the devices in use. Such a system must be used to alert employees when vinyl chloride concentrations exceed the allowable concentrations for the devices in use.

(h) Hazardous operations.

(1) Employees engaged in hazardous operations, including entry of vessels to clean polyvinyl chloride residue from vessel walls, shall be provided and required to wear and use;

(i) Respiratory protection in accordance with paragraphs (c) and (g) of this section; and

(ii) Protective garments to prevent skin contact with liquid vinyl chloride or with polyvinyl chloride residue from vessel walls. The protective garments shall be selected for the operation and its possible exposure conditions.

(2) Protective garments shall be provided clean and dry for each use.

(i) Emergency situations. A written operational plan for emergency situations shall be developed for each facility storing, handling, or otherwise using vinyl chloride as a liquid or compressed gas. Appropriate portions of the plan shall be implemented in the event of an emergency. The plan shall specifically provide that:

(1) Employees engaged in hazardous operations or correcting situations of existing hazardous releases shall be equipped as required in paragraph (h) of this section;

(2) Other employees not so equipped shall evacuate the area and not return until conditions are controlled by the methods required in paragraph (f) of this section and the emergency is abated.

(j) Training. Each employee engaged in vinyl chloride or polyvinyl chloride operations shall be provided training in a program relating to the hazards of vinyl chloride and precautions for its safe use.

(1) The program shall include:

(i) The nature of the health hazard from chronic exposure to vinyl chloride including specifically the carcinogenic hazard;

(ii) The specific nature of operations which could result in exposure to vinyl chloride in excess of the permissible limit and necessary protective s;

(iii) The purpose for, proper use, and limitations of respiratory protective devices;

(iv) The fire hazard and acute toxicity of vinyl chloride, and the necessary protective s;

(v) The purpose for and a description of the monitoring program;

(vi) The purpose for, and a description of, the medical surveillance program;

(vii) Emergency procedures;

(viii) Specific information to aid the employee in recognition of conditions which may result

in the release of vinyl chloride; and

(ix) A review of this standard at the employee's first training and indoctrination program, and annually thereafter.

(2) All materials relating to the program shall be provided upon request to the Assistant Secretary and the Director.

(k) Medical surveillance. A program of medical surveillance shall be instituted for each employee exposed, without regard to the use of respirators, to vinyl chloride in excess of the action level. The program shall provide each such employee with an opportunity for examinations and tests in accordance with this paragraph. All medical examinations and procedures shall be performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(1) At the time of initial assignment, or upon institution of medical surveillance;

(i) A general physical examination shall be performed, with specific attention to detecting enlargement of liver, spleen or kidneys, or dysfunction in these organs, and for abnormalities in skin, connective tissues and the pulmonary system (See Appendix A).

(ii) A medical history shall be taken, including the following topics:

(A) Alcohol intake;

(B) Past history of hepatitis;

(C) Work history and past exposure to potential hepatotoxic agents, including drugs and chemicals;

(D) Past history of blood transfusions; and

(E) Past history of hospitalizations.

(iii) A serum specimen shall be obtained and determinations made of:

(A) Total bilirubin;

(B) Alkaline phosphatase;

(C) Serum glutamic oxalacetic transaminase (SGOT);

(D) Serum glutamic pyruvic transaminase (SGPT); and

(E) Gamma glutamyl transpeptidase.

(2) Examinations must be provided in accordance with this paragraph at least annually.

(i) Every 6 months for each employee who has been employed in vinyl chloride or polyvinyl chloride manufacturing for 10 years or longer; and

(ii) Annually for all other employees.

(3) Each employee exposed to an emergency shall be afforded appropriate medical surveillance.

(4) A statement of each employee's suitability for continued exposure to vinyl chloride including use of protective equipment and respirators, shall be obtained from the examining physician promptly after any examination. A copy of the physician's statement shall be provided each employee.

(5) If any employee's health would be materially impaired by continued exposure, such employee shall be withdrawn from possible contact with vinyl chloride.

(6) Laboratory analyses for all biological specimens included in medical examination shall be performed by accredited laboratories.

(7) If the examining physician determines that alternative medical examinations to those required by paragraph (k)(1) of this section will provide at least equal assurance of detecting medical conditions pertinent to the exposure to vinyl chloride, the employer may accept such alternative examinations as meeting the requirements of paragraph (k)(1) of this section, if the employer obtains a statement from the examining physician setting forth the alternative examinations and the rationale for substitution. This statement shall be available upon request for examination and copying to authorized representatives of the Assistant Secretary and the Director.

(l) Communication of hazards-

(1) Hazard communication- general.

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§1910.1200) for vinyl chloride and polyvinyl chloride.

(ii) In classifying the hazards of vinyl chloride at least the following hazards are to be addressed: Cancer; central nervous system; and flammability.

(iii) Employers shall include vinyl chloride in the hazard communication program established to comply with HCS (§1910.1200. Employers shall ensure that each employee has access to labels on containers of vinyl chloride and to safety data sheets, and is trained in accordance with requirements of HCS and paragraph (j) of this section.

(2) Signs ~~and labels.~~

~~(1)(i) Entrances to regulated areas shall be posted with legible~~The employer shall post entrances to regulated areas with legible signs bearing the legend:

DANGER
VINYL CHLORIDE
MAY CAUSE CANCER
AUTHORIZED PERSONNEL ONLY

~~CANCER-SUSPECT AGENT AREA AUTHORIZED PERSONNEL ONLY~~

~~(2)(ii) The employer shall post signs at A~~areas containing hazardous operations or where an emergency~~currently exists. The signs shall be posted with legible signs and bearing the~~
legend:

DANGER

VINYL CHLORIDE

MAY CAUSE CANCER

WEAR RESPIRATORY PROTECTION AND AUTHORIZED PERSONNEL CLOTHING IN THIS AREA

~~CANCER-SUSPECT AGENT IN THIS AREA PROTECTIVE EQUIPMENT REQUIRED~~

~~AUTHORIZED PERSONNEL ONLY~~

~~(3)(iii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (1)(2)(i) of this section: Containers of polyvinyl chloride resin waste from reactors or other waste contaminated with vinyl chloride shall be legibly labeled:~~

~~CONTAMINATED WITH VINYL CHLORIDE~~
~~CANCER-SUSPECT AGENT~~

~~AUTHORIZED PERSONNEL ONLY~~

(iv) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (1)(2)(ii) of this section:

CANCER-SUSPECT AGENT AREA

PROTECTIVE EQUIPMENT REQUIRED

AUTHORIZED PERSONNEL ONLY

3. Labels.

(4) Containers of polyvinyl chloride shall be legibly labeled: (i) In addition to the other requirements in this paragraph (1), the employer shall ensure that labels for containers of polyvinyl chloride resin waste from reactors or other waste contaminated with vinyl chloride are legible and include the following information

CONTAMINATED WITH VINYL CHLORIDE

MAY CAUSE CANCER

POLYVINYL CHLORIDE (OR TRADE NAME)

Contains

VINYL CHLORIDE

VINYL CHLORIDE IS A CANCER-SUSPECT AGENT

(ii) Prior to June 1, 2015, employers may include the following information on levels of containers of polyvinyl chloride resin waste from reactors or other waste contaminated with vinyl chloride in lieu of the labeling requirements in paragraphs (1)(3)(i) of this section:

CONTAMINATED WITH VINYL CHLORIDE

CANCER-SUSPECT AGENT

(5)(4) Prior to June 1, 2015, employers may include either the following information for containers of polyvinyl chloride shall be legibly labeled either in lieu of labeling requirements in paragraphs (1)(1)(i) of this section:

VINYL CHLORIDE

VINYL CHLORIDE IS CANCER-SUSPECT AGENT

(5)

(i) Prior to June 1, 2015, employers may include either the following information in either paragraph (1)(5)(i) or (1)(5)(ii) of this section on containers of vinyl chloride in lieu of the labeling requirements in paragraph (1)(1)(i) of this section:

VINYL CHLORIDE
EXTREMELY FLAMMABLE GAS UNDER PRESSURE
CANCER SUSPECT AGENT

☒

(ii) In accordance with 49 CFR Parts 170-189, with the additional legend applied near the label or placard:

CANCER-SUSPECT AGENT

(6) No statement shall appear on or near any required sign, label or instruction which contradicts or detracts from the effect of, any required warning, information or instruction.

(m) Records.

(1) All records maintained in accordance with this section shall include the name and social security number of each employee where relevant.

(2) Records of required monitoring and measuring and medical records shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a) - (e) and (g) - (i). These records shall be provided upon request to the Director. Authorized personnel rosters shall also be provided upon request to the Assistant Secretary and the Director.

(i) Monitoring and measuring records shall:

(A) State the date of such monitoring and measuring and the concentrations determined and identify the instruments and methods used;

(B) Include any additional information necessary to determine individual employee exposures where such exposures are determined by means other than individual monitoring of employees; and

(C) Be maintained for not less than 30 years.

(ii) [Reserved]

(iii) Medical records shall be maintained for the duration of the employment of each employee plus 20 years, or 30 years, whichever is longer.

(n) Employee notification of monitoring results. The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results and the steps being taken to reduce exposures within the

permissible exposure limit either individually in writing or by posting the results in an appropriate location that is accessible to affected employees.

1910.1017 App A Supplemental medical information

APPENDIX A to 1910.1017 - SUPPLEMENTARY MEDICAL INFORMATION

When required tests under paragraph (k)(1) of this section show abnormalities, the tests should be repeated as soon as practicable, preferably within 3 to 4 weeks. If tests remain abnormal, consideration should be given to withdrawal of the employee from contact with vinyl chloride, while a more comprehensive examination is made.

Additional tests which may be useful:

A. For kidney dysfunction: urine examination for albumin, red blood cells, and exfoliative abnormal cells.

B. Pulmonary system: Forced vital capacity, Forced expiratory volume at 1 second, and chest roentgenogram (posterior-anterior, 14 X 17 inches).

C. Additional serum tests: Lactic acid dehydrogenase, lactic acid dehydrogenase isoenzyme, protein determination, and protein electrophoresis.

D. For a more comprehensive examination on repeated abnormal serum tests: Hepatitis B antigen, and liver scanning.

[39 FR 35896, Oct. 4, 1974; 39 FR 41848, Dec. 3, 1974, as amended at 40 FR 13211, Mar. 25, 1975. Redesignated at 40 FR 23072, May 28, 1975 and amended at 43 FR 49751, Oct. 24, 1978; 45 FR 35282, May 23, 1980; 54 FR 24334, June 7, 1989]

1910.1018 Inorganic arsenic.

(a) Scope and application. This section applies to all occupational exposures to inorganic arsenic except that this section does not apply to employee exposures in agriculture or resulting from pesticide application, the treatment of wood with preservatives or the utilization of arsenically preserved wood.

(b) Definitions.

"Action level" means a concentration of inorganic arsenic of 5 micrograms per cubic meter of air (5 ug/m³) averaged over any eight (8) hour period.

"Administrator" means the Administrator of the State of Wyoming Occupational Health and Safety Department, or designee.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (e) of this section.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, and Human Services, or designee.

"Inorganic arsenic" means copper aceto- arsenite and all inorganic compounds containing arsenic except arsine, measured as arsenic (As).

"W.O.H.S." means the Wyoming Occupational Health and Safety Department; Cheyenne, Wyoming 82002.

(c) Permissible exposure limit. The employer shall assure that no employee is exposed to inorganic arsenic at concentrations greater than 10 micrograms per cubic meter of air (10 ug/m³), averaged over any 8-hour period.

(d) [Reserved]

(e) Exposure monitoring

(1) General.

(i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to inorganic arsenic over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(iii) The employer shall collect full shift (for at least 7 continuous hours) personal samples including at least one sample for each shift for each job classification in each work area.

(2) Initial monitoring. Each employer who has a workplace or work operation covered by this standard shall monitor each such workplace and work operation to accurately determine the airborne concentration of inorganic arsenic to which employees may be exposed.

(3) Frequency.

(i) If the initial monitoring reveals employee exposure to be below the action level the measurements need not be repeated except as otherwise provided in paragraph (e)(4) of this section.

(ii) If the initial monitoring, required by this section, or subsequent monitoring reveals employee exposure to be above the permissible exposure limit, the employer shall repeat monitoring at least quarterly.

(iii) If the initial monitoring, required by this section, or subsequent monitoring reveals employee exposure to be above the action level and below the permissible exposure limit the employer shall repeat monitoring at least every six months.

(iv) The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least seven (7) days apart, are below the action level at which time the employer may discontinue monitoring for that employee until such time as any of the events in paragraph (e)(4) of this section occur.

(4) Additional monitoring. Whenever there has been a production, process, control or personal change which may result in new or additional exposure to inorganic arsenic, or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to inorganic arsenic, additional monitoring which complies with paragraph (e) of this section shall be conducted.

(5) Employee notification.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to affected employees.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limit, the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the corrective action taken to reduce exposure to or below the permissible exposure limit.

(6) Accuracy of measurement.

(i) The employer shall use a method of monitoring and measurement which has an accuracy (with a confidence level of 95 percent) of not less than plus or minus 25 percent for concentrations of inorganic arsenic greater than or equal to 10 ug/m³.

(ii) The employer shall use a method of monitoring and measurement which has an accuracy (with confidence level of 95 percent) of not less than plus or minus 35 percent for concentrations of inorganic arsenic greater than 5 ug/m³ but less than 10 ug/m³.

(f) Regulated area

(1) Establishment. The employer shall establish regulated areas where worker exposures to inorganic arsenic, without regard to the use of respirators, are in excess of the permissible limit.

(2) Demarcation. Regulated areas shall be demarcated and segregated from the rest of the workplace in any manner that minimizes the number of persons who will be exposed to inorganic arsenic.

(3) Access. Access to regulated areas shall be limited to authorized persons or to persons otherwise authorized by the Act or regulations issued pursuant thereto to enter such areas.

(4) Provision of respirators. All persons entering a regulated area shall be supplied with a respirator, selected in accordance with paragraph (h)(2) of this section.

(5) Prohibited activities. The employer shall assure that in regulated areas, food or beverages are not consumed, smoking products, chewing tobacco and gum are not used and cosmetics are not applied, except that these activities may be conducted in the lunchrooms, change rooms and showers required under paragraph (m) of this section. Drinking water may be consumed in the regulated area.

(g) Methods of compliance

(1) Controls.

(i) The employer shall institute at the earliest possible time but not later than December 31, 1979, engineering and work practice controls to reduce exposures to or below the permissible exposure limit, except to the extent that the employer can establish that such controls are not feasible.

(ii) Where engineering and work practice controls are not sufficient to reduce exposures to or below the permissible exposure limit, they shall nonetheless be used to reduce exposures to the lowest levels achievable by these controls and shall be supplemented by the use of respirators in accordance with paragraph (h) of this section and other necessary personal protective equipment. Employee rotation is not required as a control strategy before respiratory protection is instituted.

(2) Compliance Program.

(i) The employer shall establish and implement a written program to reduce exposures to or

below the permissible exposure limit by means of engineering and work practice controls.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation in which inorganic arsenic is emitted; e.g. machinery used, material processed, controls in place, crew size, operating procedures and maintenance practices;

(B) Engineering plans and studies used to determine methods selected for controlling exposure to inorganic arsenic;

(C) A report of the technology considered in meeting the permissible exposure limit;

(D) Monitoring data;

(E) A detailed schedule for implementation of the engineering controls and work practices that cannot be implemented immediately and for the adaption and implementation of any additional engineering and work practices necessary to meet the permissible exposure limit;

(F) Whenever the employer will not achieve the permissible exposure limit with engineering controls and work practices by December 31, 1979, the employer shall include in the compliance plan an analysis of the effectiveness of the various controls, shall install engineering controls and institute work practices on the quickest schedule feasible, and shall include in the compliance plan and implement a program to minimize the discomfort and maximize the effectiveness of respirator use; and

(G) Other relevant information.

(iii) Written plans for such a program shall be submitted upon request to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, Director, any affected employee or authorized employee representatives.

(iv) The plans required by this paragraph must be revised and updated at least annually to reflect the current status of the program.

(h) Respiratory protection

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering or work practice controls.

(ii) Work operations such as maintenance and repair activities for which the employer establishes that engineering and work-practice controls are not feasible.

(iii) Work operations for which engineering and work-practice controls are not yet sufficient to reduce employee exposures to or below the permissible exposure limit.

(iv) Emergencies.

(2) Respirator program.

(i) The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) If an employee exhibits breathing difficulty during fit testing or respirator use, they must be examined by a physician trained in pulmonary medicine to determine whether they can use a respirator while performing the required duty.

(3) Respirator selection.

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Ensure that employees do not use half mask respirators for protection against arsenic trichloride because it is absorbed rapidly through the skin.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.:

(D) Select for employee use:

(1) Air-purifying respirators that have a combination HEPA filter with an appropriate gas-sorbent cartridge or canister when the employee's exposure exceeds the permissible exposure level for inorganic arsenic and the relevant limit for other gases.

(2) Front-or back-mounted gas masks equipped with HEPA filters and acid gas canisters or any full facepiece supplied-air respirators when the inorganic arsenic concentration is at or below 500 mg/m^3 ; and half mask air-purifying respirators equipped with HEPA filters and acid gas cartridges when the inorganic arsenic concentration is at or below $100 \text{ }\mu\text{g/m}^3$.

(ii) Employees required to use respirators may choose, and the employer must provide, a powered air-purifying respirator if it will provide proper protection. In addition, the employer must provide a combination dust and acid-gas respirator to employees who are exposed to gases over the relevant exposure limits.

(i) [Reserved]

(j) Protective work clothing and equipment

(1) Provision and use. Where the possibility of skin or eye irritation from inorganic arsenic exists, and for all workers working in regulated areas, the employer shall provide at no cost to the employee and assure that employees use appropriate and clean protective work clothing and equipment such as, but not limited to:

(i) Coveralls or similar full-body work clothing;

(ii) Gloves, and shoes or coverlets;

(iii) Face shields or vented goggles when necessary to prevent eye irritation, which comply with the requirements of 1910.133(a) (2) - (6); and (iv) Impervious clothing for employees subject to exposure to arsenic trichloride.

(2) Cleaning and replacement.

(i) The employer shall provide the protective clothing required in paragraph (j) (1) of this section in a freshly laundered and dry condition at least weekly, and daily if the employee works in areas where exposures are over 100 ug/m³ of inorganic arsenic or in areas where more frequent washing is needed to prevent skin irritation.

(ii) The employer shall clean, launder, or dispose of protective clothing required by paragraph (j) (1) of this section.

(iii) The employer shall repair or replace the protective clothing and equipment as needed to maintain their effectiveness.

(iv) The employer shall assure that all protective clothing is removed at the completion of a work shift only in change rooms prescribed in paragraph (m) (1) of this section.

(v) The employer shall assure that contaminated protective clothing which is to be cleaned, laundered, or disposed of, is placed in a closed container in the change-room which prevents dispersion of inorganic arsenic outside the container.

(vi) The employer shall inform in writing any person who cleans or launders clothing

required by this section, of the potentially harmful effects including the carcinogenic effects of exposure to inorganic arsenic.

(vii) Labels on contaminated protective clothing and equipment.

(A) The employer shall assure that the containers of contaminated protective clothing and equipment in the workplace or which are to be removed from the workplace are labeled as and that the labels include the following information:

DANGER: CONTAMINATED WITH INORGANIC ARSENIC. MAY CAUSE CANCER. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF INORGANIC ARSENIC CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE OR FEDERAL REGULATIONS.

(B) Prior to June 1, 2015, employers may include the following information on containers of protective clothing and equipment in lieu of the labeling requirements in paragraphs (j)(2)(vii) of this section:

CAUTION: Clothing contaminated with inorganic arsenic; do not remove dust by blowing or shaking. Dispose of inorganic arsenic contaminated wash water in accordance with applicable local, State or Federal regulations.

(viii) The employer shall prohibit the removal of inorganic arsenic from protective clothing or equipment by blowing or shaking.

(k) Housekeeping

(1) Surfaces. All surfaces shall be maintained as free as practicable of accumulations of inorganic arsenic.

(2) Cleaning floors. Floors and other accessible surfaces contaminated with inorganic arsenic may not be cleaned by the use of compressed air, and shoveling and brushing may be used only where vacuuming or other relevant methods have been tried and found not to be effective.

(3) Vacuuming. Where vacuuming methods are selected, the vacuums shall be used and emptied in a manner to minimize the reentry of inorganic arsenic into the workplace.

(4) Housekeeping plan. A written housekeeping and maintenance plan shall be kept which shall list appropriate frequencies for carrying out housekeeping operations, and for cleaning and maintaining dust collection equipment. The plan shall be available for inspection by the Assistant Secretary.

(5) Maintenance of equipment. Periodic cleaning of dust collection and ventilation equipment

and checks of their effectiveness shall be carried out to maintain the effectiveness of the system and a notation kept of the last check of effectiveness and cleaning or maintenance.

(l) [Reserved]

(m) Hygiene facilities and practices

(1) Change rooms. The employer shall provide for employees working in regulated areas or subject to the possibility of skin or eye irritation from inorganic arsenic, clean change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing and equipment in accordance with 29 CFR 1910.141(e).

(2) Showers.

(i) The employer shall assure that employees working in regulated areas or subject to the possibility of skin or eye irritation from inorganic arsenic shower at the end of the work shift.

(ii) The employer shall provide shower facilities in accordance with 1910.141(d)(3).

(3) Lunchrooms.

(i) The employer shall provide for employees working in regulated areas, lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees working in regulated areas.

(ii) The employer shall assure that employees working in the regulated area or subject to the possibility of skin or eye irritation from exposure to inorganic arsenic wash their hands and face prior to eating.

(4) Lavatories. The employer shall provide lavatory facilities which comply with 1910.141(d)(1) and (2).

(5) Vacuuming clothes. The employer shall provide facilities for employees working in areas where exposure, without regard to the use of respirators, exceeds 100 ug/m³ to vacuum their protective clothing and clean or change shoes worn in such areas before entering change rooms, lunchrooms or shower rooms required by paragraph (j) of this section and shall assure that such employees use such facilities.

(6) Avoidance of skin irritation. The employer shall assure that no employee is exposed to skin or eye contact with arsenic trichloride, or to skin or eye contact with liquid or particulate inorganic arsenic which is likely to cause skin or eye irritation.

(n) Medical surveillance

(1) General

(i) Employees covered. The employer shall institute a medical surveillance program for the following employees:

(A) All employees who are or will be exposed above the action level, without regard to the use of respirators, at least 30 days per year; and

(B) All employees who have been exposed above the action level, without regard to respirator use, for 30 days or more per year for a total of 10 years or more of combined employment with the employer or predecessor employers prior to or after the effective date of this standard. The determination of exposures prior to the effective date of this standard shall be based upon prior exposure records, comparison with the first measurements taken after the effective date of this standard, or comparison with records of exposures in areas with similar processes, extent of engineering controls utilized and materials used by that employer.

(ii) Examination by physician. The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

(2) Initial examinations. By December 1, 1978, for employees initially covered by the medical provisions of this section, or thereafter at the time of initial assignment to an area where the employee is likely to be exposed over the action level at least 30 days per year, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history and a medical history which shall include a smoking history and the presence and degree of respiratory symptoms such as breathlessness, cough, sputum production and wheezing.

(ii) A medical examination which shall include at least the following:

(A) A standard posterior-anterior chest x-ray;

(B) A nasal and skin examination; and

(C) Other examinations which the physician believes appropriate because of the employees exposure to inorganic arsenic or because of required respirator use.

(3) Periodic examinations.

(i) Examinations must be provided in accordance with this paragraph at least annually.

(ii) Whenever a covered employee has not taken the examinations specified in paragraphs (n)(2)(i) and (n)(2)(ii) of this section within six (6) months preceding the termination of employment, the employer shall provide such examinations to the employee upon termination of employment.

(4) Additional examinations. If the employee for any reason develops signs or symptoms commonly associated with exposure to inorganic arsenic the employer shall provide an appropriate examination and emergency medical treatment.

(5) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level or anticipated exposure level;

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous medical examinations of the affected employee which is not readily available to the examining physician.

(6) Physician's written opinion.

(i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical examination and tests performed;

(B) The physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of the employee's health from exposure to inorganic arsenic;

(C) Any recommended limitations upon the employee's exposure to inorganic arsenic or upon the use of protective clothing or equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further explanation or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure.

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) Employee information and training

(1) Training program.

(i) The employer shall train each employee who is subject to exposure to inorganic arsenic above the action level without regard to respirator use, or for whom there is the possibility of skin or eye irritation from inorganic arsenic, in accordance with the requirements of this section. The employer shall institute a training program and ensure employee participation in the program.

(ii) The training program shall be provided by October 1, 1978, for employees covered by this provision, at the time of initial assignment for those subsequently covered by this provision and at least annually for other covered employees thereafter; and the employer shall assure that each employee is informed of the following:

(A) The information contained in Appendix A;

(B) The quantity, location, manner of use, storage, sources of exposure, and the specific nature of operations which could result in exposure to inorganic arsenic as well as any necessary protective s;

(C) The purpose, proper use, and limitation of respirators;

(D) The purpose and a description of the medical surveillance program as required by paragraph (n) of this section;

(E) The engineering controls and work practices associated with the employee's job assignment; and

(F) A review of this standard.

(2) Access to training materials.

(i) The employer shall make readily available to all affected employees a copy of this standard and its appendices.

(ii) The employer shall provide; upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) ~~Signs and labels~~ Communication of Hazards

(1) Hazard communication-General.

- (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements fo the Hazard Communication Standard (HCS) (§1910.1200) for inorganic arsenic.
- (ii)In classifying the hazards of inorganic arsenic at least the following hazards are to be addressed:Cancer; liver effects;skin effects; respiratory irritation; nervous system effects; and acute toxicity effects.
- (iii) Employers shall include inorganic arsenic in the hazard communication program established to complywith the HCS (§1910.1200). Employers shall ensure that each employee has access to labels on containers of inorganic arsenic and to safety data sheets, and is trained in accordance with requirements of HCS and paragraph (o) of this section.
- (iv) The employer shall ensure that no statement appears on or near any sign or label required by this paragraph (p) which contradicts or detracts from the meaning of the required sign or label.

~~–(i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.~~

~~–(ii) The employer shall assure that no statement appears on or near any sign or label required by this paragraph which contradicts or detracts from the meaning of the required sign or label.~~

(2) Signs.

- (i) The employer shall post signs demarcating regulated areas bearing the legend;

DANGER

INORGANIC ARSENIC

CANCER HAZARD MAY CAUSE CANCER

DO NOT EAT, DRINK OR SMOKE

WEAR RESPIRATORY PROTECTION IN THIS AREA

AUTHORIZED PERSONNEL ONLY

~~NO SMOKING OR EATING~~

~~RESPIRATOR REQUIRED~~

~~(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible. Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (p)(2)(i) of this section:~~

DANGER
INORGANIC ARSENIC
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
NO SMOKING OR EATING
RESPIRATOR REQUIRED

(iii) The employer shall ensure that signs required by this paragraph (p) are illuminated and cleaned as necessary so that the legend is readily visible.

~~(3) Labels. The employer shall apply precautionary labels to all shipping and storage containers of inorganic arsenic, and to all products containing inorganic arsenic except when the inorganic arsenic in the product is bound in such a manner so as to make unlikely the possibility of airborne exposure to inorganic arsenic. (Possible examples of products not requiring labels are semiconductors, light emitting diodes and glass). (i) Prior to June 1, 1015, in lieu of the labeling requirements in paragraphs (p)(1)(i) of this section, employers may apply precautionary labels to all shipping and storage containers of inorganic arsenic, and to all products containing inorganic arsenic, breaing the following legend: The label shall bear the following legend:~~

DANGER

CONTAINS INORGANIC ARSENIC

CANCER HAZARD

HARMFUL IF INHALED OR SWALLOWED

USE ONLY WITH ADEQUATE VENITLATION OR RESPIRATORY PROTECTION

(ii) Labels are not required whe the inorganic arsenic in the product is bound in such a manner so as to make unlikely the possibility of airborne exposure to inorganic arsenic. (Possible examples of products are not requiring labels are semiconductors, light emitting diodes and glass.)

(q) Recordkeeping

(1) Exposure monitoring.

(i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The date(s), number, duration location, and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure where applicable;

(B) A description of the sampling and analytical methods used and evidence of their accuracy;

(C) The type of respiratory protective devices worn, if any;

(D) Name, social security number, and job classification of the employees monitored and of all other employees whose exposure the measurement is intended to represent; and

(E) The environmental variables that could affect the measurement of the employee's exposure.

(iii) The employer shall maintain these monitoring records for at least 40 years or for the duration of employment plus 20 years, whichever, is longer.

(2) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) The name, social security number, and description of duties of the employee;

(B) A copy of the physician's written opinions;

(C) Results of any exposure monitoring done for that employee and the representative exposure levels supplied to the physician; and

(D) Any employee medical complaints related to exposure to inorganic arsenic.

(iii) The employer shall in addition keep, or assure that the examining physician keeps, the following medical records;

(A) A copy of the medical examination results including medical and work history

required under paragraph (n) of this section;

(B) A description of the laboratory procedures and a copy of any standards or guidelines used to interpret the test results or references to that information;

(C) The initial X-ray;

(D) The X-rays for the most recent 5 years; and

(E) Any X-rays with a demonstrated abnormality and all subsequent X-rays;

(iv) The employer shall maintain or assure that the physician maintains those medical records for at least 40 years, or for the duration of employment plus 20 years whichever is longer.

(3) Availability.

(i) The employer shall make available upon request all records required to be maintained by paragraph (q) of this section to the Assistant Secretary and the Director for examination and copying.

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a) - (e) and (g) - (i).

(4) Transfer of records.

(i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by this section.

(ii) The employer shall also comply with any additional requirements involving the transfer of records set in 29 CFR 1910.1020(h).

(r) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to inorganic arsenic conducted pursuant to paragraph (e) of this section.

(2) Observation procedures.

(i) Whenever observation of the monitoring of employee exposure to inorganic arsenic requires entry into an area where the use of respirators, protective clothing, or equipment is required, the employer shall provide the observer with and assure the use of such respirators, clothing, and such equipment, and shall require the observer to comply with all other applicable

safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled to;

(A) Receive an explanation of the measurement procedures;

(B) Observe all s related to the monitoring of inorganic arsenic performed at the place of exposure; and

(C) Record the results obtained or receive copies of the results when returned by the laboratory.

(s) Appendices. The information contained in the appendices to this section is not intended by itself, to create any additional obligations not otherwise imposed by this standard nor detract from any existing obligation.

1910.1018 App A Inorganic arsenic substance information sheet

APPENDIX A to 1910.1018 - INORGANIC ARSENIC SUBSTANCE INFORMATION SHEET

I. SUBSTANCE IDENTIFICATION

A. Substance. Inorganic Arsenic.

B. Definition. Copper acetoarsenite, arsenic and all inorganic compounds containing arsenic except arsine, measured as arsenic (As).

C. Permissible Exposure Limit. 10 micrograms per cubic meter of air as determined as an average over an 8-hour period. No employee may be exposed to any skin or eye contact with arsenic trichloride or to skin or eye contact likely to cause skin or eye irritation.

D. Regulated Areas. Only employees authorized by your employer should enter a regulated area.

II. HEALTH HAZARD DATA

A. Comments. The health hazard of inorganic arsenic is high.

B. Ways in which the chemical affects your body. Exposure to airborne concentrations of inorganic arsenic may cause lung cancer, and can be a skin irritant. Inorganic arsenic may also affect your body if swallowed. One compound in particular, arsenic trichloride, is especially dangerous because it can be absorbed readily through the skin. Because inorganic arsenic is a poison, you should wash your hands thoroughly prior to eating or smoking.

III. PROTECTIVE CLOTHING AND EQUIPMENT

A. Respirators. Respirators will be provided by your employer at no cost to you for routine use if your employer is in the process of implementing engineering and work practice controls or where engineering and work practice controls are not feasible or insufficient. You must wear respirators for non-routine activities or in emergency situations where you are likely to be exposed to levels of inorganic arsenic in excess of the permissible exposure limit. Since how well your respirator fits your face is very important, your employer is required to conduct fit tests to make sure the respirator seals properly when you wear it. These tests are simple and rapid and will be explained to you during training sessions.

B. Protective clothing. If you work in a regulated area, your employer is required to provide at no cost to you, and you must wear, appropriate, clean, protective clothing and equipment. The purpose of this equipment is to prevent you from bringing to your home arsenic-contaminated dust and to protect your body from repeated skin contact with inorganic arsenic likely to cause skin irritation. This clothing should include such items as coveralls or similar full-body clothing, gloves, shoes or coverlets, and aprons. Protective equipment should include face shields or vented goggles, where eye irritation may occur.

IV. HYGIENE FACILITIES AND PRACTICES

You must not eat, drink, smoke, chew gum or tobacco, or apply cosmetics in the regulated area, except that drinking water is permitted. If you work in a regulated area your employer is required to provide lunchrooms and other areas for these purposes.

If you work in a regulated area, your employer is required to provide showers, washing facilities, and change rooms. You must wash your face, and hands before eating and must shower at the end of the work shift. Do not take used protective clothing out of change rooms without your employer's permission. Your employer is required to provide for laundering or cleaning of your protective clothing.

V. SIGNS AND LABELS

Your employer is required to post warning signs and labels for your protection. Signs must be posted in regulated areas. The signs must warn that a cancer hazard is present, that only authorized employees may enter the area, and that no smoking or eating is allowed, and that

respirators must be worn.

VI. MEDICAL EXAMINATIONS

If your exposure to arsenic is over the Action Level (5 ug/m³) - (including all persons working in regulated areas) at least 30 days per year, or you have been exposed to arsenic for more than 10 years over the Action Level, your employer is required to provide you with a medical examination. The examination shall be every 6 months for employees over 45 years old or with more than 10 years exposure over the Action Level and annually for other covered employees. The medical examination must include a medical history; a chest x-ray; skin examination; and a nasal examination. The examining physician will provide a written opinion to your employer containing the results of the medical exams. You should also receive a copy of this opinion. The physician must not tell your employer any conditions he detects unrelated to occupational exposure to arsenic but must tell you those conditions.

VII. OBSERVATION OF MONITORING

Your employer is required to monitor your exposure to arsenic and you or your representatives are entitled to observe the monitoring procedure. You are entitled to receive an explanation of the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you must also be provided with and must wear the protective clothing and equipment.

VIII. ACCESS TO RECORDS

You or your representative are entitled to records of your exposure to inorganic arsenic and your medical examination records if you request your employer to provide them.

IX. TRAINING AND NOTIFICATION

Additional information on all of these items plus training as to hazards of exposure to inorganic arsenic and the engineering and work practice controls associated with your job will also be provided by your employer. If you are exposed over the permissible exposure limit, your employer must inform you of that fact and the actions he is taking to reduce your exposures.

1910.1018 App B Substance technical guidelines

APPENDIX B to 1910.1018 - SUBSTANCE TECHNICAL GUIDELINES

ARSENIC, ARSENIC TRIOXIDE, ARSENIC TRICHLORIDE (THREE EXAMPLES)

I. Physical and chemical properties

A. Arsenic (metal).

1. Formula: As.
2. Appearance: Gray metal.
3. Melting point: Sublimes without melting at 613C.
4. Specific Gravity: (H₂O=1):5.73.
5. Solubility in water: Insoluble.

B. Arsenic Trioxide.

1. Formula: As₂O₃, (As₄O₆).
2. Appearance: White powder.
3. Melting point: 315C.
4. Specific Gravity (H₂O=1):3.74.
5. Solubility in water: 3.7 grams in 100cc of water at 20c.

C. Arsenic Trichloride (liquid).

1. Formula: AsCl₃.
2. Appearance: Colorless or pale yellow liquid.
3. Melting point: 8.5C.
4. Boiling point: 130.2C.
5. Specific Gravity (H₂O=1):2.16 at 20C.
6. Vapor Pressure: 10mm Hg at 23.5C.
7. Solubility in Water: Decomposes in water.

II. Fire, explosion and reactivity data.

- A. Fire: Arsenic, arsenic Trioxide and Arsenic Trichloride are nonflammable.

B. Reactivity:

1. Conditions Contributing to instability: Heat.

2. Incompatibility: Hydrogen gas can react with inorganic arsenic to form the highly toxic gas arsine.

III. Monitoring and Measurement Procedures

Samples collected should be full shift (at least 7-hour) samples. Sampling should be done using a personal sampling pump at a flow rate of 2 liters per minute. Samples should be collected on 0.8 micrometer pore size membrane filter (37mm diameter). Volatile arsenicals such as arsenic trichloride can be most easily collected in a midget bubbler filled with 15 ml. of 0.1 N NaOH.

The method of sampling and analysis should have an accuracy of not less than + or - 25 percent (with a confidence limit of 95 percent) for 10 micrograms per cubic meter of air (10 ug/m³) and + or - 35 percent (with a confidence limit of 95 percent) for concentrations of inorganic arsenic between 5 and 10 ug/m³.

1910.1018 App C Medical surveillance guidelines

APPENDIX C to 1910.1018 - MEDICAL SURVEILLANCE GUIDELINES

I. GENERAL

Medical examinations are to be provided for all employees exposed to levels of inorganic arsenic above the action level (5 ug/m³) for at least 30 days per year (which would include among others, all employees, who work in regulated areas). Examinations are also to be provided to all employees who have had 10 years or more exposure above the action level for more than 30 days per year while working for the present or predecessor employer though they may no longer be exposed above the level.

An initial medical examination is to be provided to all such employees by December 1, 1978. In addition, an initial medical examination is to be provided to all employees who are first assigned to areas in which worker exposure will probably exceed 5 ug/m³ (after the effective date of this standard) at the time of initial assignment. In addition to its immediate diagnostic usefulness, the initial examination will provide a baseline for comparing future test results. The initial examination must include as a minimum the following elements:

(1) A work and medical history, including a smoking history, and presence and degree of respiratory symptoms such as breathlessness, cough, sputum production, and wheezing;

(2) A 14" by 17" posterior-anterior chest X-ray

(3) A nasal and skin examination; and

(4) Other examinations which the physician believes appropriate because of the employee's exposure to inorganic arsenic or because of required respirator use.

Periodic examinations are also to be provided to the employees listed above. The periodic examinations shall be given annually for those covered employees 45 years of age or less with fewer than 10 years employment in areas where employee exposure exceeds the action level (5 ug/m³). Periodic examinations need not include sputum cytology and only an updated medical history is required.

Periodic examinations for other covered employees, shall be provided every six (6) months. These examinations shall include all tests required in the initial examination, except that the medical history need only be updated.

The examination contents are minimum requirements. Additional tests such as lateral and oblique X-rays or pulmonary function tests may be useful. For workers exposed to three arsenicals which are associated with lymphatic cancer, copper acetoarsenite, potassium arsenite, or sodium arsenite the examination should also include palpation of superficial lymph nodes and complete blood count.

II. NONCARCINOGENIC EFFECTS

The OSHA standard is based on minimizing risk of exposed workers dying of lung cancer from exposure to inorganic arsenic. It will also minimize skin cancer from such exposures.

The following three sections quoted from "Occupational Diseases: A Guide to Their Recognition", Revised Edition, June 1977, National Institute for Occupational Safety and Health is included to provide information on the nonneoplastic effects of exposure to inorganic arsenic. Such effects should not occur if the OSHA standards are followed.

A. Local - Trivalent arsenic compounds are corrosive to the skin. Brief contact has no effect but prolonged contact results in a local hyperemia and later vesicular or pustular eruption. The moist mucous membranes are most sensitive to the irritant action. Conjunctiva, moist and macerated areas of skin, the eyelids, the angles of the ears, nose, mouth, and respiratory mucosa are also vulnerable to the irritant effects. The wrists are common sites of dermatitis, as are the genitalia if personal hygiene is poor. Perforations of the nasal septum may occur. Arsenic trioxide and pentoxide are capable of producing skin sensitization and contact dermatitis. Arsenic is also capable of producing keratoses, especially of the palms and soles.

B. Systemic - The acute toxic effects of arsenic are generally seen following ingestion of

inorganic arsenical compounds. This rarely occurs in an industrial setting. Symptoms develop within 1/2 to 4 hours following ingestion and are usually characterized by constriction of the throat followed by dysphagia, epigastric pain, vomiting, and watery diarrhea. Blood may appear in vomitus and stools. If the amount ingested is sufficiently high, shock may develop due to severe fluid loss, and death may ensue in 24 hours. If the acute effects are survived, exfoliative dermatitis and peripheral neuritis may develop.

Cases of acute arsenical poisoning due to inhalation are exceedingly rare in industry. When it does occur, respiratory tract symptoms—cough, chest pain, dyspnea-giddiness, headache, and extreme general weakness precede gastrointestinal symptoms. The acute toxic symptoms of trivalent arsenical poisoning are due to severe inflammation of the mucous membranes and greatly increased permeability of the blood capillaries.

Chronic arsenical poisoning due to ingestion is rare and generally confined to patients taking prescribed medications. However, it can be a concomitant of inhaled inorganic arsenic from swallowed sputum and improper eating habits. Symptoms are weight loss, nausea and diarrhea alternating with constipation, pigmentation and eruption of the skin, loss of hair, and peripheral neuritis. Chronic hepatitis and cirrhosis have been described. Polyneuritis may be the salient feature, but more frequently there are numbness and parasthenias of "glove and stocking" distribution. The skin lesions are usually melanotic and keratotic and may occasionally take the form of an intradermal cancer of the squamous cell type, but without infiltrative properties. Horizontal white lines (striations) on the fingernails and toenails are commonly seen in chronic arsenical poisoning and are considered to be a diagnostic accompaniment of arsenical polyneuritis.

Inhalation of inorganic arsenic compounds is the most common cause of chronic poisoning in the industrial situation. This condition is divided into three phases based on signs and symptoms.

First Phase: The worker complains of weakness, loss of appetite, some nausea, occasional vomiting, a sense of heaviness in the stomach, and some diarrhea.

Second Phase: The worker complains of conjunctivitis, a catarrhal state of the mucous membranes of the nose, larynx, and respiratory passage. Coryza, hoarseness, and mild tracheobronchitis may occur. Perforation of the nasal septum is common, and is probably the most typical lesion of the upper respiratory tract in occupational exposure to arsenical dust. Skin lesions, eczematoid and allergic in type, are common.

Third Phase: The worker complains of symptoms of peripheral neuritis, initially of hands and feet, which is essentially sensory. In more severe cases, motor paralyzes occur; the first muscles affected are usually the toe extensors and the peronei. In only the most severe cases will paralysis of flexor muscles of the feet or of the extensor muscles of hands occur.

Liver damage from chronic arsenical poisoning is still debated, and as yet the question is

unanswered. In cases of chronic and acute arsenical poisoning, toxic effects to the myocardium have been reported based on EKG changes. These findings, however, are now largely discounted and the EKG changes are ascribed to electrolyte disturbances concomitant with arsenicalism. Inhalation of arsenic trioxide and other inorganic arsenical dusts does not give rise to radiological evidence or pneumoconiosis. Arsenic does have a depressant effect upon the bone marrow, with disturbances of both erythropoiesis and myelopoiesis.

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[43 FR 19624, May 5, 1978; 43 FR 28472, June 30, 1978, as amended at 45 FR 35282, May 23, 1980; 54 FR 24334, June 7, 1989]

1910.1020 Access to employee exposure and medical records.

(a) *Purpose.* The purpose of this section is to provide employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act. Access by employees, their representatives, and the Assistant Secretary is necessary to yield both direct and indirect improvements in the detection, treatment, and prevention of occupational disease. Each employer is responsible for assuring compliance with this section, but the activities involved in complying with the access to medical records provisions can be carried out, on behalf of the employer, by the physician or other health care personnel in charge of employee medical records. Except as expressly provided, nothing in this section is intended to affect existing legal and ethical

obligations concerning the maintenance and confidentiality of employee medical information, the duty to disclose information to a patient/employee or any other aspect of the medical-care relationship, or affect existing legal obligations concerning the protection of trade secret information.

(b) *Scope and application.*

(1) This section applies to each general industry, maritime, and construction employer who makes, maintains, contracts for, or has access to employee exposure or medical records, or analyses thereof, pertaining to employees exposed to toxic substances or harmful physical agents.

(2) This section applies to all employee exposure and medical records, and analyses thereof, of such employees, whether or not the records are mandated by specific occupational safety and health standards.

(3) This section applies to all employee exposure and medical records, and analyses thereof, made or maintained in any manner, including on an in-house or contractual (e.g., fee-for-service) basis. Each employer shall assure that the preservation and access requirements of this section are complied with regardless of the manner in which the records are made or maintained.

(c) *Definitions.*

(1) *Access* means the right and opportunity to examine and copy.

(2) *Analysis using exposure or medical records* means any compilation of data or any statistical study based at least in part on information collected from individual employee exposure or medical records or information collected from health insurance claims records, provided that either the analysis has been reported to the employer or no further work is currently being done by the person responsible for preparing the analysis.

(3) *Designated representative* means any individual or organization to whom an employee gives written authorization to exercise a right of access. For the purposes of access to employee exposure records and analyses using exposure or medical records, a recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

(4) *Employee* means a current employee, a former employee, or an employee being assigned or transferred to work where there will be exposure to toxic substances or harmful physical agents. In the case of a deceased or legally incapacitated employee, the employee's legal representative may directly exercise all the employee's rights under this section.

(5) *Employee exposure record* means a record containing any of the following kinds of information:

(i) Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained;

(ii) Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc) but not including results which assess the biological effect of a substance or agent or which assess an employee's use of alcohol or drugs;

(iii) Material safety data sheets indicating that the material may pose a hazard to human health; or

(iv) In the absence of the above, a chemical inventory or any other record which reveals where and when used and the identity (e.g., chemical, common, or trade name) of a toxic substance or harmful physical agent.

(6)

(i) *Employee medical record* means a record concerning the health status of an employee which is made or maintained by a physician, nurse, or other health care personnel or technician, including:

(A) Medical and employment questionnaires or histories (including job description and occupational exposures),

(B) The results of medical examinations (pre-employment, pre-assignment, periodic, or episodic) and laboratory tests (including chest and other X-ray examinations taken for the purposes of establishing a base-line or detecting occupational illness, and all biological monitoring not defined as an "employee exposure record"),

(C) Medical opinions, diagnoses, progress notes, and recommendations,

(D) First aid records,

(E) Descriptions of treatments and prescriptions, and

(F) Employee medical complaints.

(ii) "Employee medical record" does not include medical information in the form of:

(A) Physical specimens (e.g., blood or urine samples) which are routinely discarded as a part of normal medical practice; or

(B) Records concerning health insurance claims if maintained separately from the employer's medical program and its records, and not accessible to the employer by employee name or other direct personal identifier (e.g., social security number, payroll number, etc.); or

(C) Records created solely in preparation for litigation which are privileged from discovery under the applicable rules of procedure or evidence; or

(D) Records concerning voluntary employee assistance programs (alcohol, drug abuse, or personal counseling programs) if maintained separately from the employer's medical program and its records.

(7) *Employer* means a current employer, a former employer, or a successor employer.

(8) *Exposure* or *exposed* means that an employee is subjected to a toxic substance or harmful physical agent in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes past exposure and potential (e.g., accidental or possible) exposure, but does not include situations where the employer can demonstrate that the toxic substance or harmful physical agent is not used, handled, stored, generated, or present in the workplace in any manner different from typical non-occupational situations.

(9) *Health Professional* means a physician, occupational health nurse, industrial hygienist, toxicologist, or epidemiologist, providing medical or other occupational health services to exposed employees.

(10) *Record* means any item, collection, or grouping of information regardless of the form or process by which it is maintained (e.g., paper document, microfiche, microfilm, X-ray film, or automated data processing).

(11) *Specific chemical identity* means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

(12)

(i) *Specific written consent* means a written authorization containing the following:

(A) The name and signature of the employee authorizing the release of medical information,

(B) The date of the written authorization,

(C) The name of the individual or organization that is authorized to release the medical information,

(D) The name of the designated representative (individual or organization) that is authorized to receive the released information,

(E) A general description of the medical information that is authorized to be released,

(F) A general description of the purpose for the release of the medical information, and

(G) A date or condition upon which the written authorization will expire (if less than one year).

(ii) A written authorization does not operate to authorize the release of medical information not in existence on the date of written authorization, unless the release of future information is expressly authorized, and does not operate for more than one year from the date of written authorization.

(iii) A written authorization may be revoked in writing prospectively at any time.

(13) *Toxic substance or harmful physical agent* means any chemical substance, biological agent (bacteria, virus, fungus, etc.), or physical stress (noise, heat, cold, vibration, repetitive motion, ionizing and non-ionizing radiation, hypo-or hyperbaric pressure, etc.) which:

(i) Is listed in the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS), which is incorporated by reference as specified in §1910.6; or

(ii) Has yielded positive evidence of an acute or chronic health hazard in testing conducted by, or known to, the employer; or

(iii) Is the subject of a material safety data sheet kept by or known to the employer indicating that the material may pose a hazard to human health.

(14) *Trade secret* means any confidential formula, pattern, process, device, or information or compilation of information that is used in an employer's business and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it.

(d) *Preservation of records.*

(1) Unless a specific occupational safety and health standard provides a different period of time, each employer shall assure the preservation and retention of records as follows:

(i) *Employee medical records.* The medical record for each employee shall be preserved and maintained for at least the duration of employment plus thirty (30) years, except that the following types of records need not be retained for any specified period:

(A) Health insurance claims records maintained separately from the employer's medical program and its records,

(B) First aid records (not including medical histories) of one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters, and the like which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job, if made on-site by a non-physician and if maintained separately from the employer's medical program and its records, and

(C) The medical records of employees who have worked for less than (1) year for the employer need not be retained beyond the term of employment if they are provided to the employee upon the termination of employment.

(ii) *Employee exposure records.* Each employee exposure record shall be preserved and maintained for at least thirty (30) years, except that:

(A) Background data to environmental (workplace) monitoring or measuring, such as laboratory reports and worksheets, need only be retained for one (1) year as long as the sampling results, the collection methodology (sampling plan), a description of the analytical and mathematical methods used, and a summary of other background data relevant to interpretation of the results obtained, are retained for at least thirty (30) years; and

(B) Material safety data sheets and paragraph (c)(5)(iv) records concerning the identity of a substance or agent need not be retained for any specified period as long as some record of the identity (chemical name if known) of the substance or agent, where it was used, and when it was used is retained for at least thirty (30) years;¹ and

¹ Material safety data sheets must be kept for those chemicals currently in use that are effected by the Hazard Communication Standard in accordance with 29 CFR 1910.1200(g).

(C) Biological monitoring results designated as exposure records by specific occupational safety and health standards shall be preserved and maintained as required by the specific standard.

(iii) *Analyses using exposure or medical records.* Each analysis using exposure or medical records shall be preserved and maintained for at least thirty (30) years.

(2) Nothing in this section is intended to mandate the form, manner, or process by which an employer preserves a record as long as the information contained in the record is preserved and retrievable, except that chest X-ray films shall be preserved in their original state.

(e) *Access to records* —

(1) *General.*

(i) Whenever an employee or designated representative requests access to a record, the employer shall assure that access is provided in a reasonable time, place, and

manner. If the employer cannot reasonably provide access to the record within fifteen (15) working days, the employer shall within the fifteen (15) working days apprise the employee or designated representative requesting the record of the reason for the delay and the earliest date when the record can be made available.

(ii) The employer may require of the requester only such information as should be readily known to the requester and which may be necessary to locate or identify the records being requested (e.g. dates and locations where the employee worked during the time period in question).

(iii) Whenever an employee or designated representative requests a copy of a record, the employer shall assure that either:

(A) A copy of the record is provided without cost to the employee or representative,

(B) The necessary mechanical copying facilities (e.g., photocopying) are made available without cost to the employee or representative for copying the record, or

(C) The record is loaned to the employee or representative for a reasonable time to enable a copy to be made.

(iv) In the case of an original X-ray, the employer may restrict access to on-site examination or make other suitable arrangements for the temporary loan of the X-ray.

(v) Whenever a record has been previously provided without cost to an employee or designated representative, the employer may charge reasonable, non-discriminatory administrative costs (i.e., search and copying expenses but not including overhead expenses) for a request by the employee or designated representative for additional copies of the record, except that

(A) An employer shall not charge for an initial request for a copy of new information that has been added to a record which was previously provided; and

(B) An employer shall not charge for an initial request by a recognized or certified collective bargaining agent for a copy of an employee exposure record or an analysis using exposure or medical records.

(vi) Nothing in this section is intended to preclude employees and collective bargaining agents from collectively bargaining to obtain access to information in addition to that available under this section.

(2) *Employee and designated representative access —*

(i) *Employee exposure records.*

(A) Except as limited by paragraph (f) of this section, each employer shall, upon request, assure the access to each employee and designated representative to employee exposure records relevant to the employee. For the purpose of this section, an exposure record relevant to the employee consists of:

(1) A record which measures or monitors the amount of a toxic substance or harmful physical agent to which the employee is or has been exposed;

(2) In the absence of such directly relevant records, such records of other employees with past or present job duties or working conditions related to or similar to those of the employee to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents to which the employee is or has been subjected, and

(3) Exposure records to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents at workplaces or under working conditions to which the employee is being assigned or transferred.

(B) Requests by designated representatives for unconsented access to employee exposure records shall be in writing and shall specify with reasonable particularity:

(1) The records requested to be disclosed; and

(2) The occupational health need for gaining access to these records.

(ii) *Employee medical records.*

(A) Each employer shall, upon request, assure the access of each employee to employee medical records of which the employee is the subject, except as provided in paragraph (e)(2)(ii)(D) of this section.

(B) Each employer shall, upon request, assure the access of each designated representative to the employee medical records of any employee who has given the designated representative specific written consent. Appendix A to this section contains a sample form which may be used to establish specific written consent for access to employee medical records.

(C) Whenever access to employee medical records is requested, a physician representing the employer may recommend that the employee or designated representative:

(1) Consult with the physician for the purposes of reviewing and discussing the records requested,

(2) Accept a summary of material facts and opinions in lieu of the records requested, or

(3) Accept release of the requested records only to a physician or other designated representative.

(D) Whenever an employee requests access to his or her employee medical records, and a physician representing the employer believes that direct employee access to information contained in the records regarding a specific diagnosis of a terminal illness or a psychiatric condition could be detrimental to the employee's health, the employer may inform the employee that access will only be provided to a designated representative of the employee having specific written consent, and deny the employee's request for direct access to this information only. Where a designated representative with specific written consent requests access to information so withheld, the employer shall assure the access of the designated representative to this information, even when it is known that the designated representative will give the information to the employee.

(E) A physician, nurse, or other responsible health care personnel maintaining medical records may delete from requested medical records the identity of a family member, personal friend, or fellow employee who has provided confidential information concerning an employee's health status.

(iii) *Analyses using exposure or medical records.*

(A) Each employee shall, upon request, assure the access of each employee and designated representative to each analysis using exposure or medical records concerning the employee's working conditions or workplace.

(B) Whenever access is requested to an analysis which reports the contents of employee medical records by either direct identifier (name, address, social security number, payroll number, etc.) or by information which could reasonably be used under the circumstances indirectly to identify specific employees (exact age, height, weight, race, sex, date of initial employment, job title, etc.), the employer shall assure that personal identifiers are removed before access is provided. If the employer can demonstrate that removal of personal identifiers from an analysis is not feasible, access to the personally identifiable portions of the analysis need not be provided.

(3) *OSHA access.*

(i) Each employer shall, upon request, and without derogation of any rights under the Constitution or the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*, that the employer chooses to exercise, assure the prompt access of representatives of the Assistant Secretary of Labor for Occupational Safety and Health to employee exposure and medical records and to analyses using exposure or medical records. Rules of agency practice and procedure governing OSHA access to employee medical records are contained in 29 CFR 1913.10.

(ii) Whenever OSHA seeks access to personally identifiable employee medical information by presenting to the employer a written access order pursuant to 29 CFR

1913.10(d), the employer shall prominently post a copy of the written access order and its accompanying cover letter for at least fifteen (15) working days.

(f) *Trade secrets.*

(1) Except as provided in paragraph (f)(2) of this section, nothing in this section precludes an employer from deleting from records requested by a health professional, employee, or designated representative any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in mixture, as long as the health professional, employee, or designated representative is notified that information has been deleted. Whenever deletion of trade secret information substantially impairs evaluation of the place where or the time when exposure to a toxic substance or harmful physical agent occurred, the employer shall provide alternative information which is sufficient to permit the requesting party to identify where and when exposure occurred.

(2) The employer may withhold the specific chemical identity, including the chemical name and other specific identification of a toxic substance from a disclosable record provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) All other available information on the properties and effects of the toxic substance is disclosed;

(iii) The employer informs the requesting party that the specific chemical identity is being withheld as a trade secret; and

(iv) The specific chemical identity is made available to health professionals, employees and designated representatives in accordance with the specific applicable provisions of this paragraph.

(3) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a toxic substance is necessary for emergency or first-aid treatment, the employer shall immediately disclose the specific chemical identity of a trade secret chemical to the treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (f)(4) and (f)(5), as soon as circumstances permit.

(4) In non-emergency situations, an employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (f)(2) of this section, to a health professional, employee, or designated representative if:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information would not enable the health professional, employee or designated representative to provide the occupational health services described in paragraph (f)(4)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, employee, or designated representative and the employer or contractor of the services of the health professional or designated representative agree in a written confidentiality agreement that the health professional, employee or designated representative will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (f)(7) of this section, except as authorized by the terms of the agreement or by the employer.

(5) The confidentiality agreement authorized by paragraph (f)(4)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(6) Nothing in this section is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(7) If the health professional, employee or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the employer who provided the information shall be informed by the health professional prior to, or at the same time as, such disclosure.

(8) If the employer denies a written request for disclosure of a specific chemical identity, the denial must:

(i) Be provided to the health professional, employee or designated representative within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

(9) The health professional, employee, or designated representative whose request for information is denied under paragraph (f)(4) of this section may refer the request and the written denial of the request to OSHA for consideration.

(10) When a health professional employee, or designated representative refers a denial to OSHA under paragraph (f)(9) of this section, OSHA shall consider the evidence to determine if:

(i) The employer has supported the claim that the specific chemical identity is a trade secret;

(ii) The health professional employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and

(iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

(11)

(i) If OSHA determines that the specific chemical identity requested under paragraph (f)(4) of this section is not a *bona fide* trade secret, or that it is a trade secret but the requesting health professional, employee or designated representatives has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means for complying with the terms of such agreement, the employer will be subject to citation by OSHA.

(ii) If an employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health needs are met without an undue risk of harm to the employer.

(12) Notwithstanding the existence of a trade secret claim, an employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is trade secret.

(g) *Employee information.*

(1) Upon an employee's first entering into employment, and at least annually thereafter, each employer shall inform current employees covered by this section of the following:

(i) The existence, location, and availability of any records covered by this section;

(ii) The person responsible for maintaining and providing access to records; and

(iii) Each employee's rights of access to these records.

(2) Each employer shall keep a copy of this section and its appendices, and make copies readily available, upon request, to employees. The employer shall also distribute to current employees any informational materials concerning this section which are made available to the employer by the Assistant Secretary of Labor for Occupational Safety and Health.

(h) *Transfer of records.*

(1) Whenever an employer is ceasing to do business, the employer shall transfer all records subject to this section to the successor employer. The successor employer shall receive and maintain these records.

(2) Whenever an employer is ceasing to do business and there is no successor employer to receive and maintain the records subject to this standard, the employer shall notify affected current employees of their rights of access to records at least three (3) months prior to the cessation of the employer's business.

(i) *Appendices.* The information contained in appendices A and B to this section is not intended, by itself, to create any additional obligations not otherwise imposed by this section nor detract from any existing obligation.

Appendix A to §1910.1020—Sample Authorization Letter for the Release of Employee Medical Record Information to a Designated Representative (Non-Mandatory)

I, _____ (full name of worker/patient), hereby authorize _____ (individual or organization holding the medical records) to release to _____ (individual or organization authorized to receive the medical information), the following medical information from my personal medical records:

(Describe generally the information desired to be released)

I give my permission for this medical information to be used for the following purpose:

but I do not give permission for any other use or re-disclosure of this information.

Note: Several extra lines are provided below so that you can place additional restrictions on this authorization letter if you want to. You may, however, leave these lines blank. On the other hand, you may want to (1) specify a particular expiration date for this letter (if less than one year); (2) describe medical information to be created in the future that you intend to be covered by this authorization letter; or (3) describe portions of the medical information in your records which you do not intend to be released as a result of this letter.)

Full name of Employee or Legal Representative

Signature of Employee or Legal Representative

Date of Signature

Appendix B to §1910.1020—Availability of NIOSH Registry of Toxic Effects of Chemical Substances (RTECS) (Non-Mandatory)

The final regulation, 29 CFR 1910.1020, applies to all employee exposure and medical records, and analyses thereof, of employees exposed to toxic substances or harmful physical agents (paragraph (b)(2)). The term *toxic substance or harmful physical agent* is defined by paragraph (c)(13) to encompass chemical substances, biological agents, and physical stresses for which there is evidence of harmful health effects. The regulation uses the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS) as one of the chief sources of information as to whether evidence of harmful health effects exists. If a substance is listed in the latest printed RTECS, the regulation applies to exposure and medical records (and analyses of these records) relevant to employees exposed to the substance.

It is appropriate to note that the final regulation does not require that employers purchase a copy of RTECS, and many employers need not consult RTECS to ascertain whether their employee exposure or medical records are subject to the rule. Employers who do not currently have the latest printed edition of the NIOSH RTECS, however, may desire to obtain a copy. The RTECS is issued in an annual printed edition as mandated by section 20(a)(6) of the Occupational Safety and Health Act (29 U.S.C. 669(a)(6)).

The Introduction to the 1980 printed edition describes the RTECS as follows:

“The 1980 edition of the Registry of Toxic Effects of Chemical Substances, formerly known as the Toxic Substances list, is the ninth revision prepared in compliance with the requirements of Section 20(a)(6) of the Occupational Safety and Health Act of 1970 (Public Law 91–596). The original list was completed on June 28, 1971, and has been updated annually in book format. Beginning in October 1977, quarterly revisions have been provided in microfiche. This edition of the Registry contains 168,096 listings of chemical substances: 45,156 are names of different chemicals with their associated toxicity data and 122,940 are synonyms. This edition includes approximately 5,900 new chemical compounds that did not appear in the 1979 Registry. (p. xi)

“The Registry's purposes are many, and it serves a variety of users. It is a single source document for basic toxicity information and for other data, such as chemical identifiers and information necessary for the preparation of safety directives and hazard evaluations for chemical substances. The various types of toxic effects linked to literature citations provide researchers and occupational health scientists with an introduction to the toxicological literature, making their own review of the toxic hazards of a given substance easier. By presenting data on the lowest reported doses that produce effects by several routes of entry in various species, the Registry furnishes valuable information to those responsible for preparing safety data sheets for chemical substances in the workplace. Chemical and production engineers can use the Registry to identify the hazards which may be associated with chemical intermediates in the development of final products, and thus can more readily select substitutes or alternative processes which may be less hazardous. Some organizations, including health agencies and chemical companies, have included the NIOSH Registry accession numbers with the listing of chemicals in their files to reference toxicity information associated with those chemicals. By including foreign language chemical names, a start has been made toward providing rapid identification of substances produced in other countries. (p. xi)

“In this edition of the Registry, the editors intend to identify “all known toxic substances” which may exist in the environment and to provide pertinent data on the toxic effects from known doses entering an organism by any route described. (p xi)

“It must be reemphasized that the entry of a substance in the Registry does not automatically mean that it must be avoided. A listing does mean, however, that the substance has the documented potential of being harmful if misused, and care must be exercised to prevent tragic consequences. Thus, the Registry lists many substances that are common in everyday life and are in nearly every household in the United States. One can name a variety of such dangerous substances: prescription and non-prescription drugs; food additives; pesticide concentrates, sprays, and dusts; fungicides; herbicides; paints; glazes, dyes; bleaches and other household cleaning agents; alkalies; and various solvents and diluents. The list is extensive because chemicals have become an integral part of our existence.”

The RTECS printed edition may be purchased from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402 (202-783-3238).

Some employers may desire to subscribe to the quarterly update to the RTECS which is published in a microfiche edition. An annual subscription to the quarterly microfiche may be purchased from the GPO (Order the “Microfiche Edition, Registry of Toxic Effects of Chemical Substances”). Both the printed edition and the microfiche edition of RTECS are available for review at many university and public libraries throughout the country. The latest RTECS editions may also be examined at the OSHA Technical Data Center, Room N2439—Rear, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (202-523-9700), or at any OSHA Regional or Area Office (*See*, major city telephone directories under United States Government-Labor Department).

[53 FR 38163, Sept. 29, 1988; 53 FR 49981, Dec. 13, 1988, as amended at 54 FR 24333, June 7, 1989; 55 FR 26431, June 28, 1990; 61 FR 9235, Mar. 7, 1996. Redesignated at 61 FR 31430, June 20, 1996, as amended at 71 FR 16673, Apr. 3, 2006]

1910.1025 Lead. CPL 2-2.47

(a) Scope and application.

(1) This section applies to all occupational exposure to lead, except as provided in paragraph (a)(2).

(2) This section does not apply to the construction industry or to agricultural operations covered by 29 CFR Part 1928.

(b) Definitions. "Action level" means employee exposure, without regard to the use of respirators, to an airborne concentration of lead of 30 micrograms per cubic meter of air (30 ug/m(3)) averaged over an 8-hour period.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Director" means the Director, National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health, Education, and Welfare, or designee.

"Lead" means metallic lead, all inorganic lead compounds, and organic lead soaps. Excluded from this definition are all other organic lead compounds.

(c) Permissible exposure limit (PEL).

(1) The employer shall assure that no employee is exposed to lead at concentrations greater than fifty micrograms per cubic meter of air (50 ug/m(3)) averaged over an 8-hour period.

(2) If an employee is exposed to lead for more than 8 hours in any work day, the permissible exposure limit, as a time weighted average (TWA) for that day, shall be reduced according to the following formula:

Maximum permissible limit (in ug/m(3))=400 divided by hours worked in the day.

(3) When respirators are used to supplement engineering and work practice controls to comply with the PEL and all the requirements of paragraph (f) have been met, employee exposure, for

the purpose of determining whether the employer has complied with the PEL, may be considered to be at the level provided by the protection factor of the respirator for those periods the respirator is worn. Those periods may be averaged with exposure levels during periods when respirators are not worn to determine the employee's daily TWA exposure.

(d) Exposure monitoring

(1) General.

(i) For the purposes of paragraph (d), employee exposure is that exposure which would occur if the employee were not using a respirator.

(ii) With the exception of monitoring under paragraph (d)(3), the employer shall collect full shift (for at least 7 continuous hours) personal samples including at least one sample for each shift for each job classification in each work area.

(iii) Full shift personal samples shall be representative of the monitored employee's regular, daily exposure to lead.

(2) Initial determination. Each employer who has a workplace or work operation covered by this standard shall determine if any employee may be exposed to lead at or above the action level.

(3) Basis of initial determination.

(i) The employer shall monitor employee exposures and shall base initial determinations on the employee exposure monitoring results and any of the following, relevant considerations:

(A) Any information, observations, or calculations which would indicate employee exposure to lead;

(B) Any previous measurements of airborne lead; and

(C) Any employee complaints of symptoms which may be attributable to exposure to lead.

(ii) Monitoring for the initial determination may be limited to a representative sample of the exposed employees who the employer reasonably believes are exposed to the greatest airborne concentrations of lead in the workplace.

(iii) Measurements of airborne lead made in the preceding 12 months may be used to satisfy the requirement to monitor under paragraph (d)(3)(i) if the sampling and analytical methods used meet the accuracy and confidence levels of paragraph (d)(9) of this section.

(4) Positive initial determination and initial monitoring.

(i) Where a determination conducted under paragraphs (d) (2) and (3) of this section shows the possibility of any employee exposure at or above the action level, the employer shall conduct monitoring which is representative of the exposure for each employee in the workplace who is exposed to lead.

(ii) Measurements of airborne lead made in the preceding 12 months may be used to satisfy this requirement if the sampling and analytical methods used meet the accuracy and confidence levels of paragraph (d)(9) of this section.

(5) Negative initial determination. Where a determination, conducted under paragraphs (d) (2) and (3) of this section is made that no employee is exposed to airborne concentrations of lead at or above the action level, the employer shall make a written record of such determination. The record shall include at least the information specified in paragraph (d)(3) of this section and shall also include the date of determination, location within the worksite, and the name and social security number of each employee monitored.

(6) Frequency.

(i) If the initial monitoring reveals employee exposure to be below the action level the measurements need not be repeated except as otherwise provided in paragraph (d)(7) of this section.

(ii) If the initial determination or subsequent monitoring reveals employee exposure to be at or above the action level but below the permissible exposure limit the employer shall repeat monitoring in accordance with this paragraph at least every 6 months. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level at which time the employer may discontinue monitoring for that employee except as otherwise provided in paragraph (d)(7) of this section.

(iii) If the initial monitoring reveals that employee exposure is above the permissible exposure limit the employer shall repeat monitoring quarterly. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the PEL but at or above the action level at which time the employer shall repeat monitoring for that employee at the frequency specified in paragraph (d)(6)(ii), except as otherwise provided in paragraph (d)(7) of this section.

(7) Additional monitoring. Whenever there has been a production, process, control or personnel change which may result in new or additional exposure to lead, or whenever the employer has any other reason to suspect a change which may result in new or additional

exposures to lead, additional monitoring in accordance with this paragraph shall be conducted.

(8) Employee notification.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to affected employees.

(ii) Whenever the results indicate that the representative employee exposure, without regard to respirators, exceeds the permissible exposure limit, the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the corrective action taken or to be taken to reduce exposure to or below the permissible exposure limit.

(9) Accuracy of measurement. The employer shall use a method of monitoring and analysis which has an accuracy (to a confidence level of 95%) of not less than plus or minus 20 percent for airborne concentrations of lead equal to or greater than 30 ug/m(3).

(e) Methods of compliance

(1) Engineering and work practice controls.

(i) Where any employee is exposed to lead above the permissible exposure limit for more than 30 days per year, the employer shall implement engineering and work practice controls (including administrative controls) to reduce and maintain employee exposure to lead in accordance with the implementation schedule in Table I below, except to the extent that the employer can demonstrate that such controls are not feasible. Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposure to or below the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest feasible level and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (f) of this section.

(ii) Where any employee is exposed to lead above the permissible exposure limit, but for 30 days or less per year, the employer shall implement engineering controls to reduce exposures to 200 ug/m(3), but thereafter may implement any combination of engineering, work practice (including administrative controls), and respiratory controls to reduce and maintain employee exposure to lead to or below 50 ug/m(3)

TABLE I

| Industry | Compliance dates(1): (50 UG/M(3)) |
|---|--------------------------------------|
| Lead chemicals, secondary copper smeting. | July 19, 1996. |
| Nonferrous foundries. | July 19, 1996(2). |
| Brass and bronze ingot manufacture. | 6 years(3). |

Footnote(1) Calculated by counting from the date the stay on implementation of paragraph (e)(1) was lifted by the U.S. Court of Appeals for the District of Columbia, the number of years specified in the 1978 lead standard and subsequent amendments for compliance with the PEL of 50 ug/m(3) for exposure to airborne concentrations of lead levels for the particular industry.

Footnote(2) Large nonferrous foundries (20 or more employees) are required to achieve the PEL of 50 ug/m(3) by means of engineering and work practice controls. Small nonferrous foundries (fewer than 20 employees) are required to achieve an 8-hour TWA of 75 ug/m(3) by such controls.

Footnote(3) Expressed as the number of years from the date on which the Court lifts the stay on the implementation of paragraph (e)(1) for this industry for employers to achieve a lead in air concentration of 75 ug/m(3). Compliance with paragraph (e) in this industry is determined by a compliance directive that incorporates elements from the settlement agreement between OSHA and representatives of the injury. are required to comply within five years.

(2) Respiratory protection. Where engineering and work practice controls do not reduce employee exposure to or below the 50 ug/m(3) permissible exposure limit, the employer shall supplement these controls with respirators in accordance with paragraph (f).

(3) Compliance program.

(i) Each employer shall establish and implement a written compliance program to reduce exposures to or below the permissible exposure limit, and interim levels if applicable, solely by means of engineering and work practice controls in accordance with the implementation schedule in paragraph (e)(1).

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation in which lead is emitted; e.g. machinery used, material processed, controls in place, crew size, employee job responsibilities, operating procedures and maintenance practices;

(B) A description of the specific means that will be employed to achieve compliance,

including engineering plans and studies used to determine methods selected for controlling exposure to lead;

(C) A report of the technology considered in meeting the permissible exposure limit;

(D) Air monitoring data which documents the source of lead emissions;

(E) A detailed schedule for implementation of the program, including documentation such as copies of purchase orders for equipment, construction contracts, etc.;

(F) A work practice program which includes items required under paragraphs (g), (h) and (i) of this regulation;

(G) An administrative control schedule required by paragraph (e)(6), if applicable;

(H) Other relevant information.

(iii) Written programs shall be submitted upon request to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, Director, any affected employee or authorized employee representatives.

(iv) Written programs must be revised and updated at least annually to reflect the current status of the program.

(4) Mechanical ventilation.

(i) When ventilation is used to control exposure, measurements which demonstrate the effectiveness of the system in controlling exposure, such as capture velocity, duct velocity, or static pressure shall be made at least every 3 months. Measurements of the system's effectiveness in controlling exposure shall be made within 5 days of any change in production, process, or control which might result in a change in employee exposure to lead.

(ii) Recirculation of air. If air from exhaust ventilation is recirculated into the workplace, the employer shall assure that (A) the system has a high efficiency filter with reliable back-up filter; and (B) controls to monitor the concentration of lead in the return air and to bypass the recirculation system automatically if it fails are installed, operating, and maintained.

(5) Administrative controls. If administrative controls are used as a means of reducing employees TWA exposure to lead, the employer shall establish and implement a job rotation schedule which includes:

(i) Name or identification number of each affected employee;

(ii) Duration and exposure levels at each job or work station where each affected employee is located; and

(iii) Any other information which may be useful in assessing the reliability of administrative controls to reduce exposure to lead.

(f) Respiratory protection

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement engineering or work-practice controls.

(ii) Work operations for which engineering and work-practice controls are not sufficient to reduce employee exposures to or below the permissible exposure limit.

(iii) Periods when an employee requests a respirator.

(2) Respirator program.

(i) The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) If an employee has breathing difficulty during fit testing or respirator use, the employer must provide the employee with a medical examination in accordance with paragraph (j) (3)(i)(C) of this section to determine whether or not the employee can use a respirator while performing the required duty.

(3) Respirator selection.

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with full facepiece respirators instead of half mask respirators for protection against lead aerosols that cause eye or skin irritation at the use concentrations.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.

(ii) Employers must provide employees with a powered air-purifying respirator (PAPR) instead of a negative pressure respirator selected according to paragraph (f)(3)(i) of this standard when an employee chooses to use a PAPR and it provides adequate protection to the employee as specified by paragraph (f)(3)(i) of this standard.

(g) Protective work clothing and equipment

(1) Provision and use. If an employee is exposed to lead above the PEL, without regard to the use of respirators or where the possibility of skin or eye irritation exists, the employer shall provide at no cost to the employee and assure that the employee uses appropriate protective work clothing and equipment such as, but not limited to:

(i) Coveralls or similar full-body work clothing;

(ii) Gloves, hats, and shoes or disposable shoe coverlets; and

(iii) Face shields, vented goggles, or other appropriate protective equipment which complies with 1910.133 of this Part.

(2) Cleaning and replacement.

(i) The employer shall provide the protective clothing required in paragraph (g)(1) of this section in a clean and dry condition at least weekly, and daily to employees whose exposure levels without regard to a respirator are over 200 $\mu\text{g}/\text{m}^3$ of lead as an 8-hour TWA.

(ii) The employer shall provide for the cleaning, laundering, or disposal of protective clothing and equipment required by paragraph (g)(1) of this section.

(iii) The employer shall repair or replace required protective clothing and equipment as needed to maintain their effectiveness.

(iv) The employer shall assure that all protective clothing is removed at the completion of a work shift only in change rooms provided for that purpose as prescribed in paragraph (i)(2) of this section.

(v) The employer shall assure that contaminated protective clothing which is to be cleaned, laundered, or disposed of, is placed in a closed container in the change-room which prevents dispersion of lead outside the container.

(vi) ~~The employer shall inform in writing any person who cleans or launders protective clothing or equipment of the potentially harmful effects of exposure to lead.~~ Labeling of contaminated protective clothing and equipment.

(vii)(A) The employer shall ~~assure~~ ensure that labels of bags or that the containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) are labelled as include the following information:

~~CAUTION Danger: CLOTHING CONTAMINATED WITH LEAD. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.~~
DANGER: CLOTHING AND EQUIPMENT CONTAMINATED WITH LEAD. MAY DAMAGE FERTILITY OR THE UNBORN CHILD. CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM. DO NOT EAT, DRINK OR SMOKE WHEN HANDLING. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

(B) Prior to June 1, 2015, employers may include the following information on bags or containers of contaminated protective clothing and equipment in lieu of the labeling requirements in paragraphs (g)(2)(vii)(A) of this section:

CAUTION: CLOTHING CONTAMINATED WITH LEAD. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

(viii) The employer shall prohibit the removal of lead from protective clothing or equipment by blowing, shaking, or any other means which disperses lead into the air.

(h) Housekeeping

(1) Surfaces. All surfaces shall be maintained as free as practicable of accumulations of lead.

(2) Cleaning floors.

(i) Floors and other surfaces where lead accumulates may not be cleaned by the use of compressed air.

(ii) Shoveling, dry or wet sweeping, and brushing may be used only where vacuuming or other equally effective methods have been tried and found not to be effective.

(3) Vacuuming. Where vacuuming methods are selected, the vacuums shall be used and emptied in a manner which minimizes the reentry of lead into the workplace.

(i) Hygiene facilities and practices.

(1) The employer shall assure that in areas where employees are exposed to lead above the PEL, without regard to the use of respirators, food or beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied, except in change rooms, lunchrooms, and showers required under paragraphs (i)(2) - through (i)(4) of this section.

(2) Change rooms.

(i) The employer shall provide clean change rooms for employees who work in areas where their airborne exposure to lead is above the PEL, without regard to the use of respirators.

(ii) The employer shall assure that change rooms are equipped with separate storage facilities for protective work clothing and equipment and for street clothes which prevent cross-contamination.

(3) Showers.

(i) The employer shall assure that employees who work in areas where their airborne exposure to lead is above the PEL, without regard to the use of respirators, shower at the end of the work shift.

(ii) The employer shall provide shower facilities in accordance with 1910.141 (d)(3) of this part.

(iii) The employer shall assure that employees who are required to shower pursuant to paragraph (i)(3)(i) do not leave the workplace wearing any clothing or equipment worn during the work shift.

(4) Lunchrooms.

(i) The employer shall provide lunchroom facilities for employees who work in areas where their airborne exposure to lead is above the PEL, without regard to the use of respirators.

(ii) The employer shall assure that lunchroom facilities have a temperature controlled, positive pressure, filtered air supply, and are readily accessible to employees.

(iii) The employer shall assure that employees who work in areas where their airborne exposure to lead is above the PEL without regard to the use of a respirator wash their hands and face prior to eating, drinking, smoking or applying cosmetics.

(iv) The employer shall assure that employees do not enter lunchroom facilities with protective work clothing or equipment unless surface lead dust has been removed by vacuuming, downdraft booth, or other cleaning method.

(5) Lavatories. The employer shall provide an adequate number of lavatory facilities which comply with 1910.141(d) (1) and (2) of this part.

(j) Medical surveillance

(1) General.

(i) The employer shall institute a medical surveillance program for all employees who are or may be exposed at or above the action level for more than 30 days per year.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician.

(iii) The employer shall provide the required medical surveillance including multiple physician review under paragraph (j)(3)(iii) without cost to employees and at a reasonable time and place.

(2) Biological monitoring

(i) Blood lead and ZPP level sampling and analysis. The employer shall make available biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin levels to each employee covered under paragraph (j)(1)(i) of this section on the following schedule:

(A) At least every 6 months to each employee covered under paragraph (j)(1)(i) of this section;

(B) At least every two months for each employee whose last blood sampling and analysis indicated a blood lead level at or above 40 ug/100 g of whole blood. This frequency shall continue until two consecutive blood samples and analyses indicate a blood lead level below 40 ug/100 g of whole blood; and

(C) At least monthly during the removal period of each employee removed from exposure to lead due to an elevated blood lead level.

(ii) Follow-up blood sampling tests. Whenever the results of a blood lead level test indicate that an employee's blood lead level is at or above the numerical criterion for medical removal under paragraph (k)(1)(i)(A) of this section, the employer shall provide a second (follow-up) blood sampling test within two weeks after the employer receives the results of the first blood sampling test.

(iii) Accuracy of blood lead level sampling and analysis. Blood lead level sampling and analysis provided pursuant to this section shall have an accuracy (to a confidence level of 95 percent) within plus or minus 15 percent or 6 ug/100ml, whichever is greater, and shall be conducted by a laboratory licensed by the Center for Disease Control, United States Department of Health, Education and Welfare (CDC) or which has received a satisfactory grade in blood lead proficiency testing from CDC in the prior twelve months.

(iv) Employee notification. Within five working days after the receipt of biological monitoring results, the employer shall notify in writing each employee whose blood lead level is at or above 40 ug/100 g:

(A) of that employee's blood lead level; and

(B) that the standard requires temporary medical removal with Medical Removal Protection benefits when an employee's blood lead level exceeds the numerical criterion for medical removal under paragraph (k)(1)(i) of this section.

(3) Medical examinations and consultations

(i) Frequency. The employer shall make available medical examinations and consultations to each employee covered under paragraph (j)(1)(i) of this section on the following schedule:

(A) At least annually for each employee for whom a blood sampling test conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 ug/100 g;

(B) Prior to assignment for each employee being assigned for the first time to an area in which airborne concentrations of lead are at or above the action level;

(C) As soon as possible, upon notification by an employee either that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice concerning the effects of current or past exposure to lead on the employee's ability to procreate a healthy child, or that the employee has demonstrated difficulty in breathing during a respirator fitting test or during use; and

(D) As medically appropriate for each employee either removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited pursuant to a final medical determination.

(ii) Content. Medical examinations made available pursuant to paragraph (j)(3)(i)(A)-(B) of this section shall include the following elements:

(A) A detailed work history and a medical history, with particular attention to past lead exposure (occupational and non-occupational), personal habits (smoking, hygiene), and past gastrointestinal, hematologic, renal, cardiovascular, reproductive and neurological problems;

(B) A thorough physical examination, with particular attention to teeth, gums, hematologic, gastrointestinal, renal, cardiovascular, and neurological systems. Pulmonary status should be evaluated if respiratory protection will be used;

(C) A blood pressure measurement;

(D) A blood sample and analysis which determines:

(1) Blood lead level;

(2) Hemoglobin and hematocrit determinations, red cell indices, and examination of peripheral smear morphology;

(3) Zinc protoporphyrin;

(4) Blood urea nitrogen; and,

(5) Serum creatinine;

(E) A routine urinalysis with microscopic examination; and

(F) Any laboratory or other test which the examining physician deems necessary by sound medical practice. The content of medical examinations made available pursuant to paragraph (j)(3)(i)(C) - (D) of this section shall be determined by an examining physician and, if requested by an employee, shall include pregnancy testing or laboratory evaluation of male fertility.

(iii) Multiple physician review mechanism.

(A) If the employer selects the initial physician who conducts any medical examination or consultation provided to an employee under this section, the employee may designate a second physician:

(1) To review any findings, determinations or recommendations of the initial physician; and

(2) To conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

(B) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation pursuant to this section. The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the foregoing notification, or receipt of the initial physician's written opinion, whichever is later:

(1) The employee informing the employer that he or she intends to seek a second medical opinion, and

(2) The employee initiating s to make an appointment with a second physician.

(C) If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve any disagreement.

(D) If the two physicians have been unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician:

(1) To review any findings, determinations or recommendations of the prior physicians; and

(2) To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(E) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(iv) Information provided to examining and consulting physicians.

(A) The employer shall provide an initial physician conducting a medical examination or consultation under this section with the following information:

(1) A copy of this regulation for lead including all Appendices;

(2) A description of the affected employee's duties as they relate to the employee's exposure;

(3) The employee's exposure level or anticipated exposure level to lead and to

any other toxic substance (if applicable);

(4) A description of any personal protective equipment used or to be used;

(5) Prior blood lead determinations; and

(6) All prior written medical opinions concerning the employee in the employer's possession or control.

(B) The employer shall provide the foregoing information to a second or third physician conducting a medical examination or consultation under this section upon request either by the second or third physician, or by the employee.

(v) Written medical opinions.

(A) The employer shall obtain and furnish the employee with a copy of a written medical opinion from each examining or consulting physician which contains the following information:

(1) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at increased risk of material impairment of the employee's health from exposure to lead;

(2) Any recommended special protective measures to be provided to the employee, or limitations to be placed upon the employee's exposure to lead;

(3) Any recommended limitation upon the employee's use of respirators, including a determination of whether the employee can wear a powered air purifying respirator if a physician determines that the employee cannot wear a negative pressure respirator; and

(4) The results of the blood lead determinations.

(B) The employer shall instruct each examining and consulting physician to:

(1) Not reveal either in the written opinion, or in any other means of communication with the employer, findings, including laboratory results, or diagnoses unrelated to an employee's occupational exposure to lead; and

(2) Advise the employee of any medical condition, occupational or nonoccupational, which dictates further medical examination or treatment.

(vi) Alternate Physician Determination Mechanisms. The employer and an employee or authorized employee representative may agree upon the use of any expeditious alternate physician determination mechanism in lieu of the multiple physician review mechanism provided

by this paragraph so long as the alternate mechanism otherwise satisfies the requirements contained in this paragraph.

(4) Chelation.

(i) The employer shall assure that any person whom he retains, employs, supervises or controls does not engage in prophylactic chelation of any employee at any time.

(ii) If therapeutic or diagnostic chelation is to be performed by any person in paragraph (j)(4)(i), the employer shall assure that it be done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring and that the employee is notified in writing prior to its occurrence.

(k) Medical Removal Protection

(1) Temporary medical removal and return of an employee

(i) Temporary removal due to elevated blood lead levels

(A) The employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 60 ug/100 g of whole blood; and,

(B) The employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that the average of the last three blood sampling tests conducted pursuant to this section (or the average of all blood sampling tests conducted over the previous six (6) months, whichever is longer) indicates that the employee's blood lead level is at or above 50 ug/100 g of whole blood; provided, however, that an employee need not be removed if the last blood sampling test indicates a blood lead level below 40 ug/100 g of whole blood.

(ii) Temporary removal due to a final medical determination.

(A) The employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a final medical determination results in a medical finding, determination, or opinion that the employee has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead.

(B) For the purposes of this section, the phrase "final medical determination" shall mean the outcome of the multiple physician review mechanism or alternate medical determination mechanism used pursuant to the medical surveillance provisions of this section.

(C) Where a final medical determination results in any recommended special protective measures for an employee, or limitations on an employee's exposure to lead, the employer shall implement and act consistent with the recommendation.

(iii) Return of the employee to former job status.

(A) The employer shall return an employee to his or her former job status:

(1) For an employee removed due to a blood lead level at or above 60 ug/100 g, or due to an average blood lead level at or above 50 ug/100 g, when two consecutive blood sampling tests indicate that the employee's blood lead level is below 40 ug/100 g of whole blood;

(2) For an employee removed due to a final medical determination, when a subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead.

(B) For the purposes of this section, the requirement that an employer return an employee to his or her former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

(iv) Removal of other employee special protective measure or limitations. The employer shall remove any limitations placed on an employee or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

(v) Employer options pending a final medical determination. Where the multiple physician review mechanism, or alternate medical determination mechanism used pursuant to the medical surveillance provisions of this section, has not yet resulted in a final medical determination with respect to an employee, the employer shall act as follows:

(A) Removal. The employer may remove the employee from exposure to lead, provide special protective measures to the employee, or place limitations upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status.

(B) Return. The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions. If (1)

the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician or (2) The employee has been on removal status for the preceding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(2) Medical removal protection benefits

(i) Provision of medical removal protection benefits. The employer shall provide to an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

(ii) Definition of medical removal protection benefits. For the purposes of this section, the requirement that an employer provide medical removal protection benefits means that the employer shall maintain the earnings, seniority and other employment rights and benefits of an employee as though the employee had not been removed from normal exposure to lead or otherwise limited.

(iii) Follow-up medical surveillance during the period of employee removal or limitation. During the period of time that an employee is removed from normal exposure to lead or otherwise limited, the employer may condition the provision of medical removal protection benefits upon the employee's participation in follow-up medical surveillance made available pursuant to this section.

(iv) Workers' compensation claims. If a removed employee files a claim for workers' compensation payments for a lead-related disability, then the employer shall continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation shall be reduced by such amount. The employer shall receive no credit for workers' compensation payments received by the employee for treatment related expenses.

(v) Other credits. The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from employment with another employer made possible by virtue of the employee's removal.

(vi) Employees whose blood lead levels do not adequately decline within 18 months of removal. The employer shall take the following measures with respect to any employee removed from exposure to lead due to an elevated blood lead level whose blood lead level has not declined within the past eighteen (18) months of removal so that the employee has been returned to his or her former job status:

(A) The employer shall make available to the employee a medical examination pursuant to this section to obtain a final medical determination with respect to the employee;

(B) The employer shall assure that the final medical determination obtained indicates whether or not the employee may be returned to his or her former job status, and if not, what s should be taken to protect the employee's health;

(C) Where the final medical determination has not yet been obtained, or once obtained indicates that the employee may not yet be returned to his or her former job status, the employer shall continue to provide medical removal protection benefits to the employee until either the employee is returned to former job status, or a final medical determination is made that the employee is incapable of ever safely returning to his or her former job status.

(D) Where the employer acts pursuant to a final medical determination which permits the return of the employee to his or her former job status despite what would otherwise be an unacceptable blood lead level, later questions concerning removing the employee again shall be decided by a final medical determination. The employer need not automatically remove such an employee pursuant to the blood lead level removal criteria provided by this section.

(vii) Voluntary Removal or Restriction of An Employee. Where an employer, although not required by this section to do so, removes an employee from exposure to lead or otherwise places limitations on an employee due to the effects of lead exposure on the employee's medical condition, the employer shall provide medical removal protection benefits to the employee equal to that required by paragraph (k)(2)(i) of this section.

(l) Employee information and training

(1) Training program.

(i) Each employer who has a workplace in which there is a potential exposure to airborne lead at any level shall inform employees of the content of Appendices A and B of this regulation.

(ii) The employer shall train each employee who is subject to exposure to lead at or above the action level, or for whom the possibility of skin or eye irritation exists, in accordance with the requirements of this section. The employer shall institute a training program and ensure employee participation in the program.

(iii) The employer shall provide initial training by 180 days from the effective date for those employees covered by paragraph (l)(1) (ii) on the standard's effective date and prior to the time of initial job assignment for those employees subsequently covered by this paragraph.

(iv) The training program shall be repeated at least annually for each employee.

(v) The employer shall assure that each employee is informed of the following:

(A) The content of this standard and its appendices;

(B) The specific nature of the operations which could result in exposure to lead above the action level;

(C) The purpose, proper selection, fitting, use, and limitations of respirators;

(D) The purpose and a description of the medical surveillance program, and the medical removal protection program including information concerning the adverse health effects associated with excessive exposure to lead (with particular attention to the adverse reproductive effects on both males and females);

(E) The engineering controls and work practices associated with the employee's job assignment;

(F) The contents of any compliance plan in effect; and

(G) Instructions to employees that chelating agents should not routinely be used to remove lead from their bodies and should not be used at all except under the direction of a licensed physician;

(2) Access to information and training materials.

(i) The employer shall make readily available to all affected employees a copy of this standard and its appendices.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(iii) In addition to the information required by paragraph (1)(1)(v), the employer shall include as part of the training program, and shall distribute to employees, any materials pertaining to the Occupational Safety and Health Act, the regulations issued pursuant to that Act, and this lead standard, which are made available to the employer by the Assistant Secretary.

(m) ~~Signs~~Communication of hazards

(1) ~~General~~Hazard communication—general.

(i) ~~The employer may use signs required by other statutes, regulations or ordinances in addition to, or in combination with, signs required by this paragraph.~~ Chemical manufacturers,

importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for lead.

~~(ii) The employer shall assure that no statement appears on or near any sign required by this paragraph which contradicts or detracts from the meaning of the required sign. In classifying the hazards of lead at least the following hazards are to be addressed: Reproductive/developmental toxicity; central nervous system effects; kidney effects; blood effects; and acute toxicity effects.~~

(iii) Employers shall include lead in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of lead and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l) of this section.

(2) Signs.

(i) The employer shall post the following warning signs in each work area where the PEL is exceeded:

WARNING

~~LEAD WORK AREA~~

POISON

~~NO SMOKING OR EATING~~

DANGER

LEAD

MAY DAMAGE FERTILITY OR THE UNBORN CHILD

CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM

DO NOT EAT, DRINK OR SMOKE IN THIS AREA

~~(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible. The employer shall ensure that no statement appears on or near any sign required by this paragraph (m)(2) which contradicts or detracts from the meaning of the required sign.~~

(iii) The employer shall ensure that signs required by this paragraph (m)(2) are illuminated and cleaned as necessary so that the legend is readily visible.

(iv) The employer may use signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs required by this paragraph (m)(2).

(v) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (m)(2)(ii) of this section:

WARNING

LEAD WORK AREA
POISON
NO SMOKING OR EATING

(n) Recordkeeping

(1) Exposure monitoring.

(i) The employer shall establish and maintain an accurate record of all monitoring required in paragraph (d) of this section.

(ii) This record shall include:

(A) The date(s), number, duration, location and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure where applicable;

(B) A description of the sampling and analytical methods used and evidence of their accuracy;

(C) The type of respiratory protective devices worn, if any;

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent; and

(E) The environmental variables that could affect the measurement of employee exposure.

(iii) The employer shall maintain these monitoring records for at least 40 years or for the duration of employment plus 20 years, whichever is longer.

(2) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (j) of this section.

(ii) This record shall include:

(A) The name, social security number, and description of the duties of the employee;

(B) A copy of the physician's written opinions;

(C) Results of any airborne exposure monitoring done for that employee and the

representative exposure levels supplied to the physician; and

(D) Any employee medical complaints related to exposure to lead.

(iii) The employer shall keep, or assure that the examining physician keeps, the following medical records:

(A) A copy of the medical examination results including medical and work history required under paragraph (j) of this section;

(B) A description of the laboratory procedures and a copy of any standards or guidelines used to interpret the test results or references to that information;

(C) A copy of the results of biological monitoring.

(iv) The employer shall maintain or assure that the physician maintains those medical records for at least 40 years, or for the duration of employment plus 20 years, whichever is longer.

(3) Medical removals.

(i) The employer shall establish and maintain an accurate record for each employee removed from current exposure to lead pursuant to paragraph (k) of this section.

(ii) Each record shall include:

(A) The name and social security number of the employee;

(B) The date on each occasion that the employee was removed from current exposure to lead as well as the corresponding date on which the employee was returned to his or her former job status;

(C) A brief explanation of how each removal was or is being accomplished; and

(D) A statement with respect to each removal indicating whether or not the reason for the removal was an elevated blood lead level.

(iii) The employer shall maintain each medical removal record for at least the duration of an employee's employment.

(4) Availability.

(i) The employer shall make available upon request all records required to be maintained by paragraph (n) of this section to the Assistant Secretary and the Director for examination and

copying.

(ii) Environmental monitoring, medical removal, and medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a) - (e) and (2) - (i). Medical removal records shall be provided in the same manner as environmental monitoring records.

(5) Transfer of records.

(i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (n) of this section.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records required to be maintained by this section for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained by this section, the employer shall notify the Director at least 3 months prior to the disposal of such records and shall transmit those records to the Director if requested within the period.

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(o) Observation of monitoring.

(1) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to lead conducted pursuant to paragraph (d) of this section.

(2) Observation procedures.

(i) Whenever observation of the monitoring of employee exposure to lead requires entry into an area where the use of respirators, protective clothing or equipment is required, the employer shall provide the observer with and assure the use of such respirators, clothing and such equipment, and shall require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all s related to the monitoring of lead performed at the place of exposure;

and

(C) Record the results obtained or receive copies of the results when returned by the laboratory.

(p) Appendices. The information contained in the appendices to this section is not intended by itself, to create any additional obligations not otherwise imposed by this standard nor detract from any existing obligation.

1910.1025 App A Substance data sheet for occupational exposure to lead

APPENDIX A to 1910.1025 - SUBSTANCE DATA SHEET FOR OCCUPATIONAL EXPOSURE TO LEAD

I. SUBSTANCE IDENTIFICATION

A. Substance: Pure lead (Pb) is a heavy metal at room temperature and pressure and is a basic chemical element. It can combine with various other substances to form numerous lead compounds.

B. Compounds Covered by the Standard: The word "lead" when used in this standard means elemental lead, all inorganic lead compounds and a class of organic lead compounds called lead soaps. This standard does not apply to other organic lead compounds.

C. Uses: Exposure to lead occurs in at least 120 different occupations, including primary and secondary lead smelting, lead storage battery manufacturing, lead pigment manufacturing and use, solder manufacturing and use, shipbuilding and ship repairing, auto manufacturing, and printing.

D. Permissible Exposure: The Permissible Exposure Limit (PEL) set by the standard is 50 micrograms of lead per cubic meter of air (50 ug/m³), averaged over an 8-hour workday.

E. Action Level: The standard establishes an action level of 30 micrograms per cubic meter of air (30 ug/m³), time weighted average, based on an 8-hour work-day. The action level initiates several requirements of the standard, such as exposure monitoring, medical surveillance, and training and education.

II. HEALTH HAZARD DATA

A. Ways in which lead enters your body. When absorbed into your body in certain doses lead is a toxic substance. The object of the lead standard is to prevent absorption of harmful quantities of lead. The standard is intended to protect you not only from the immediate toxic effects of lead, but also from the serious toxic effects that may not become apparent until years of exposure have passed.

Lead can be absorbed into your body by inhalation (breathing) and ingestion (eating). Lead (except for certain organic lead compounds not covered by the standard, such as tetraethyl lead) is not absorbed through your skin. When lead is scattered in the air as a dust, fume or mist it can be inhaled and absorbed through your lungs and upper respiratory tract. Inhalation of airborne lead is generally the most important source of occupational lead absorption. You can also absorb lead through your digestive system if lead gets into your mouth and is swallowed. If you handle food, cigarettes, chewing tobacco, or make-up which have lead on them or handle them with hands contaminated with lead, this will contribute to ingestion.

A significant portion of the lead that you inhale or ingest gets into your blood stream. Once in your blood stream, lead is circulated throughout your body and stored in various organs and body tissues. Some of this lead is quickly filtered out of your body and excreted, but some remains in the blood and other tissues. As exposure to lead continues, the amount stored in your body will increase if you are absorbing more lead than your body is excreting. Even though you may not be aware of any immediate symptoms of disease, this lead stored in your tissues can be slowly causing irreversible damage, first to individual cells, then to your organs and whole body systems.

B. Effects of overexposure to lead

(1) Short term (acute) overexposure. Lead is a potent, systemic poison that serves no known useful function once absorbed by your body. Taken in large enough doses, lead can kill you in a matter of days. A condition affecting the brain called acute encephalopathy may arise which develops quickly to seizures, coma, and death from cardiorespiratory arrest. A short term dose of lead can lead to acute encephalopathy. Short term occupational exposures of this magnitude are highly unusual, but not impossible. Similar forms of encephalopathy may, however, arise from extended, chronic exposure to lower doses of lead. There is no sharp dividing line between rapidly developing acute effects of lead, and chronic effects which take longer to acquire. Lead adversely affects numerous body systems, and causes forms of health impairment and disease which arise after periods of exposure as short as days or as long as several years.

(2) Long-term (chronic) overexposure. Chronic overexposure to lead may result in severe damage to your blood-forming, nervous, urinary and reproductive systems. Some common symptoms of chronic overexposure include loss of appetite, metallic taste in the mouth, anxiety, constipation, nausea, pallor, excessive tiredness, weakness, insomnia, headache, nervous irritability, muscle and joint pain or soreness, fine tremors, numbness, dizziness, hyperactivity and colic. In lead colic there may be severe abdominal pain.

Damage to the central nervous system in general and the brain (encephalopathy) in particular is one of the most severe forms of lead poisoning. The most severe, often fatal, form of encephalopathy may be preceded by vomiting, a feeling of dullness progressing to drowsiness and stupor, poor memory, restlessness, irritability, tremor, and convulsions. It may arise suddenly

with the onset of seizures, followed by coma, and death. There is a tendency for muscular weakness to develop at the same time. This weakness may progress to paralysis often observed as a characteristic "wrist drop" or "foot drop" and is a manifestation of a disease to the nervous system called peripheral neuropathy.

Chronic overexposure to lead also results in kidney disease with few, if any, symptoms appearing until extensive and most likely permanent kidney damage has occurred. Routine laboratory tests reveal the presence of this kidney disease only after about two-thirds of kidney function is lost. When overt symptoms of urinary dysfunction arise, it is often too late to correct or prevent worsening conditions, and progression to kidney dialysis or death is possible.

Chronic overexposure to lead impairs the reproductive systems of both men and women. Overexposure to lead may result in decreased sex drive, impotence and sterility in men. Lead can alter the structure of sperm cells raising the risk of birth defects. There is evidence of miscarriage and stillbirth in women whose husbands were exposed to lead or who were exposed to lead themselves. Lead exposure also may result in decreased fertility, and abnormal menstrual cycles in women. The course of pregnancy may be adversely affected by exposure to lead since lead crosses the placental barrier and poses risks to developing fetuses. Children born of parents either one of whom were exposed to excess lead levels are more likely to have birth defects, mental retardation, behavioral disorders or die during the first year of childhood.

Overexposure to lead also disrupts the blood-forming system resulting in decreased hemoglobin (the substance in the blood that carries oxygen to the cells) and ultimately anemia. Anemia is characterized by weakness, pallor and fatigability as a result of decreased oxygen carrying capacity in the blood.

(3) Health protection goals of the standard. Prevention of adverse health effects for most workers from exposure to lead throughout a working lifetime requires that worker blood lead (PbB) levels be maintained at or below forty micrograms per one hundred grams of whole blood (40 ug/100g). The blood lead levels of workers (both male and female workers) who intend to have children should be maintained below 30 ug/100g to minimize adverse reproductive health effects to the parents and to the developing fetus.

The measurement of your blood lead level is the most useful indicator of the amount of lead being absorbed by your body. Blood lead levels (PbB) are most often reported in units of milligrams (mg) or micrograms (ug) of lead (1 mg=1000 ug) per 100 grams (100g), 100 milliliters (100 ml) or deciliter (dl) of blood. These three units are essentially the same. Sometime PbB's are expressed in the form of mg% or ug%. This is a shorthand notation for 100g, 100 ml, or dl.

PbB measurements show the amount of lead circulating in your blood stream, but do not give any information about the amount of lead stored in your various tissues. PbB measurements merely show current absorption of lead, not the effect that lead is having on your body or the effects that past lead exposure may have already caused. Past research into lead-related diseases,

however, has focused heavily on associations between PbBs and various diseases. As a result, your PbB is an important indicator of the likelihood that you will gradually acquire a lead-related health impairment or disease.

Once your blood lead level climbs above 40 ug/100g, your risk of disease increases. There is a wide variability of individual response to lead, thus it is difficult to say that a particular PbB in a given person will cause a particular effect. Studies have associated fatal encephalopathy with PbBs as low as 150 ug/100g. Other studies have shown other forms of diseases in some workers with PbBs well below 80 ug/100g. Your PbB is a crucial indicator of the risks to your health, but one other factor is also extremely important. This factor is the length of time you have had elevated PbBs. The longer you have an elevated PbB, the greater the risk that large quantities of lead are being gradually stored in your organs and tissues (body burden). The greater your overall body burden, the greater the chances of substantial permanent damage.

The best way to prevent all forms of lead-related impairments and diseases-both short term and long term- is to maintain your PbB below 40 ug/100g. The provisions of the standard are designed with this end in mind. Your employer has prime responsibility to assure that the provisions of the standard are complied with both by the company and by individual workers. You as a worker, however, also have a responsibility to assist your employer in complying with the standard. You can play a key role in protecting your own health by learning about the lead hazards and their control, learning what the standard requires, following the standard where it governs your own actions, and seeing that your employer complies with provisions governing his actions.

(4) Reporting signs and symptoms of health problems. You should immediately notify your employer if you develop signs or symptoms associated with lead poisoning or if you desire medical advice concerning the effects of current or past exposure to lead on your ability to have a healthy child. You should also notify your employer if you have difficulty breathing during a respirator fit test or while wearing a respirator. In each of these cases your employer must make available to you appropriate medical examinations or consultations. These must be provided at no cost to you and at a reasonable time and place.

The standard contains a procedure whereby you can obtain a second opinion by a physician of your choice if the employer selected the initial physician. This procedure, however, was delayed by the Court of Appeals in March of 1979, and will not go into effect until after the Court's decision on the overall validity of the standard.

(Approved by the Office of Management and Budget under control number 1218-0092)

1910.1025 App B Employee standard summary

APPENDIX B to 1910.1025 - EMPLOYEE STANDARD SUMMARY

This appendix summarizes key provisions of the standard that you as a worker should become familiar with.

The appendix discusses the entire standard, but some portions of the standard were temporarily postponed (stayed) by federal court on March 1, 1979. This litigation concerns the validity of the entire lead standard, and a final decision is expected in 1980. Most of the lead standard is currently legally in effect, however. The following discussion in the Appendix notes those few provisions of the standard which have been temporarily stayed.

I. PERMISSIBLE EXPOSURE LIMIT (PEL) - PARAGRAPH (C)

The standard sets a permissible exposure limit (PEL) of fifty micrograms of lead per cubic meter of air (50 ug/m³), averaged over an 8-hour work-day. This is the highest level of lead in air to which you may be permissibly exposed over an 8-hour workday. Since it is an 8-hour average it permits short exposures above the PEL so long as for each 8-hour work day your average exposure does not exceed the PEL.

This standard recognizes that your daily exposure to lead can extend beyond a typical 8-hour workday as the result of overtime or other alterations in your work schedule. To deal with this, the standard contains a formula which reduces your permissible exposure when you are exposed more than 8 hours. For example, if you are exposed to lead for 10 hours a day, the maximum permitted average exposure would be 40 ug/m³.

II. EXPOSURE MONITORING - PARAGRAPH (D)

If lead is present in the workplace where you work in any quantity, your employer is required to make an initial determination of whether the action level is exceeded for any employee. This initial determination must include instrument monitoring of the air for the presence of lead and must cover the exposure of a representative number of employees who are reasonably believed to have the highest exposure levels. If your employer has conducted appropriate air sampling for lead in the past year he may use these results. If there have been any employee complaints of symptoms which may be attributable to exposure to lead or if there is any other information or observations which would indicate employee exposure to lead, this must also be considered as part of the initial determination. This initial determination must have been completed by March 31, 1979. If this initial determination shows that a reasonable possibility exists that any employee may be exposed, without regard to respirators, over the action level (30 ug/m³) your employer must set up an air monitoring program to determine the exposure level of every employee exposed to lead at your workplace.

In carrying out this air monitoring program, your employer is not required to monitor the exposure of every employee, but he must monitor a representative number of employees and job types. Enough sampling must be done to enable each employee's exposure level to be reasonably represented by at least one full shift (at least 7 hours) air sample. In addition, these air samples

must be taken under conditions which represent each employee's regular, daily exposure to lead. All initial exposure monitoring must have been completed by May 30, 1979.

If you are exposed to lead and air sampling is performed, your employer is required to quickly notify you in writing of air monitoring results which represent your exposure. If the results indicate your exposure exceeds the PEL (without regard to your use of respirators), then your employer must also notify you of this in writing, and provide you with a description of the corrective action that will be taken to reduce your exposure.

Your exposure must be rechecked by monitoring every six months if your exposure is over the action level but below the PEL. Air monitoring must be repeated every 3 months if you are exposed over the PEL. Your employer may discontinue monitoring for you if 2 consecutive measurements, taken at least two weeks apart, are below the action level. However, whenever there is a production, process, control, or personnel change at your workplace which may result in new or additional exposure to lead, or whenever there is any other reason to suspect a change which may result in new or additional exposure to lead, your employer must perform additional monitoring.

III. METHODS OF COMPLIANCE - PARAGRAPH (E)

Your employer is required to assure that no employee is exposed to lead in excess of the PEL. The standard establishes a priority of methods to be used to meet the PEL. Due to the temporary ruling by the United States Circuit Court of Appeals, your employer will not be legally required to use the preferred engineering and work practice controls. Until the litigation is completed, your employer may meet the PEL by requiring you to wear respirators. Alternatively, the employer may choose to implement engineering and work practice controls even though they are not legally required. Also, OSHA's previous lead standard is still in effect. This does require your employer to use feasible engineering and administrative controls to reduce employee exposure levels, but only to a level of 200 micrograms of lead per cubic meter of air (200 ug/m³).

IV. RESPIRATORY PROTECTION - PARAGRAPH (F)

Your employer is required to select respirators from the seven types listed in Table II of the Respiratory Protection section of the standard (Sec. 1910.1025 (f)). Any respirator chosen must be approved by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 42 CFR part 84. This respirator selection table will enable your employer to choose a type of respirator that will give you a proper amount of protection based on your airborne lead exposure. Your employer may select a type of respirator that provides greater protection than that required by the standard; that is, one recommended for a higher concentration of lead than is present in your workplace. For example, a powered air-purifying respirator (PAPR) is much more protective than a typical negative pressure respirator, and may also be more comfortable to wear. A PAPR has a filter, cartridge, or canister to clean the air, and

a power source that continuously blows filtered air into your breathing zone. Your employer might make a PAPR available to you to ease the burden of having to wear a respirator for long periods of time. The standard provides that you can obtain a PAPR upon request.

Your employer is required to select respirators from the seven types listed in Table II of the Respiratory Protection section of the standard. Any respirator chosen must be approved by the Mine Safety and Health Administration (MSHA) or the National Institute for Occupational Safety and Health (NIOSH). This respirator selection table will enable your employer to choose a type of respirator which will give you a proper amount of protection based on your airborne lead exposure. Your employer may select a type of respirator that provides greater protection than that required by the standard; that is, one recommended for a higher concentration of lead than is present in your workplace. For example, a powered air purifying respirator (PAPR) is much more protective than a typical negative pressure respirator, and may also be more comfortable to wear. A PAPR has a filter, cartridge or canister to clean the air, and a power source which continuously blows filtered air into your breathing zone. Your employer might make a PAPR available to you to ease the burden of having to wear a respirator for long periods of time. The standard provides that you can obtain a PAPR upon request, but this requirement has been stayed as a part of the pending litigation.

Your employer must also start a Respiratory Protection Program. This program must include written procedures for the proper selection, use, cleaning, storage, and maintenance of respirators.

Your employer must ensure that your respirator facepiece fits properly. Proper fit of a respirator facepiece is critical to your protection from airborne lead. Obtaining a proper fit on each employee may require your employer to make available several different types of respirator masks. To ensure that your respirator fits properly and that facepiece leakage is minimal, your employer must give you either a qualitative or quantitative fit test as specified in Appendix A of the Respiratory Protection standard located at 29 CFR 1910.134.

You must also receive from your employer proper training in the use of respirators. Your employer is required to teach you how to wear a respirator, to know why it is needed, and to understand its limitations.

Until March 1, 1980, your employer must test the effectiveness of your negative pressure respirator initially and at least every six months thereafter with a "qualitative fit test." In this test, the fit of the facepiece is checked by seeing if you can smell a substance placed outside the respirator. If you can, there is appreciable leakage where the facepiece meets your face.

The standard provides that if your respirator uses filter elements, you must be given an opportunity to change the filter elements whenever an increase in breathing resistance is detected. You also must be permitted to periodically leave your work area to wash your face and respirator facepiece whenever necessary to prevent skin irritation. If you ever have difficulty in breathing during a fit test or while using a respirator, your employer must make a medical examination

available to you to determine whether you can safely wear a respirator. The result of this examination may be to give you a positive pressure respirator (which reduces breathing resistance) or to provide alternative means of protection.

V. PROTECTIVE WORK CLOTHING AND EQUIPMENT - PARAGRAPH (G)

If you are exposed to lead above the PEL, or if you are exposed to lead compounds such as lead arsenate or lead azide which can cause skin and eye irritation, your employer must provide you with protective work clothing and equipment appropriate for the hazard. If work clothing is provided, it must be provided in a clean and dry condition at least weekly, and daily if your airborne exposure to lead is greater than 200 ug/m³. Appropriate protective work clothing and equipment can include coveralls or similar full-body work clothing, gloves, hats, shoes or disposable shoe coverlets, and face shields or vented goggles. Your employer is required to provide all such equipment at no cost to you. He is responsible for providing repairs and replacement as necessary, and also is responsible for the cleaning, laundering or disposal of protective clothing and equipment. Contaminated work clothing or equipment must be removed in change rooms and not worn home or you will extend your exposure and expose your family since lead from your clothing can accumulate in your house, car, etc. Contaminated clothing which is to be cleaned, laundered or disposed of must be placed in closed containers in the change room. At no time may lead be removed from protective clothing or equipment by any means which disperses lead into the workroom air.

VI. HOUSEKEEPING - PARAGRAPH (H)

Your employer must establish a housekeeping program sufficient to maintain all surfaces as free as practicable of accumulations of lead dust. Vacuuming is the preferred method of meeting this requirement, and the use of compressed air to clean floors and other surfaces is absolutely prohibited. Dry or wet sweeping, shoveling, or brushing may not be used except where vacuuming or other equally effective methods have been tried and do not work. Vacuums must be used and emptied in a manner which minimizes the reentry of lead into the workplace.

VII. HYGIENE FACILITIES AND PRACTICES - PARAGRAPH (I)

The standard requires that change rooms, showers, and filtered air lunchrooms be constructed and made available to workers exposed to lead above the PEL. These requirements have temporarily been delayed by the court of appeals in situations where new facilities must be constructed, or where substantial renovations must be made to existing facilities. When the PEL is exceeded and these facilities are available, however, the employer must assure that food and beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied, except in these facilities. Change rooms, showers, and lunchrooms, if available, must be used by workers exposed in excess of the PEL. After showering, no clothing or equipment

worn during the shift may be worn home, and this includes shoes and underwear. Your own clothing worn during the shift should be carried home and cleaned carefully so that it does not contaminate your home. Lunchrooms may not be entered with protective clothing or equipment unless surface dust has been removed by vacuuming, downdraft booth, or other cleaning method. Finally, workers exposed above the PEL must wash both their hands and faces prior to eating, drinking, smoking or applying cosmetics.

All of the facilities and hygiene practices just discussed are essential to minimize additional sources of lead absorption from inhalation or ingestion of lead that may accumulate on you, your clothes, or your possessions. Strict compliance with these provisions can virtually eliminate several sources of lead exposure which significantly contribute to excessive lead absorption.

VIII. MEDICAL SURVEILLANCE - PARAGRAPH (J)

The medical surveillance program is part of the standard's comprehensive approach to the prevention of lead-related disease. Its purpose is to supplement the main thrust of the standard which is aimed at minimizing airborne concentrations of lead and sources of ingestion. Only medical surveillance can determine if the other provisions of the standard have affectively protected you as an individual. Compliance with the standard's provision will protect most workers from the adverse effects of lead exposure, but may not be satisfactory to protect individual workers (1) who have high body burdens of lead acquired over past years, (2) who have additional uncontrolled sources of non-occupational lead exposure, (3) who exhibit unusual variations in lead absorption rates, or (4) who have specific non-work related medical conditions which could be aggravated by lead exposure (e.g., renal disease, anemia). In addition, control systems may fail, or hygiene and respirator programs may be inadequate. Periodic medical surveillance of individual workers will help detect those failures. Medical surveillance will also be important to protect your reproductive ability-regardless of whether you are a man or woman.

All medical surveillance required by the standard must be performed by or under the supervision of a licensed physician. The employer must provide required medical surveillance without cost to employees and at a reasonable time and place. The standard's medical surveillance program has two parts-periodic biological monitoring and medical examinations.

Your employer's obligation to offer you medical surveillance is triggered by the results of the air monitoring program. Medical surveillance must be made available to all employees who are exposed in excess of the action level for more than 30 days a year. The initial phase of the medical surveillance program, which includes blood lead level tests and medical examinations, must be completed for all covered employees no later than August 28, 1979. Priority within this first round of medical surveillance must be given to employees whom the employer believes to be at greatest risk from continued exposure (for example, those with the longest prior exposure to lead, or those with the highest current exposure). Thereafter, the employer must periodically make medical surveillance-both biological monitoring and medical examinations-available to all covered employees.

Biological monitoring under the standard consists of blood lead level (PbB) and zinc protoporphyrin tests at least every 6 months after the initial PbB test. A zinc protoporphyrin (ZPP) test is a very useful blood test which measures an effect of lead on your body, but this test has been temporarily stayed by the Court. Thus biological monitoring under the standard is currently limited to PbB testing. If a worker's PbB exceeds 40 ug/100g the monitoring frequency must be increased from every 6 months to at least every 2 months and not reduced until two consecutive PbBs indicate a blood lead level below 40 ug/100g. Each time your PbB is determined to be over 40 ug/100g, your employer must notify you of this in writing within five working days of his receipt of the test results. The employer must also inform you that the standard requires temporary medical removal with economic protection when your PbB exceeds certain criteria. (See Discussion of Medical Removal Protection-Paragraph (k).) During the first year of the standard, this removal criterion is 80 ug/100g. Anytime your PbB exceeds 80 ug/100g your employer must make available to you a prompt follow-up PbB test to ascertain your PbB. If the two tests both exceed 80 ug/100g and you are temporarily removed, then your employer must make successive PbB tests available to you on a monthly basis during the period of your removal.

Medical examinations beyond the initial one must be made available on an annual basis if your blood lead level exceeds 40 ug/100g at any time during the preceding year. The initial examination will provide information to establish a baseline to which subsequent data can be compared. An initial medical examination must also be made available (prior to assignment) for each employee being assigned for the first time to an area where the airborne concentration of lead equals or exceeds the action level. In addition, a medical examination or consultation must be made available as soon as possible if you notify your employer that you are experiencing signs or symptoms commonly associated with lead poisoning or that you have difficulty breathing while wearing a respirator or during a respirator fit test. You must also be provided a medical examination or consultation if you notify your employer that you desire medical advice concerning the effects of current or past exposure to lead on your ability to procreate a healthy child.

Finally, appropriate follow-up medical examinations or consultations may also be provided for employees who have been temporarily removed from exposure under the medical removal protection provisions of the standard. (See Part IX, below.)

The standard specifies the minimum content of pre-assignment and annual medical examinations. The content of other types of medical examinations and consultations is left up to the sound discretion of the examining physician. Pre-assignment and annual medical examinations must include (1) a detailed work history and medical history, (2) a thorough physical examination, and (3) a series of laboratory tests designed to check your blood chemistry and your kidney function. In addition, at any time upon your request, a laboratory evaluation of male fertility will be made (microscopic examination of a sperm sample), or a pregnancy test will be given.

The standard does not require that you participate in any of the medical procedures, tests, etc.

which your employer is required to make available to you. Medical surveillance can, however, play a very important role in protecting your health. You are strongly encouraged, therefore, to participate in a meaningful fashion. The standard contains a multiple physician review mechanism which would give you a chance to have a physician of your choice directly participate in the medical surveillance program. If you were dissatisfied with an examination by a physician chosen by your employer, you could select a second physician to conduct an independent analysis. The two doctors would attempt to resolve any differences of opinion, and select a third physician to resolve any firm * dispute. As a result, generally your employer will choose the physician who conducts medical surveillance under the lead standard-unless you and your employer can agree on the choice of a physician or physicians. Some companies and unions have agreed in advance, for example, to use certain independent medical laboratories or panels of physicians. Any of these arrangements are acceptable so long as required medical surveillance is made available to workers.

The standard requires your employer to provide certain information to a physician to aid in his or her examination of you. This information includes (1) the standard and its appendices, (2) a description of your duties as they relate to lead exposure, (3) your exposure level, (4) a description of personal protective equipment you wear, (5) prior blood lead level results, and (6) prior written medical opinions concerning you that the employer has. After a medical examination or consultation the physician must prepare a written report which must contain (1) the physician's opinion as to whether you have any medical condition which places you at increased risk of material impairment to health from exposure to lead, (2) any recommended special protective measures to be provided to you, (3) any blood lead level determinations, and (4) any recommended limitation on your use of respirators. This last element must include a determination of whether you can wear a powered air purifying respirator (PAPR) if you are found unable to wear a negative pressure respirator.

The medical surveillance program of the lead standard may at some point in time serve to notify certain workers that they have acquired a disease or other adverse medical condition as a result of occupational lead exposure. If this is true, these workers might have legal rights to compensation from public agencies, their employers, firms that supply hazardous products to their employers, or other persons. Some states have laws, including worker compensation laws, that disallow a worker who learns of a job-related health impairment to sue, unless the worker sues within a short period of time after learning of the impairment. (This period of time may be a matter of months or years.) An attorney can be consulted about these possibilities. It should be stressed that OSHA is in no way trying to either encourage or discourage claims or lawsuits. However, since results of the standard's medical surveillance program can significantly affect the legal remedies of a worker who has acquired a job-related disease or impairment, it is proper for OSHA to make you aware of this.

The medical surveillance section of the standard also contains provisions dealing with chelation. Chelation is the use of certain drugs (administered in pill form or injected into the body) to reduce the amount of lead absorbed in body tissues. Experience accumulated by the

medical and scientific communities has largely confirmed the effectiveness of this type of therapy for the treatment of very severe lead poisoning. On the other hand, it has also been established that there can be a long list of extremely harmful side effects associated with the use of chelating agents. The medical community has balanced the advantages and disadvantages resulting from the use of chelating agents in various circumstances and has established when the use of these agents is acceptable. The standard includes these accepted limitations due to a history of abuse of chelation therapy by some lead companies. The most widely used chelating agents are calcium disodium EDTA, (Ca Na₂ EDTA), Calcium Disodium Versenate (Versenate), and d-penicillamine (pencillamine or Cupramine).

The standard prohibits "prophylactic chelation" of any employee by any person the employer retains, supervises or controls. "Prophylactic chelation" is the routine use of chelating or similarly acting drugs to prevent elevated blood levels in workers who are occupationally exposed to lead, or the use of these drugs to routinely lower blood lead levels to predesignated concentrations believed to be 'safe'. It should be emphasized that where an employer takes a worker who has no symptoms of lead poisoning and has chelation carried out by a physician (either inside or outside of a hospital) solely to reduce the worker's blood lead level, that will generally be considered prophylactic chelation. The use of a hospital and a physician does not mean that prophylactic chelation is not being performed. Routine chelation to prevent increased or reduce current blood lead levels is unacceptable whatever the setting.

The standard allows the use of "therapeutic" or "diagnostic" chelation if administered under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring. Therapeutic chelation responds to severe lead poisoning where there are marked symptoms. Diagnostic chelation involved giving a patient a dose of the drug then collecting all urine excreted for some period of time as an aid to the diagnosis of lead poisoning.

In cases where the examining physician determines that chelation is appropriate, you must be notified in writing of this fact before such treatment. This will inform you of a potentially harmful treatment, and allow you to obtain a second opinion.

IX. MEDICAL REMOVAL PROTECTION - PARAGRAPH (K)

Excessive lead absorption subjects you to increased risk of disease. Medical removal protection (MRP) is a means of protecting you when, for whatever reasons, other methods, such as engineering controls, work practices, and respirators, have failed to provide the protection you need. MRP involves the temporary removal of a worker from his or her regular job to a place of significantly lower exposure without any loss of earnings, seniority, or other employment rights or benefits. The purpose of this program is to cease further lead absorption and allow your body to naturally excrete lead which has previously been absorbed. Temporary medical removal can result from an elevated blood lead level, or a medical opinion. Up to 18 months of protection is provided as a result of either form of removal. The vast majority of removed workers, however, will return to their former jobs long before this eighteen month period expires. The standard

contains special provisions to deal with the extraordinary but possible case where a longterm worker's blood lead level does not adequately decline during eighteen months of removal.

During the first year of the standard, if your blood lead level is 80 ug/100g or above you must be removed from any exposure where your air lead level without a respirator would be 100 ug/m(3) or above. If you are removed from your normal job you may not be returned until your blood lead level declines to at least 60 ug/100g. These criteria for removal and return will change according to the following schedule:

| | : Removal blood lead (ug/100 g) | : Air lead (ug/m(3)) | : Return blood lead (ug/100 g) |
|-----------------------|---------------------------------|----------------------|--------------------------------|
| After Mar. 1, 1980... | :70 and above.... | : 50 and above.. | : At or below 50. |
| After Mar. 1, 1981... | :60 and above.... | : 30 and above.. | : At or below 40. |
| After Mar. 1, 1983... | :50 and above | : 30 and above.. | : Do. |
| | :averaged over | : | : |
| | :six months..... | : | : |

You may also be removed from exposure even if your blood lead levels are below these criteria if a final medical determination indicates that you temporarily need reduced lead exposure for medical reasons. If the physician who is implementing your employers medical program makes a final written opinion recommending your removal or other special protective measures, your employer must implement the physician's recommendation. If you are removed in this manner, you may only be returned when the doctor indicates that it is safe for you to do so.

The standard does not give specific instructions dealing with what an employer must do with a removed worker. Your job assignment upon removal is a matter for you, your employer and your union (if any) to work out consistent with existing procedures for job assignments. Each removal must be accomplished in a manner consistent with existing collective bargaining relationships. Your employer is given broad discretion to implement temporary removals so long as no attempt is made to override existing agreements. Similarly, a removed worker is provided no right to veto an employer's choice which satisfies the standard.

In most cases, employers will likely transfer removed employees to other jobs with sufficiently low lead exposure. Alternatively, a worker's hours may be reduced so that the time weighted average exposure is reduced, or he or she may be temporarily laid off if no other alternative is feasible.

In all of these situation, MRP benefits must be provided during the period of removal-i.e., you continue to receive the same earnings, seniority, and other rights and benefits you would have had if you had not been removed. Earnings includes more than just your base wage; it includes overtime, shift differentials, incentives, and other compensation you would have earned if you

had not been removed. During the period of removal you must also be provided with appropriate follow-up medical surveillance. If you were removed because your blood lead level was too high, you must be provided with a monthly blood test. If a medical opinion caused your removal, you must be provided medical tests or examinations that the doctor believes to be appropriate. If you do not participate in this follow up medical surveillance, you may lose your eligibility for MRP benefits.

When you are medically eligible to return to your former job, your employer must return you to your "former job status." This means that you are entitled to the position, wages, benefits, etc., you would have had if you had not been removed. If you would still be in your old job if no removal had occurred that is where you go back. If not, you are returned consistent with whatever job assignment discretion your employer would have had if no removal had occurred. MRP only seeks to maintain your rights, not expand them or diminish them.

If you are removed under MRP and you are also eligible for worker compensation or other compensation for lost wages, your employer's MRP benefits obligation is reduced by the amount that you actually receive from these other sources. This is also true if you obtain other employment during the time you are laid off with MRP benefits.

The standard also covers situations where an employer voluntarily removes a worker from exposure to lead due to the effects of lead on the employee's medical condition, even though the standard does not require removal. In these situations MRP benefits must still be provided as though the standard required removal. Finally, it is important to note that in all cases where removal is required, respirators cannot be used as a substitute. Respirators may be used before removal becomes necessary, but not as an alternative to a transfer to a low exposure job, or to a lay-off with MRP benefits.

X. EMPLOYEE INFORMATION AND TRAINING - PARAGRAPH (1)

Your employer is required to provide an information and training program for all employees exposed to lead above the action level or who may suffer skin or eye irritation from lead. This program must inform these employees of the specific hazards associated with their work environment, protective measures which can be taken, the danger of lead to their bodies (including their reproductive systems), and their rights under the standard. In addition your employer must make readily available to all employees, including those exposed below the action level, a copy of the standard and its appendices and must distribute to all employees any materials provided to the employer by the Occupational Safety and Health Administration (OSHA).

Your employer is required to complete this training program for all employees by August 28, 1979. After this date, all new employees must be trained prior to initial assignment to areas where there is a possibility of exposure over the action level.

This training program must also be provided at least annually thereafter.

XI. SIGNS - PARAGRAPH (M)

The standard requires that the following warning sign be posted in work areas where the exposure to lead exceeds the PEL:

WARNING

LEAD WORK AREA

NO SMOKING OR EATING

DANGER

LEAD

MAY DAMAGE FERTILITY OR THE UNBORN CHILD

CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM

DO NOT EAT, DRINK OR SMOKE IN THIS AREA

~~This requirement, however, has been stayed by the Court of Appeals.~~
However, prior to June 1, 2016, employers may use the following legend in lieu of that specified above:

WARNING

LEAD WORK AREA

POISON

NO SMOKING OR EATING

XII. RECORDKEEPING - PARAGRAPH (N)

Your employer is required to keep all records of exposure monitoring for airborne lead. These records must include the name and job classification of employees measured, details of the sampling and analytic techniques, the results of this sampling, and the type of respiratory protection being worn by the person sampled. Your employer is also required to keep all records of biological monitoring and medical examination results. These must include the names of the employees, the physician's written opinion, and a copy of the results of the examination. All of the above kinds of records must be kept for 40 years, or for at least 20 years after your termination of employment, whichever is longer.

Recordkeeping is also required if you are temporarily removed from your job under the medical removal protection program. This record must include your name and social security number, the date of your removal and return, how the removal was or is being accomplished, and whether or not the reason for the removal was an elevated blood lead level. Your employer is required to keep each medical removal record only for as long as the duration of an employee's employment.

The standard requires that if you request to see or copy environmental monitoring, blood lead level monitoring, or medical removal records, they must be made available to you or to a representative that you authorize. Your union also has access to these records. Medical records other than PbB's must also be provided upon request to you, to your physician or to any other person whom you may specifically designate. Your union does not have access to your personal medical records unless you authorize their access.

XIII. OBSERVATIONS OF MONITORING - PARAGRAPH (O)

When air monitoring for lead is performed at your workplace as required by this standard, your employer must allow you or someone you designate to act as an observer of the monitoring. Observers are entitled to an explanation of the measurement procedure, and to record the results obtained. Since results will not normally be available at the time of the monitoring, observers are entitled to record or receive the results of the monitoring when returned by the laboratory. Your employer is required to provide the observer with any personal protective devices required to be worn by employees working in the area that is being monitored. The employer must require the observer to wear all such equipment and to comply with all other applicable safety and health procedures.

XIV. FOR ADDITIONAL INFORMATION

A. Copies of the Standard and explanatory materials can be obtained by writing or calling the OSHA Docket Office, U.S. Department of Labor, room N2634, 200 Constitution Avenue, N.W., Washington, DC 20210. Telephone: (202) 219-7894. The following publications are available:

1. The standard and summary of the statement of reasons (preamble), Federal Register, Volume 43, pp. 52952-53014, November 14, 1978.
2. The full statement of reasons (preamble) Federal Register, vol. 43, pp. 54354-54509, November 21, 1978.
3. Partial Administrative Stay and Corrections to the standard, (44 FR 5446-5448) January 26, 1979.
4. Notice of the Partial Judicial Stay (44 FR 14554-14555) March 13, 1979.

5. Corrections to the preamble, Federal Register, vol. 44, pp. 20680-20681, April 6, 1979.
6. Additional correction to the preamble concerning the construction industry, Federal Register, vol. 44, p. 50338, August 28, 1979.
7. Appendices to the standard (Appendices A, B, C), Federal Register, Vol. 44, pp. 60980-60995, October 23, 1979.
8. Corrections to appendices, Federal Register, Vol. 44, 68828, November 30, 1979.
9. Revision to the standard and additional appendix (Appendix D), Federal Register, Vol. 47, pp. 51117-51119, November 12, 1982.
10. Notice of reopening of lead rulemaking for nine remand industry sectors, Federal Register, vol. 53, pp. 11511-11513, April 7, 1988.
11. Statement of reasons, Federal Register, vol. 54, pp. 29142-29275, July 11, 1989.
12. Statement of reasons, Federal Register, vol. 55, pp. 3146-3167, January 30, 1990.
13. Correction to appendix B, Federal Register, vol. 55, pp. 4998-4999, February 13, 1991.
14. Correction to appendices, Federal Register, vol. 56, p. 24686, May 31, 1991.

B. Additional information about the standard, its enforcement, and your employer's compliance can be obtained from the nearest OSHA Area Office listed in your telephone directory under United States Government/Department of Labor.

1910.1025 App C Medical surveillance guidelines

APPENDIX C to 1910.1025 - MEDICAL SURVEILLANCE GUIDELINES

INTRODUCTION

The primary purpose of the Occupational Safety and Health Act of 1970 is to assure, so far as possible, safe and healthful working conditions for every working man and woman. The occupational health standard for inorganic lead(1) was promulgated to protect workers exposed to inorganic lead including metallic lead, all inorganic lead compounds and organic lead soaps.

FOOTNOTE:(1)The term inorganic lead used throughout the medical surveillance appendices is

meant to be synonymous with the definition of lead set forth in the standard.

Under this final standard in effect as of March 1, 1979, occupational exposure to inorganic lead is to be limited to 50 ug/m(3) (micrograms per cubic meter) based on an 8 hour time-weighted average (TWA). This level of exposure eventually must be achieved through a combination of engineering, work practice and other administrative controls. Periods of time ranging from 1 to 10 years are provided for different industries to implement these controls. The schedule which is based on individual industry considerations is given in Table 1. Until these controls are in place, respirators must be used to meet the 50 ug/m(3) exposure limit.

The standard also provides for a program of biological monitoring and medical surveillance for all employees exposed to levels of inorganic lead above the action level of 30 ug/m(3) (TWA) for more than 30 days per year.

The purpose of this document is to outline the medical surveillance provisions of the standard for inorganic lead, and to provide further information to the physician regarding the examination and evaluation of workers exposed to inorganic lead.

Section 1 provides a detailed description of the monitoring procedure including the required frequency of blood testing for exposed workers, provisions for medical removal protection (MRP), the recommended right of the employee to a second medical opinion, and notification and recordkeeping requirements of the employer. A discussion of the requirements for respirator use and respirator monitoring and OSHA's position on prophylactic chelation therapy are also included in this section.

Section 2 discusses the toxic effects and clinical manifestations of lead poisoning and effects of lead intoxication on enzymatic pathways in heme synthesis. The adverse effects on both male and female reproductive capacity and on the fetus are also discussed.

Section 3 outlines the recommended medical evaluation of the worker exposed to inorganic lead including details of the medical history, physical examination, and recommended laboratory tests, which are based on the toxic effects of lead as discussed in Section 2.

Section 4 provides detailed information concerning the laboratory tests available for the monitoring of exposed workers. Included also is a discussion of the relative value of each test and the limitations and precautions which are necessary in the interpretation of the laboratory results.

Table 1

:-----:-----:
: : Effective date :

| | 1979 | 1980 | 1981 | 1982 | 1984 | 1989 |
|--|------|------|------|------|------|---------|
| Permissible airborne lead levels by industry ($\mu\text{g}/\text{m}^3$)(1) | 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | | (final) |
| 1. Primary lead production | 200 | 200 | 200 | 100 | 100 | 50 |
| 2. Secondary lead production | 200 | 200 | 200 | 100 | 50 | 50 |
| 3. Lead-acid battery manufacturing | 200 | 200 | 100 | 100 | 50 | 50 |
| 4. Nonferrous foundries | 200 | 100 | 100 | 100 | 50 | 50 |
| 5. Lead pigment manufacturing | 200 | 200 | 200 | 100 | 50 | 50 |
| 6. All other industries | 200 | 50 | 50 | 50 | 50 | 50 |

(1) Airborne levels to be achieved without reliance on respirator protection through a combination of engineering, work practice and other administrative controls. While these controls are being implemented respirators must be used to meet the 50 $\mu\text{g}/\text{m}^3$ exposure limit.

I. MEDICAL SURVEILLANCE AND MONITORING REQUIREMENTS FOR WORKERS EXPOSED TO INORGANIC LEAD

Under the occupational health standard for inorganic lead, a program of biological monitoring and medical surveillance is to be made available to all employees exposed to lead above the action level of 30 $\mu\text{g}/\text{m}^3$ TWA for more than 30 days each year. This program consists of periodic blood sampling and medical evaluation to be performed on a schedule which is defined by previous laboratory results, worker complaints or concerns, and the clinical assessment of the examining physician.

Under this program, the blood lead level of all employees who are exposed to lead above the action level of 30 $\mu\text{g}/\text{m}^3$ is to be determined at least every six months. The frequency is increased to every two months for employees whose last blood lead level was between 40 $\mu\text{g}/100$ g whole blood and the level requiring employee medical removal to be discussed below. For employees who are removed from exposure to lead due to an elevated blood lead, a new blood lead level must be measured monthly. A zinc protoporphyrin (ZPP) measurement is required on each occasion that a blood lead level measurement is made.

An annual medical examination and consultation performed under the guidelines discussed in Section 3 is to be made available to each employee for whom a blood test conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 $\mu\text{g}/100$ g. Also, an examination is to be given to all employees prior to their assignment to an area in which airborne lead concentrations reach or exceed the action level. In addition, a medical examination must be provided as soon as possible after notification by an employee that the employee has developed

signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice regarding lead exposure and the ability to procreate a healthy child, or that the employee has demonstrated difficulty in breathing during a respirator fitting test or during respirator use. An examination is also to be made available to each employee removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited or specially protected pursuant to medical recommendations.

Results of biological monitoring or the recommendations of an examining physician may necessitate removal of an employee from further lead exposure pursuant to the standard's medical removal protection (MRP) program. The object of the MRP program is to provide temporary medical removal to workers either with substantially elevated blood lead levels or otherwise at risk of sustaining material health impairment from continued substantial exposure to lead. The following guidelines which are summarized in Table 2 were created under the standard for the temporary removal of an exposed employee and his or her subsequent return to work in an exposure area.

Table 2

| Match | Effective date |
|------------|--|
| level to | |
| same below | Mar. 1, 1979 : Mar. 1, 1980 : Mar. 1, 1981 : Mar. 1, 1982 Mar. 1, 1983 (final) |
| A. | 80 µg/100 g : 70µg/100 g : 60 µg/100 g : 60 µg/100 g 60µg/100 g or average of last three |
| B. | |
| 1. | Every 6 months : Every 6 months : Every 6 months : Every 6 months Every 6 months. |
| 2. | Every 2 months : Every 2 months : Every 2 months : Every 2 months Every 2 months. |
| 3. | Every 1 month : Every 1 month : Every 1 month : Every 1 month Every 1 month. |
| C. | 100 µg/m3 8 hr TWA : 50 µg/m3 8 hr TWA : 30 µg/m3 8 hr TWA : 30 µg/m3 8 hr TWA : 30 µg/m3 8 hr TWA. |
| D. | 60 µg/100 g : 50 µg/100 g : 40 µg/100 g : 40 µg/100 g : 40 µg/100 g. |
| Match | Effective date |
| level to | |

| | | | |
|---------------------------|---------------------------------|--|---|
| : same below | : Mar. 1, 1982 | : Mar. 1, 1983 (final) | : |
| :-----:-----:-----:-----: | | | |
| : A. | : 60 µg/100 g | : 60µg/100 g or average of last three | : |
| : | : | : blood samples or all blood samples | : |
| : | : | : over previous 6 months (whichever | : |
| : | : | : is over a longer time period) is 50 | : |
| : | : | : µg/100 g or greater unless last | : |
| : | : | : blood sample is 40 µg/100 g or less. | : |
| : B. | : | : | : |
| : 1. | : Every 6 months | : Every 6 months. | : |
| : 2. | : Every 2 months | : Every 2 months. | : |
| : 3. | : Every 1 month | : Every 1 month. | : |
| : C. | : 30 µg/m ³ 8 hr TWA | : 30 µg/m ³ 8 hr TWA. | : |
| : D. | : 40 µg/100 g | : 40 µg/100 g. | : |
| :-----:-----:-----:-----: | | | |

- A. Blood lead level requiring employee medical removal. (Level must be confirmed with second follow-up blood lead level within two weeks of first report.)
- B. Frequency which employees exposed to action level of lead (30 µg/m³ TWA) must have blood lead level checked (ZPP is also required in each occasion that a blood lead is obtained.):
 - 1. Last blood lead level less than 40 µg/100
 - 2. Last blood lead level between 40 µg/100 g and level requiring medical removal (see A above)
 - 3. Employees removed from exposure to lead because of an elevated blood lead level
- C. Permissible airborne exposure limit for workers removed from work due to an elevated blood lead level (without regard to respirator protection)
- D. Blood lead level confirmed with a second blood analysis, at which employee may return to work. Permissible exposure without regard to respirator protection is listed by industry in Table I

Note: When medical opinion indicates that an employee is at risk of material impairment from exposure to lead, the physician can remove an employee from exposures exceeding the action level (or less) or recommend special protective measures as deemed appropriate and necessary. Medical monitoring during the medical removal period can be more stringent than noted in the table above if the physician so specifies. Return to work or removal of limitations and special protections is permitted when the physician indicates that the worker is no longer at risk of material impairment.

Under the standard's ultimate worker removal criteria, a worker is to be removed from any work having any eight hour TWA exposure to lead of 30 ug/m(3) or more whenever either of the following circumstances apply: (1) a blood lead level of 60 ug/100 g or greater is obtained and confirmed by a second follow-up blood lead level performed within two weeks after the employer receives the results of the first blood sampling test, or (2) the average of the previous three blood lead determinations or the average of all blood lead determinations conducted during

the previous six months, whichever encompasses the longest time period, equals or exceeds 50 ug/100 g, unless the last blood sample indicates a blood lead level at or below 40 ug/100 g in which case the employee need not be removed. Medical removal is to continue until two consecutive blood lead levels are 40 ug/100 g or less.

During the first two years that the ultimate removal criteria are being phased in, the return criteria have been set to assure that a worker's blood lead level has substantially declined during the period of removal. From March 1, 1979 to March 1, 1980, the blood lead level requiring employee medical removal is 80 ug/100 g. Workers found to have a confirmed blood lead at this level or greater need only be removed from work having a daily 8 hour TWA exposure to lead at or above 100 ug/m(3). Workers so removed are to be returned to work when their blood lead levels are at or below 60 ug/100 g of whole blood. From March 1, 1980 to March 1, 1981, the blood lead level requiring medical removal is 70 ug/100 g. During this period workers need only be removed from jobs having a daily 8 hour TWA exposure to lead at or above 50 ug/m(3) and are to be returned to work when a level of 50 ug/100 g is achieved. Beginning March 1, 1981, return depends on a worker's blood lead level declining to 40 ug/100 g of whole blood.

As part of the standard, the employer is required to notify in writing each employee whose blood lead level exceeds 40 ug/100 g. In addition each such employee is to be informed that the standard requires medical removal with MRP benefits, discussed below, when an employee's blood lead level exceeds the above defined limits.

In addition to the above blood lead level criteria, temporary worker removal may also take place as a result of medical determinations and recommendations. Written medical opinions must be prepared after each examination pursuant to the standard. If the examining physician includes a medical finding, determination or opinion that the employee has a medical condition which places the employee at increased risk of material health impairment from exposure to lead, then the employee must be removed from exposure to lead at or above the action level. Alternatively, if the examining physician recommends special protective measures for an employee (e.g., use of a powered air purifying respirator) or recommends limitations on an employee's exposure to lead, then the employer must implement these recommendations. Recommendations may be more stringent than the specific provisions of the standard. The examining physician, therefore, is given broad flexibility to tailor special protective procedures to the needs of individual employees. This flexibility extends to the evaluation and management of pregnant workers and male and female workers who are planning to raise children. Based on the history, physical examination, and laboratory studies, the physician might recommend special protective measures or medical removal for an employee who is pregnant or who is planning to conceive a child when, in the physician's judgment, continued exposure to lead at the current job would pose a significant risk. The return of the employee to his or her former job status, or the removal of special protections or limitations, depends upon the examining physician determining that the employee is no longer at increased risk of material impairment or that special measures are no longer needed.

During the period of any form of special protection or removal, the employer must maintain the worker's earnings, seniority, and other employment rights and benefits (as though the worker had not been removed) for a period of up to 18 months. This economic protection will maximize meaningful worker participation in the medical surveillance program, and is appropriate as part of the employer's overall obligation to provide a safe and healthful workplace. The provisions of MRP benefits during the employee's removal period may, however, be conditioned upon participation in medical surveillance.

On rare occasions, an employee's blood lead level may not acceptably decline within 18 months of removal. This situation will arise only in unusual circumstances, thus the standard relies on an individual medical examination to determine how to protect such an employee. This medical determination is to be based on both laboratory values, including lead levels, zinc protoporphyrin levels, blood counts, and other tests felt to be warranted, as well as the physician's judgment that any symptoms or findings on physical examination are a result of lead toxicity. The medical determination may be that the employee is incapable of ever safely returning to his or her former job status. The medical determination may provide additional removal time past 18 months for some employees or specify special protective measures to be implemented.

The lead standard provides for a multiple physician review in cases where the employee wishes a second opinion concerning potential lead poisoning or toxicity. If an employee wishes a second opinion, he or she can make an appointment with a physician of his or her choice. This second physician will review the findings, recommendations or determinations of the first physician and conduct any examinations, consultations or tests deemed necessary in an attempt to make a final medical determination. If the first and second physicians do not agree in their assessment they must try to resolve their differences. If they cannot reach an agreement then they must designate a third physician to resolve the dispute. This multiple physician review mechanism has been temporarily stayed during the pending litigation, but OSHA recommends that it be used if disputes arise over medical determinations.

The employer must provide examining and consulting physicians with the following specific information: a copy of the lead regulations and all appendices, a description of the employee's duties as related to exposure, the exposure level to lead and any other toxic substances (if applicable), a description of personal protective equipment used, blood lead levels, and all prior written medical opinions regarding the employee in the employer's possession or control. The employer must also obtain from the physician and provide the employee with a written medical opinion containing blood lead levels, the physicians's opinion as to whether the employee is at risk of material impairment to health, any recommended protective measures for the employee if further exposure is permitted, as well as any recommended limitations upon an employee's use of respirators.

Employers must instruct each physician not to reveal to the employer in writing or in any other way his or her findings, laboratory results, or diagnoses which are felt to be unrelated to occupational lead exposure. They must also instruct each physician to advise the employee of any

occupationally or non-occupationally related medical condition requiring further treatment or evaluation.

The standard provides for the use of respirators where engineering and other primary controls have not been fully implemented. However, the use of respirator protection shall not be used in lieu of temporary medical removal due to elevated blood lead levels or findings that an employee is at risk of material health impairment. This is based on the numerous inadequacies of respirators including skin rash where the facepiece makes contact with the skin, unacceptable stress to breathing in some workers with underlying cardiopulmonary impairment, difficulty in providing adequate fit, the tendency for respirators to create additional hazards by interfering with vision, hearing, and mobility, and the difficulties of assuring the maximum effectiveness of a complicated work practice program involving respirators. Respirators do, however, serve a useful function where engineering and work practice controls are inadequate by providing supplementary, interim, or short-term protection, provided they are properly selected for the environment in which the employee will be working, properly fitted to the employee, maintained and cleaned periodically, and worn by the employee when required.

In its final standard on occupational exposure to inorganic lead, OSHA has prohibited prophylactic chelation. Diagnostic and therapeutic chelation are permitted only under the supervision of a licensed physician with appropriate medical monitoring in an acceptable clinical setting. The decision to initiate chelation therapy must be made on an individual basis and take into account the severity of symptoms felt to be a result of lead toxicity along with blood lead levels, ZPP levels, and other laboratory tests as appropriate. EDTA and penicillamine which are the primary chelating agents used in the therapy of occupational lead poisoning have significant potential side effects and their use must be justified on the basis of expected benefits to the worker. Unless frank and severe symptoms are present, therapeutic chelation is not recommended given the opportunity to remove a worker from exposure and allow the body to naturally excrete accumulated lead. As a diagnostic aid, the chelation mobilization test using CA-EDTA has limited applicability. According to some investigators, the test can differentiate between lead-induced and other nephropathies. The test may also provide an estimation of the mobile fraction of the total body lead burden.

Employers are required to assure that accurate records are maintained on exposure monitoring, medical surveillance, and medical removal for each employee. Exposure monitoring and medical surveillance records must be kept for 40 years or the duration of employment plus 20 years, whichever is longer, while medical removal records must be maintained for the duration of employment. All records required under the standard must be made available upon request to the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health. Employers must also make environmental and biological monitoring and medical removal records available to affected employees and to former employees or their authorized employee representatives. Employees or their specifically designated representatives have access to their entire medical surveillance records.

In addition, the standard requires that the employer inform all workers exposed to lead at or above the action level of the provisions of the standard and all its appendices, the purpose and description of medical surveillance and provisions for medical removal protection if temporary removal is required. An understanding of the potential health effects of lead exposure by all exposed employees along with full understanding of their rights under the lead standard is essential for an effective monitoring program.

II. ADVERSE HEALTH EFFECTS OF INORGANIC LEAD

Although the toxicity of lead has been known for 2,000 years, the knowledge of the complex relationship between lead exposure and human response is still being refined. Significant research into the toxic properties of lead continues throughout the world, and it should be anticipated that our understanding of thresholds of effects and margins of safety will be improved in future years. The provisions of the lead standard are founded on two prime medical judgments: first, the prevention of adverse health effects from exposure to lead throughout a working lifetime requires that worker blood lead levels be maintained at or below 40 $\mu\text{g}/100\text{ g}$ and second, the blood lead levels of workers, male or female, who intend to parent in the near future should be maintained below 30 $\mu\text{g}/100\text{ g}$ to minimize adverse reproductive health effects to the parents and developing fetus. The adverse effects of lead on reproduction are being actively researched and OSHA encourages the physician to remain abreast of recent developments in the area to best advise pregnant workers or workers planning to conceive children.

The spectrum of health effects caused by lead exposure can be subdivided into five developmental stages: normal, physiological changes of uncertain significance, pathophysiological changes, overt symptoms (morbidity), and mortality. Within this process there are no sharp distinctions, but rather a continuum of effects. Boundaries between categories overlap due to the wide variation of individual responses and exposures in the working population. OSHA's development of the lead standard focused on pathophysiological changes as well as later stages of disease.

1. Heme Synthesis Inhibition. The earliest demonstrated effect of lead involves its ability to inhibit at least two enzymes of the heme synthesis pathway at very low blood levels. Inhibition of delta aminolevulinic acid dehydrase (ALA-D) which catalyzes the conversion of delta-aminolevulinic acid (ALA) to protoporphyrin is observed at a blood lead level below 20 $\mu\text{g}/100\text{ g}$ whole blood. At a blood lead level of 40 $\mu\text{g}/100\text{ g}$, more than 20% of the population would have 70% inhibition of ALA-D. There is an exponential increase in ALA excretion at blood lead levels greater than 40 $\mu\text{g}/100\text{ g}$.

Another enzyme, ferrochelatase, is also inhibited at low blood lead levels. Inhibition of ferrochelatase leads to increased free erythrocyte protoporphyrin (FEP) in the blood which can then bind to zinc to yield zinc protoporphyrin. At a blood lead level of 50 $\mu\text{g}/100\text{ g}$ or greater,

nearly 100% of the population will have an increase in FEP. There is also an exponential relationship between blood lead levels greater than 40 ug/100 g and the associated ZPP level, which has led to the development of the ZPP screening test for lead exposure.

While the significance of these effects is subject to debate, it is OSHA's position that these enzyme disturbances are early stages of a disease process which may eventually result in the clinical symptoms of lead poisoning. Whether or not the effects do progress to the later stages of clinical disease, disruption of these enzyme processes over a working lifetime is considered to be a material impairment of health.

One of the eventual results of lead-induced inhibition of enzymes in the heme synthesis pathway is anemia which can be asymptomatic if mild but associated with a wide array of symptoms including dizziness, fatigue, and tachycardia when more severe. Studies have indicated that lead levels as low as 50 ug/100 g can be associated with a definite decreased hemoglobin, although most cases of lead-induced anemia, as well as shortened red-cell survival times, occur at lead levels exceeding 80 ug/100 g. Inhibited hemoglobin synthesis is more common in chronic cases whereas shortened erythrocyte life span is more common in acute cases.

In lead-induced anemias, there is usually a reticulocytosis along with the presence of basophilic stippling, and ringed sideroblasts, although none of the above are pathognomonic for lead-induced anemia.

2. Neurological Effects. Inorganic lead has been found to have toxic effects on both the central and peripheral nervous systems. The earliest stages of lead-induced central nervous system effects first manifest themselves in the form of behavioral disturbances and central nervous system symptoms including irritability, restlessness, insomnia and other sleep disturbances, fatigue, vertigo, headache, poor memory, tremor, depression, and apathy. With more severe exposure, symptoms can progress to drowsiness, stupor, hallucinations, delirium, convulsions and coma.

The most severe and acute form of lead poisoning which usually follows ingestion or inhalation of large amounts of lead is acute encephalopathy which may arise precipitously with the onset of intractable seizures, coma, cardiorespiratory arrest, and death within 48 hours.

While there is disagreement about what exposure levels are needed to produce the earliest symptoms, most experts agree that symptoms definitely can occur at blood lead levels of 60 ug/100 g whole blood and therefore recommend a 40 ug/100 g maximum. The central nervous system effects frequently are not reversible following discontinued exposure or chelation therapy and when improvement does occur, it is almost always only partial.

The peripheral neuropathy resulting from lead exposure characteristically involves only motor function with minimal sensory damage and has a marked predilection for the extensor muscles of

the most active extremity. The peripheral neuropathy can occur with varying degrees of severity. The earliest and mildest form which can be detected in workers with blood lead levels as low as 50 ug/100 g is manifested by slowing of motor nerve conduction velocity often without clinical symptoms. With progression of the neuropathy there is development of painless extensor muscle weakness usually involving the extensor muscles of the fingers and hand in the most active upper extremity, followed in severe cases by wrist drop or, much less commonly, foot drop.

In addition to slowing of nerve conduction, electromyographical studies in patients with blood lead levels greater than 50 ug/100 g have demonstrated a decrease in the number of acting motor unit potentials, an increase in the duration of motor unit potentials, and spontaneous pathological activity including fibrillations and fasciculations. Whether these effects occur at levels of 40 ug/100 g is undetermined.

While the peripheral neuropathies can occasionally be reversed with therapy, again such recovery is not assured particularly in the more severe neuropathies and often improvement is only partial. The lack of reversibility is felt to be due in part to segmental demyelination.

3. Gastrointestinal. Lead may also affect the gastrointestinal system producing abdominal colic or diffuse abdominal pain, constipation, obstipation, diarrhea, anorexia, nausea and vomiting. Lead colic rarely develops at blood lead levels below 80 ug/100 g.

4. Renal. Renal toxicity represents one of the most serious health effects of lead poisoning. In the early stages of disease nuclear inclusion bodies can frequently be identified in proximal renal tubular cells. Renal function remains normal and the changes in this stage are probably reversible. With more advanced disease there is progressive interstitial fibrosis and impaired renal function. Eventually extensive interstitial fibrosis ensues with sclerotic glomeruli and dilated and atrophied proximal tubules; all represent end stage kidney disease. Azotemia can be progressive, eventually resulting in frank uremia necessitating dialysis. There is occasionally associated hypertension and hyperuricemia with or without gout.

Early kidney disease is difficult to detect. The urinalysis is normal in early lead nephropathy and the blood urea nitrogen and serum creatinine increase only when two-thirds of kidney function is lost. Measurement of creatinine clearance can often detect earlier disease as can other methods of measurement of glomerular filtration rate. An abnormal Ca-EDTA mobilization test has been used to differentiate between lead-induced and other nephropathies, but this procedure is not widely accepted. A form of Fanconi syndrome with aminoaciduria, glycosuria, and hyperphosphaturia indicating severe injury to the proximal renal tubules is occasionally seen in children.

5. Reproductive effects. Exposure to lead can have serious effects on reproductive function in both males and females. In male workers exposed to lead there can be a decrease in sexual drive, impotence, decreased ability to produce healthy sperm, and sterility. Malformed sperm (teratospermia), decreased number of sperm (hypospermia), and sperm with decreased motility

(asthenospermia) can all occur. Teratospermia has been noted at mean blood lead levels of 53 ug/100 g and hypospermia and asthenospermia at 41 ug/100 g. Furthermore, there appears to be a dose-response relationship for teratospermia in lead exposed workers.

Women exposed to lead may experience menstrual disturbances including dysmenorrhea, menorrhagia and amenorrhea. Following exposure to lead, women have a higher frequency of sterility, premature births, spontaneous miscarriages, and stillbirths.

Germ cells can be affected by lead and cause genetic damage in the egg or sperm cells before conception and result in failure to implant, miscarriage, stillbirth, or birth defects.

Infants of mothers with lead poisoning have a higher mortality during the first year and suffer from lowered birth weights, slower growth, and nervous system disorders.

Lead can pass through the placental barrier and lead levels in the mother's blood are comparable to concentrations of lead in the umbilical cord at birth. Transplacental passage becomes detectable at 12-14 weeks of gestation and increases until birth.

There is little direct data on damage to the fetus from exposure to lead but it is generally assumed that the fetus and newborn would be at least as susceptible to neurological damage as young children. Blood lead levels of 50-60 ug/100 g in children can cause significant neurobehavioral impairments and there is evidence of hyperactivity at blood levels as low as 25 ug/100 g. Given the overall body of literature concerning the adverse health effects of lead in children, OSHA feels that the blood lead level in children should be maintained below 30 ug/100 g with a population mean of 15 ug/100 g. Blood lead levels in the fetus and newborn likewise should not exceed 30 ug/100 g.

Because of lead's ability to pass through the placental barrier and also because of the demonstrated adverse effects of lead on reproductive function in both the male and female as well as the risk of genetic damage of lead on both the ovum and sperm, OSHA recommends a 30 ug/100 g maximum permissible blood lead level in both males and females who wish to bear children.

6. Other toxic effects. Debate and research continue on the effects of lead on the human body. Hypertension has frequently been noted in occupationally exposed individuals although it is difficult to assess whether this is due to lead's adverse effects on the kidney or if some other mechanism is involved. Vascular and electrocardiographic changes have been detected but have not been well characterized. Lead is thought to impair thyroid function and interfere with the pituitary-adrenal axis, but again these effects have not been well defined.

III. MEDICAL EVALUATION

The most important principle in evaluating a worker for any occupational disease including lead

poisoning is a high index of suspicion on the part of the examining physician. As discussed in Section 2, lead can affect numerous organ systems and produce a wide array of signs and symptoms, most of which are non-specific and subtle in nature at least in the early stages of disease. Unless serious concern for lead toxicity is present, many of the early clues to diagnosis may easily be overlooked.

The crucial initial in the medical evaluation is recognizing that a worker's employment can result in exposure to lead. The worker will frequently be able to define exposures to lead and lead containing materials but often will not volunteer this information unless specifically asked. In other situations the worker may not know of any exposures to lead but the suspicion might be raised on the part of the physician because of the industry or occupation of the worker. Potential occupational exposure to lead and its compounds occur in at least 120 occupations, including lead smelting, the manufacture of lead storage batteries, the manufacture of lead pigments and products containing pigments, solder manufacture, shipbuilding and ship repair, auto manufacturing, construction, and painting.

Once the possibility for lead exposure is raised, the focus can then be directed toward eliciting information from the medical history, physical exam, and finally from laboratory data to evaluate the worker for potential lead toxicity.

A complete and detailed work history is important in the initial evaluation. A listing of all previous employment with information on work processes, exposure to fumes or dust, known exposures to lead or other toxic substances, respiratory protection used, and previous medical surveillance should all be included in the worker's record. Where exposure to lead is suspected, information concerning on-the-job personal hygiene, smoking or eating habits in work areas, laundry procedures, and use of any protective clothing or respiratory protection equipment should be noted. A complete work history is essential in the medical evaluation of a worker with suspected lead toxicity, especially when long term effects such as neurotoxicity and nephrotoxicity are considered.

The medical history is also of fundamental importance and should include a listing of all past and current medical conditions, current medications including proprietary drug intake, previous surgeries and hospitalizations, allergies, smoking history, alcohol consumption, and also non-occupational lead exposures such as hobbies (hunting, riflery). Also known childhood exposures should be elicited. Any previous history of hematological, neurological, gastrointestinal, renal, psychological, gynecological, genetic, or reproductive problems should be specifically noted.

A careful and complete review of systems must be performed to assess both recognized complaints and subtle or slowly acquired symptoms which the worker might not appreciate as being significant. The review of symptoms should include the following:

General-weight loss, fatigue, decreased appetite.

Head, Eyes, Ears, Nose, Throat (HEENT)-headaches, visual disturbances or decreased visual acuity, hearing deficits or tinnitus, pigmentation of the oral mucosa, or metallic taste in mouth.

Cardio-pulmonary-shortness of breath, cough, chest pains, palpitations, or orthopnea.

Gastrointestinal-nausea, vomiting, heartburn, abdominal pain, constipation or diarrhea.

Neurologic-irritability, insomnia, weakness (fatigue), dizziness, loss of memory, confusion, hallucinations, incoordination, ataxia, decreased strength in hands or feet, disturbances in gait, difficulty in climbing stairs, or seizures.

Hematologic-pallor, easy fatigability, abnormal blood loss, melena.

Reproductive (male and female and spouse where relevant)-history of infertility, impotence, loss of libido, abnormal menstrual periods, history of miscarriages, stillbirths, or children with birth defects.

Musculo-skeletal-muscle and joint pains.

The physical examination should emphasize the neurological, gastrointestinal, and cardiovascular systems. The worker's weight and blood pressure should be recorded and the oral mucosa checked for pigmentation characteristic of a possible Burtonian or lead line on the gingiva. It should be noted, however, that the lead line may not be present even in severe lead poisoning if good oral hygiene is practiced.

The presence of pallor on skin examination may indicate an anemia, which if severe might also be associated with a tachycardia. If an anemia is suspected, an active search for blood loss should be undertaken including potential blood loss through the gastrointestinal tract.

A complete neurological examination should include an adequate mental status evaluation including a search for behavioral and psychological disturbances, memory testing, evaluation for irritability, insomnia, hallucinations, and mental clouding. Gait and coordination should be examined along with close observation for tremor. A detailed evaluation of peripheral nerve function including careful sensory and motor function testing is warranted. Strength testing particularly of extensor muscle groups of all extremities is of fundamental importance.

Cranial nerve evaluation should also be included in the routine examination.

The abdominal examination should include auscultation for bowel sounds and abdominal bruits and palpation for organomegaly, masses, and diffuse abdominal tenderness.

Cardiovascular examination should evaluate possible early signs of congestive heart failure.

Pulmonary status should be addressed particularly if respirator protection is contemplated.

As part of the medical evaluation, the lead standard requires the following laboratory studies:

1. Blood lead level
2. Hemoglobin and hematocrit determinations, red cell indices, and examination of the peripheral blood smear to evaluate red blood cell morphology
3. Blood urea nitrogen
4. Serum creatinine
5. Routine urinalysis with microscopic examination.
6. A zinc protoporphyrin level (This requirement is currently not in effect due to the pending litigation, but is recommended nonetheless).

In addition to the above, the physician is authorized to order any further laboratory or other tests which he or she deems necessary in accordance with sound medical practice. The evaluation must also include pregnancy testing or laboratory evaluation of male fertility if requested by the employee.

Additional tests which are probably not warranted on a routine basis but may be appropriate when blood lead and ZPP levels are equivocal include delta aminolevulinic acid and coproporphyrin concentrations in the urine, and dark-field illumination for detection of basophilic stippling in red blood cells.

If an anemia is detected further studies including a careful examination of the peripheral smear, reticulocyte count, stool for occult blood, serum iron, total iron binding capacity, bilirubin, and, if appropriate, vitamin B12 and folate may be of value in attempting to identify the cause of the anemia.

If a peripheral neuropathy is suspected, nerve conduction studies are warranted both for diagnosis and as a basis to monitor any therapy.

If renal disease is questioned, a 24 hour urine collection for creatinine clearance, protein, and electrolytes may be indicated. Elevated uric acid levels may result from lead-induced renal disease and a serum uric acid level might be performed.

An electrocardiogram and chest x-ray may be obtained as deemed appropriate.

Sophisticated and highly specialized testing should not be done routinely and where indicated should be under the direction of a specialist.

IV. LABORATORY EVALUATION

The blood lead level at present remains the single most important test to monitor lead exposure and is the test used in the medical surveillance program under the lead standard to guide employee medical removal. The ZPP which has several advantages over the blood lead level is, due to the pending litigation, not required under the standard. Because of its relatively recent development and the lack of extensive data concerning its interpretation, the ZPP currently remains an ancillary test.

This section will discuss the blood lead level and ZPP in detail and will outline their relative advantages and disadvantages. Other blood tests currently available to evaluate lead exposure will also be reviewed.

The blood lead level is a good index of current or recent lead absorption when there is no anemia present and when the worker has not taken any chelating agents. However, blood lead levels along with urinary lead levels do not necessarily indicate the total body burden of lead and are not adequate measures of past exposure. One reason for this is that lead has a high affinity for bone and up to 90% of the body's total lead is deposited there. A very important component of the total lead body burden is lead in soft tissue (liver, kidney, and brain). This fraction of the lead body burden, the biologically active lead, is not entirely reflected by blood lead levels since it is a function of the dynamics of lead absorption, distribution, deposition in bone and excretion. Following discontinuation of exposure to lead, the excess body burden is only slowly mobilized from bone and other relatively stable body stores and excreted. Consequently, a high blood lead level may only represent recent heavy exposure to lead without a significant total body excess and likewise a low blood lead level does not exclude an elevated total body burden of lead.

Also due to its correlation with recent exposures, the blood lead level may vary considerably over short time intervals.

To minimize laboratory error and erroneous results due to contamination, blood specimens must be carefully collected after thorough cleaning of the skin with appropriate methods using lead-free blood containers and analyzed by a reliable laboratory. Under the standard, samples must be analyzed in laboratories which are approved by the Center for Disease Control (CDC) or which have received satisfactory grades in proficiency testing by the CDC in the previous year. Analysis is to be made using atomic absorption spectrophotometry, anodic stripping voltammetry or any method which meets the accuracy requirements set forth by the standard.

The determination of lead in urine is generally considered a less reliable monitoring technique than analysis of whole blood primarily due to individual variability in urinary excretion capacity as well as the technical difficulty of obtaining accurate 24 hour urine collections. In addition, workers with renal insufficiency, whether due to lead or some other cause, may have decreased lead clearance and consequently urine lead levels may underestimate the true lead burden.

Therefore, urine lead levels should not be used as a routine test.

The zinc protoporphyrin test, unlike the blood lead determination, measures an adverse metabolic effect of lead and as such is a better indicator of lead toxicity than the level of blood lead itself. The level of ZPP reflects lead absorption over the preceding 3 to 4 months, and therefore is a better indicator of lead body burden. The ZPP requires more time than the blood lead to read significantly elevated levels; the return to normal after discontinuing lead exposure is also slower. Furthermore, the ZPP test is simpler, faster, and less expensive to perform and no contamination is possible. Many investigators believe it is the most reliable means of monitoring chronic lead absorption.

Zinc protoporphyrin results from the inhibition of the enzyme ferrochelatase which catalyzes the insertion of an iron molecule into the protoporphyrin molecule, which then becomes heme. If iron is not inserted into the molecule then zinc, having a greater affinity for protoporphyrin, takes the place of the iron, forming ZPP.

An elevation in the level of circulating ZPP may occur at blood lead levels as low as 20-30 ug/100 g in some workers. Once the blood lead level has reached 40 ug/100 g there is more marked rise in the ZPP value from its normal range of less than 100 ug/100 ml. Increases in blood lead levels beyond 40 ug/100 g are associated with exponential increases in ZPP.

Whereas blood lead levels fluctuate over short time spans, ZPP levels remain relatively stable. ZPP is measured directly in red blood cells and is present for the cell's entire 120 day life-span. Therefore, the ZPP level in blood reflects the average ZPP production over the previous 3-4 months and consequently the average lead exposure during that time interval.

It is recommended that a hematocrit be determined whenever a confirmed ZPP of 50 ug/100 ml whole blood is obtained to rule out a significant underlying anemia. If the ZPP is in excess of 100 ug/100 ml and not associated with abnormal elevations in blood lead levels, the laboratory should be checked to be sure that blood leads were determined using atomic absorption spectrophotometry anodic stripping voltammetry, or any method which meets the accuracy requirements set forth by the standard by a CDC approved laboratory which is experienced in lead level determinations. Repeat periodic blood lead studies should be obtained in all individuals with elevated ZPP levels to be certain that an associated elevated blood lead level has not been missed due to transient fluctuations in blood leads.

ZPP has a characteristic fluorescence spectrum with a peak at 594 nm which is detectable with a hematofluorimeter. The hematofluorimeter is accurate and portable and can provide on-site, instantaneous results for workers who can be frequently tested via a finger prick.

However, careful attention must be given to calibration and quality control procedures. Limited data on blood lead-ZPP correlations and the ZPP levels which are associated with the adverse health effects discussed in Section 2 are the major limitations of the test. Also it is difficult to

correlate ZPP levels with environmental exposure and there is some variation of response with age and sex. Nevertheless, the ZPP promises to be an important diagnostic test for the early detection of lead toxicity and its value will increase as more data is collected regarding its relationship to other manifestations of lead poisoning.

Levels of delta-aminolevulinic acid (ALA) in the urine are also used as a measure of lead exposure. Increasing concentrations of ALA are believed to result from the inhibition of the enzyme delta-aminolevulinic acid dehydrase (ALA-D). Although the test is relatively easy to perform, inexpensive, and rapid, the disadvantages include variability in results, the necessity to collect a complete 24 hour urine sample which has a specific gravity greater than 1.010, and also the fact that ALA decomposes in the presence of light.

The pattern of porphyrin excretion in the urine can also be helpful in identifying lead intoxication. With lead poisoning, the urine concentrations of coproporphyrins I and II, porphobilinogen and uroporphyrin I rise. The most important increase, however, is that of coproporphyrin III; levels may exceed 5,000 ug/1 in the urine in lead poisoned individuals, but its correlation with blood lead levels and ZPP are not as good as those of ALA. Increases in urinary porphyrins are not diagnostic of lead toxicity and may be seen in porphyria, some liver diseases, and in patients with high reticulocyte counts.

Summary. The Occupational Safety and Health Administration's standard for inorganic lead places significant emphasis on the medical surveillance of all workers exposed to levels of inorganic lead above the action level of 30 ug/m³ TWA. The physician has a fundamental role in this surveillance program, and in the operation of the medical removal protection program.

Even with adequate worker education on the adverse health effects of lead and appropriate training in work practices, personal hygiene and other control measures, the physician has a primary responsibility for evaluating potential lead toxicity in the worker. It is only through a careful and detailed medical and work history, a complete physical examination and appropriate laboratory testing that an accurate assessment can be made. Many of the adverse health effects of lead toxicity are either irreversible or only partially reversible and therefore early detection of disease is very important.

This document outlines the medical monitoring program as defined by the occupational safety and health standard for inorganic lead. It reviews the adverse health effects of lead poisoning and describes the important elements of the history and physical examinations as they relate to these adverse effects. Finally, the appropriate laboratory testing for evaluating lead exposure and toxicity is presented.

It is hoped that this review and discussion will give the physician a better understanding of the OSHA standard with the ultimate goal of protecting the health and well-being of the worker exposed to lead under his or her care.

1910.1025 App D Qualitative fit test protocols [Reserved]
APPENDIX D to 1910.1025 - QUALITATIVE FIT TEST PROTOCOLS [Reserved]

1910.1026 Chromium (VI).

(a) Scope.

(1) This standard applies to occupational exposures to chromium (VI) in all forms and compounds in general industry, except:

(2) Exposures that occur in the application of pesticides regulated by the Environmental Protection Agency or another Federal government agency (e.g., the treatment of wood with preservatives);

(3) Exposures to portland cement; or

(4) Where the employer has objective data demonstrating that a material containing chromium or a specific process, operation, or activity involving chromium cannot release dusts, fumes, or mists of chromium (VI) in concentrations at or above $0.5 \mu\text{g}/\text{m}^3$ as an 8-hour time-weighted average (TWA) under any expected conditions of use.

(b) **Definitions.** For the purposes of this section the following definitions apply:

Action level means a concentration of airborne chromium (VI) of 2.5 micrograms per cubic meter of air ($2.5 \mu\text{g}/\text{m}^3$) calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chromium (VI) [hexavalent chromium or Cr(VI)] means chromium with a valence of positive six, in any form and in any compound.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence that results, or is likely to result, in an uncontrolled release of chromium (VI). If an incidental release of chromium (VI) can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.

Employee exposure means the exposure to airborne chromium (VI) that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent

efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.

Historical monitoring data means data from chromium (VI) monitoring conducted prior to May 30, 2006, obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to chromium (VI) associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional [PLHCP] is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (k) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of chromium (VI) exceeds, or can reasonably be expected to exceed, the PEL.

This section means this § 1910.1026 chromium (VI) standard

(c) Permissible exposure limit (PEL). The employer shall ensure that no employee is exposed to an airborne concentration of chromium (VI) in excess of 5 micrograms per cubic meter of air ($5 \mu\text{g}/\text{m}^3$), calculated as an 8-hour time-weighted average (TWA).

(d) Exposure determination.

(1) General. Each employer who has a workplace or work operation covered by this section shall determine the 8-hour TWA exposure for each employee exposed to chromium (VI). This determination shall be made in accordance with either paragraph (d)(2) or paragraph (d)(3) of this section.

(2) Scheduled monitoring option.

(i) The employer shall perform initial monitoring to determine the 8-hour TWA exposure for each employee on the basis of a sufficient number of personal breathing zone air samples to accurately characterize full shift exposure on each shift, for each job classification, in each work area. Where an employer does representative sampling instead of sampling all employees in order to meet this requirement, the employer shall sample the employee(s) expected to have the highest chromium (VI) exposures.

(ii) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

(iii) If monitoring reveals employee exposures to be at or above the action level, the employer shall perform periodic monitoring at least every six months.

(iv) If monitoring reveals employee exposures to be above the PEL, the employer shall perform periodic monitoring at least every three months.

(v) If periodic monitoring indicates that employee exposures are below the action level, and the result is confirmed by the result of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(vi) The employer shall perform additional monitoring when there has been any change in the production process, raw materials, equipment, personnel, work practices, or control methods that may result in new or additional exposures to chromium (VI), or when the employer has any reason to believe that new or additional exposures have occurred.

(3) Performance-oriented option. The employer shall determine the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data, historical monitoring data, or objective data sufficient to accurately characterize employee exposure to chromium (VI).

(4) Employee notification of determination results.

(i) Within 15 work days after making an exposure determination in accordance with paragraph (d)(2) or paragraph (d)(3) of this section, the employer shall individually notify each affected employee in writing of the results of that determination or post the results in an appropriate location accessible to all affected employees.

(ii) Whenever the exposure determination indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(5) Accuracy of measurement. Where air monitoring is performed to comply with the requirements of this section, the employer shall use a method of monitoring and analysis that can measure chromium (VI) to within an accuracy of plus or minus 25 percent (+/- 25%) and can produce accurate measurements to within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(6) Observation of monitoring.

(i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to chromium (VI).

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures.

(e) Regulated areas.

(1) Establishment. The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of chromium (VI) is, or can reasonably be expected to be, in excess of the PEL.

(2) Demarcation. The employer shall ensure that regulated areas are demarcated from the rest of the workplace in a manner that adequately establishes and alerts employees of the boundaries of the regulated area.

(3) Access. The employer shall limit access to regulated areas to:

(i) Persons authorized by the employer and required by work duties to be present in the regulated area;

(ii) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; or

(iii) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(f) Methods of compliance.

(1) Engineering and work practice controls.

(i) Except as permitted in paragraph (f)(1)(ii) and paragraph (f)(1)(iii) of this section, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(ii) Where painting of aircraft or large aircraft parts is performed in the aerospace

industry, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below $25 \mu\text{g}/\text{m}^3$ unless the employer can demonstrate that such controls are not feasible. The employer shall supplement such engineering and work practice controls with the use of respiratory protection that complies with the requirements of paragraph (g) of this section to achieve the PEL.

(iii) Where the employer can demonstrate that a process or task does not result in any employee exposure to chromium (VI) above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.

(2) Prohibition of rotation. The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(g) Respiratory protection.

(1) General. Where respiratory protection is required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respiratory protection is required during:

(i) Periods necessary to install or implement feasible engineering and work practice controls;

(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or

(v) Emergencies.

(2) Respiratory protection program. Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134, which covers each employee required to use a respirator.

(h) Protective work clothing and equipment.

(1) Provision and use. Where a hazard is present or is likely to be present from skin or eye

contact with chromium (VI), the employer shall provide appropriate personal protective clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.

(2) Removal and storage.

(i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with chromium (VI) at the end of the work shift or at the completion of their tasks involving chromium (VI) exposure, whichever comes first.

(ii) The employer shall ensure that no employee removes chromium (VI)-contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.

(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.

~~(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200. The employer shall ensure that bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal are labeled in accordance with the requirements of the Hazard Communication Standard, § 1910.1200.~~

(3) Cleaning and replacement.

(i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.

(ii) The employer shall prohibit the removal of chromium (VI) from protective clothing and equipment by blowing, shaking, or any other means that disperses chromium (VI) into the air or onto an employee's body.

(iii) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with chromium (VI) of the potentially harmful effects of exposure to chromium (VI) and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with chromium (VI) and effectively prevents the release of airborne chromium (VI) in excess of the PEL.

(i) Hygiene areas and practices.

(1) General. Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1910.141. Where skin contact with chromium (VI) occurs, the employer shall provide washing facilities in conformance with 29 CFR 1910.141. Eating and drinking areas provided by the employer shall also be in conformance with § 1910.141.

(2) Change rooms. The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.

(3) Washing facilities.

(i) The employer shall provide readily accessible washing facilities capable of removing chromium (VI) from the skin, and shall ensure that affected employees use these facilities when necessary.

(ii) The employer shall ensure that employees who have skin contact with chromium (VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(4) Eating and drinking areas.

(i) Whenever the employer allows employees to consume food or beverages at a worksite where chromium (VI) is present, the employer shall ensure that eating and drinking areas and surfaces are maintained as free as practicable of chromium (VI).

(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface chromium (VI) has been removed from the clothing and equipment by methods that do not disperse chromium (VI) into the air or onto an employee's body.

(5) Prohibited activities. The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas, or in areas where skin or eye contact with chromium (VI) occurs; or carry the products associated with these activities, or store such products in these areas.

(j) Housekeeping.

(1) General. The employer shall ensure that:

(i) All surfaces are maintained as free as practicable of accumulations of chromium (VI).

(ii) All spills and releases of chromium (VI) containing material are cleaned up promptly.

(2) Cleaning methods.

(i) The employer shall ensure that surfaces contaminated with chromium (VI) are cleaned by HEPA-filter vacuuming or other methods that minimize the likelihood of exposure to chromium (VI).

(ii) Dry shoveling, dry sweeping, and dry brushing may be used only where HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure to chromium (VI) have been tried and found not to be effective.

(iii) The employer shall not allow compressed air to be used to remove chromium (VI) from any surface unless:

(A) The compressed air is used in conjunction with a ventilation system designed to capture the dust cloud created by the compressed air; or

(B) No alternative method is feasible.

(iv) The employer shall ensure that cleaning equipment is handled in a manner that minimizes the reentry of chromium (VI) into the workplace.

(3) Disposal. The employer shall ensure that:

(i) Waste, scrap, debris, and any other materials contaminated with chromium (VI) and consigned for disposal are collected and disposed of in sealed, impermeable bags or other closed, impermeable containers.

(ii) Bags or containers of waste, scrap, debris, and any other materials contaminated with chromium (VI) that are consigned for disposal are labeled in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200.

(k) Medical surveillance.

(1) General.

(i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:

(A) Who are or may be occupationally exposed to chromium (VI) at or above the action level for 30 or more days a year;

(B) Experiencing signs or symptoms of the adverse health effects associated with chromium (VI) exposure; or

(C) Exposed in an emergency.

(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.

(2) Frequency. The employer shall provide a medical examination:

(i) Within 30 days after initial assignment, unless the employee has received a chromium (VI) related medical examination that meets the requirements of this paragraph within the last twelve months;

(ii) Annually;

(iii) Within 30 days after a PLHCP's written medical opinion recommends an additional examination;

(iv) Whenever an employee shows signs or symptoms of the adverse health effects associated with chromium (VI) exposure;

(v) Within 30 days after exposure during an emergency which results in an uncontrolled release of chromium (VI); or

(vi) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (k) of this section was less than six months prior to the date of termination.

(3) Contents of examination. A medical examination consists of:

(i) A medical and work history, with emphasis on: Past, present, and anticipated future exposure to chromium (VI); any history of respiratory system dysfunction; any history of asthma, dermatitis, skin ulceration, or nasal septum perforation; and smoking status and history;

(ii) A physical examination of the skin and respiratory tract; and

(iii) Any additional tests deemed appropriate by the examining PLHCP.

(4) Information provided to the PLHCP. The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to chromium (VI);

(ii) The employee's former, current, and anticipated levels of occupational exposure to chromium (VI);

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer.

(5) PLHCP's written medical opinion.

(i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:

(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to chromium (VI);

(B) Any recommended limitations upon the employee's exposure to chromium (VI) or upon the use of personal protective equipment such as respirators;

(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to chromium (VI) exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to chromium (VI).

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(l) Communication of chromium (VI) hazards to employees.

~~(1) General. In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, employers shall comply with the following requirements: Hazard communication§general~~

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for

chromium (VI).

(ii) In classifying the hazards of chromium (VI) at least the following hazards are to be addressed: Cancer, eye irritation, and skin sensitization.

(iii) Employers shall include chromium (VI) in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of chromium (VI) and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l)(2) of this section.

(2) Employee information and training.

(i) The employer shall ensure that each employee can demonstrate knowledge of at least the following:

(A) The contents of this section; and

(B) The purpose and a description of the medical surveillance program required by paragraph (k) of this section.

(ii) The employer shall make a copy of this section readily available without cost to all affected employees.

(m) Recordkeeping.

(1) Air monitoring data.

(i) The employer shall maintain an accurate record of all air monitoring conducted to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation involving exposure to chromium (VI) that is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and the results of samples taken;

(E) Type of personal protective equipment, such as respirators worn; and

(F) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) Historical monitoring data.

(i) Where the employer has relied on historical monitoring data to determine exposure to chromium (VI), the employer shall establish and maintain an accurate record of the historical monitoring data relied upon.

(ii) The record shall include information that reflects the following conditions:

(A) The data were collected using methods that meet the accuracy requirements of paragraph (d)(5) of this section;

(B) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which exposure is being determined;

(C) The characteristics of the chromium (VI) containing material being handled when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined;

(D) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.

(iii) The employer shall ensure that historical exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(3) Objective data.

(i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The chromium containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing, or analysis of the material for the release of chromium (VI);

(D) A description of the process, operation, or activity and how the data support the determination; and

(E) Other data relevant to the process, operation, activity, material, or employee exposures.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(4) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (k) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's written opinions;

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(n) Dates.

(1) For employers with 20 or more employees, all obligations of this section, except engineering controls required by paragraph (f) of this section, commence November 27, 2006.

(2) For employers with 19 or fewer employees, all obligations of this section, except engineering controls required by paragraph (f) of this section, commence May 30, 2007.

(3) Except as provided in (n)(4), for all employers, engineering controls required by paragraph (f) of this section shall be implemented no later than May 31, 2010.

(4) In facilities that become parties to the settlement agreement included in Appendix A,

engineering controls required by paragraph (f) of this section shall be implemented no later than December 31, 2008.

[71 FR 10374, Feb. 28, 2006; 71 FR 63242, Oct. 30, 2006]

1910.1027 Cadmium.

(a) Scope. This standard applies to all occupational exposures to cadmium and cadmium compounds, in all forms, and in all industries covered by the Occupational Safety and Health Act, except the construction-related industries, which are covered under 29 CFR 1926.63.

(b) Definitions.

Action level (AL) is defined as an airborne concentration of cadmium of 2.5 micrograms per cubic meter of air (2.5 $\mu\text{g}/\text{m}^3$ (Footnote 3)), calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person authorized by the employer and required by work duties to be present in regulated areas or any person authorized by the OSH Act or regulations issued under it to be in regulated areas.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Employee exposure and similar language referring to the air cadmium level to which an employee is exposed means the exposure to airborne cadmium that would occur if the employee were not using respiratory protective equipment.

Final medical determination is the written medical opinion of the employee's health status by the examining physician under paragraphs (l)(3)-(12) of this section or, if multiple physician review under paragraph (l)(13) of this section or the alternative physician determination under paragraph (l)(14) of this section is invoked, it is the final, written medical finding, recommendation or determination that emerges from that process.

High-efficiency particulate air (HEPA) filter means a filter capable of trapping and retaining at least 99.97 percent of mono-dispersed particles of 0.3 micrometers in diameter.

Regulated area means an area demarcated by the employer where an employee's exposure to

airborne concentrations of cadmium exceeds, or can reasonably be expected to exceed the permissible exposure limit (PEL).

This section means this cadmium standard.

(c) Permissible Exposure Limit (PEL). The employer shall assure that no employee is exposed to an airborne concentration of cadmium in excess of five micrograms per cubic meter of air (5 µg/m³(Footnote 3)), calculated as an eight-hour time-weighted average exposure (TWA).

(d) Exposure monitoring

(1) General.

(i) Each employer who has a workplace or work operation covered by this section shall determine if any employee may be exposed to cadmium at or above the action level.

(ii) Determinations of employee exposure shall be made from breathing zone air samples that reflect the monitored employee's regular, daily 8-hour TWA exposure to cadmium.

(iii) Eight-hour TWA exposures shall be determined for each employee on the basis of one or more personal breathing zone air samples reflecting full shift exposure on each shift, for each job classification, in each work area. Where several employees perform the same job tasks, in the same job classification, on the same shift, in the same work area, and the length, duration, and level of cadmium exposures are similar, an employer may sample a representative fraction of the employees instead of all employees in order to meet this requirement. In representative sampling, the employer shall sample the employee(s) expected to have the highest cadmium exposures.

(2) Specific.

(i) Initial monitoring. Except as provided for in paragraphs (d)(2)(ii) and (d)(2)(iii) of this section, the employer shall monitor employee exposures and shall base initial determinations on the monitoring results.

(ii) Where the employer has monitored after September 14, 1991, under conditions that in all important aspects closely resemble those currently prevailing and where that monitoring satisfies all other requirements of this section, including the accuracy and confidence levels of paragraph (d)(6) of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

(iii) Where the employer has objective data, as defined in paragraph (n)(2) of this section, demonstrating that employee exposure to cadmium will not exceed the action level under the expected conditions of processing, use, or handling, the employer may rely upon such data instead of implementing initial monitoring.

(3) Monitoring Frequency (periodic monitoring).

(i) If the initial monitoring or periodic monitoring reveals employee exposures to be at or above the action level, the employer shall monitor at a frequency and pattern needed to represent the levels of exposure of employees and where exposures are above the PEL to assure the adequacy of respiratory selection and the effectiveness of engineering and work practice controls. However, such exposure monitoring shall be performed at least every six months. The employer, at a minimum, shall continue these semi-annual measurements unless and until the conditions set out in paragraph (d)(3)(ii) of this section are met.

(ii) If the initial monitoring or the periodic monitoring indicates that employee exposures are below the action level and that result is confirmed by the results of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(4) Additional Monitoring. The employer also shall institute the exposure monitoring required under paragraphs (d)(2)(i) and (d)(3) of this section whenever there has been a change in the raw materials, equipment, personnel, work practices, or finished products that may result in additional employees being exposed to cadmium at or above the action level or in employees already exposed to cadmium at or above the action level being exposed above the PEL, or whenever the employer has any reason to suspect that any other change might result in such further exposure.

(5) Employee Notification of Monitoring Results.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) Wherever monitoring results indicate that employee exposure exceeds the PEL, the employer shall include in the written notice a statement that the PEL has been exceeded and a description of the corrective action being taken by the employer to reduce employee exposure to or below the PEL.

(6) Accuracy of measurement. The employer shall use a method of monitoring and analysis that has an accuracy of not less than plus or minus 25 percent (25%), with a confidence level of 95 percent, for airborne concentrations of cadmium at or above the action level, the permissible exposure limit (PEL), and the separate engineering control air limit (SECAL).

(e) Regulated areas.

(1) Establishment. The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of cadmium is, or can reasonably be expected to be in excess of the permissible exposure limit (PEL).

(2) Demarcation. Regulated areas shall be demarcated from the rest of the workplace in any manner that adequately establishes and alerts employees of the boundaries of the regulated area.

(3) Access. Access to regulated areas shall be limited to authorized persons.

(4) Provision of respirators. Each person entering a regulated area shall be supplied with and required to use a respirator, selected in accordance with paragraph (g)(2) of this section.

(5) Prohibited activities. The employer shall assure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas, carry the products associated with these activities into regulated areas, or store such products in those areas.

(f) Methods of compliance.

(1) Compliance hierarchy.

(i) Except as specified in paragraphs (f)(1) (ii), (iii) and (iv) of this section the employer shall implement engineering and work practice controls to reduce and maintain employee exposure to cadmium at or below the PEL, except to the extent that the employer can demonstrate that such controls are not feasible.

(ii) Except as specified in paragraphs (f)(1) (iii) and (iv) of this section, in industries where a separate engineering control air limit (SECAL) has been specified for particular processes (See Table 1 in this paragraph (f)(1)(ii)), the employer shall implement engineering and work practice controls to reduce and maintain employee exposure at or below the SECAL, except to the extent that the employer can demonstrate that such controls are not feasible.

TABLE 1. - Separate Engineering Control Airborne Limits (SECALs) For Processes In Selected Industries

| Industry | Process | SECAL (ug/m(3)) |
|-------------------------|--|--------------------|
| Nickel Cadmium Battery | Plate making, plate preparation.... | 50 |
| | All other processes..... | 15 |
| Zinc/Cadmium Refining * | Cadmium refining, casting, melting, oxide production, sinter plant... | 50 |
| | Calcine, crushing, milling, blending | 50 |
| Pigment Manufacture | Calcine, crushing, milling, blending | 50 |
| | All other processes..... | 15 |
| Stabilizers * | Cadmium oxide charging, crushing, | |

| | | |
|-----------------|--|----|
| Lead Smelting * | drying, blending..... | 50 |
| | Sinter plant, blast furnace, baghouse, yard area..... | 50 |
| Plating * | Mechanical plating..... | 15 |

Footnote(*) Processes in these industries that are not specified in this table must achieve the PEL using engineering controls and work practices as required in f(1)(i)

(iii) The requirement to implement engineering and work practice controls to achieve the PEL or, where applicable, the SECAL does not apply where the employer demonstrates the following:

(A) The employee is only intermittently exposed; and

(B) The employee is not exposed above the PEL on 30 or more days per year (12 consecutive months).

(iv) Wherever engineering and work practice controls are required and are not sufficient to reduce employee exposure to or below the PEL or, where applicable, the SECAL, the employer nonetheless shall implement such controls to reduce exposures to the lowest levels achievable. The employer shall supplement such controls with respiratory protection that complies with the requirements of paragraph (g) of this section and the PEL.

(v) The employer shall not use employee rotation as a method of compliance.

(2) Compliance program.

(i) Where the PEL is exceeded, the employer shall establish and implement a written compliance program to reduce employee exposure to or below the PEL by means of engineering and work practice controls, as required by paragraph (f)(1) of this section. To the extent that engineering and work practice controls cannot reduce exposures to or below the PEL, the employer shall include in the written compliance program the use of appropriate respiratory protection to achieve compliance with the PEL.

(ii) Written compliance programs shall include at least the following:

(A) A description of each operation in which cadmium is emitted; e.g., machinery used, material processed, controls in place, crew size, employee job responsibilities, operating procedures, and maintenance practices;

(B) A description of the specific means that will be employed to achieve compliance, including engineering plans and studies used to determine methods selected for controlling exposure to cadmium, as well as, where necessary, the use of appropriate respiratory protection

to achieve the PEL;

(C) A report of the technology considered in meeting the PEL;

(D) Air monitoring data that document the sources of cadmium emissions;

(E) A detailed schedule for implementation of the program, including documentation such as copies of purchase orders for equipment, construction contracts, etc.;

(F) A work practice program that includes items required under paragraphs (h), (i), and (j) of this section;

(G) A written plan for emergency situations, as specified in paragraph (h) of this section; and

(H) Other relevant information.

(iii) The written compliance programs shall be reviewed and updated at least annually, or more often if necessary, to reflect significant changes in the employer's compliance status.

(iv) Written compliance programs shall be provided upon request for examination and copying to affected employees, designated employee representatives as well as to the Assistant Secretary, and the Director.

(3) Mechanical ventilation.

(i) When ventilation is used to control exposure, measurements that demonstrate the effectiveness of the system in controlling exposure, such as capture velocity, duct velocity, or static pressure shall be made as necessary to maintain its effectiveness.

(ii) Measurements of the system's effectiveness in controlling exposure shall be made as necessary within five working days of any change in production, process, or control that might result in a significant increase in employee exposure to cadmium.

(iii) Recirculation of air. If air from exhaust ventilation is recirculated into the workplace, the system shall have a high efficiency filter and be monitored to assure effectiveness.

(iv) Procedures shall be developed and implemented to minimize employee exposure to cadmium when maintenance of ventilation systems and changing of filters is being conducted.

(g) Respiratory protection.

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this

paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work practice controls when employee exposure levels exceed the PEL.

(ii) Maintenance and repair activities, and brief or intermittent operations, for which employee exposures exceed the PEL and engineering and work-practice controls are not feasible or are not required.

(iii) Activities in regulated areas specified in paragraph (e) of this section.

(iv) Work operations for which the employer has implemented all feasible engineering and work-practice controls and such controls are not sufficient to reduce employee exposures to or below the PEL.

(v) Work operations for which an employee is exposed to cadmium at or above the action level, and the employee requests a respirator.

(vi) Work operations for which an employee is exposed to cadmium above the PEL and engineering controls are not required by paragraph (f)(1)(ii) of this section.

(vii) Emergencies.

(2) Respirator program.

(i) The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) No employees must use a respirator if, based on their most recent medical examination, the examining physician determines that they will be unable to continue to function normally while using a respirator. If the physician determines that the employee must be limited in, or removed from, their current job because of their inability to use a respirator, the limitation or removal must be in accordance with paragraphs (1) (11) and (12) of this section.

(iii) If an employee has breathing difficulty during fit testing or respirator use, the employer must provide the employee with a medical examination in accordance with paragraph (1)(6)(ii) of this section to determine if the employee can use a respirator while performing the required duties.

(3) Respirator selection.

Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with full facepiece respirators when they experience eye irritation.

(C) Provide HEPA filters for powered and non-powered air-purifying respirators.

(ii) The employer must provide an employee with a powered air-purifying respirator instead of a negative-pressure respirator when an employee who is entitled to a respirator chooses to use this type of respirator and such a respirator provides adequate protection to the employee.

(h) Emergency situations. The employer shall develop and implement a written plan for dealing with emergency situations involving substantial releases of airborne cadmium. The plan shall include provisions for the use of appropriate respirators and personal protective equipment. In addition, employees not essential to correcting the emergency situation shall be restricted from the area and normal operations halted in that area until the emergency is abated.

(i) Protective work clothing and equipment

(1) Provision and use. If an employee is exposed to airborne cadmium above the PEL or where skin or eye irritation is associated with cadmium exposure at any level, the employer shall provide at no cost to the employee, and assure that the employee uses, appropriate protective work clothing and equipment that prevents contamination of the employee and the employee's garments. Protective work clothing and equipment includes, but is not limited to:

(i) Coveralls or similar full-body work clothing;

(ii) Gloves, head coverings, and boots or foot coverings; and

(iii) Face shields, vented goggles, or other appropriate protective equipment that complies with 29 CFR 1910.133.

(2) Removal and storage.

(i) The employer shall assure that employees remove all protective clothing and equipment contaminated with cadmium at the completion of the work shift and do so only in change rooms provided in accordance with paragraph (j)(1) of this section.

(ii) The employer shall assure that no employee takes cadmium-contaminated protective clothing or equipment from the workplace, except for employees authorized to do so for purposes of laundering, cleaning, maintaining, or disposing of cadmium contaminated protective clothing and equipment at an appropriate location or facility away from the workplace.

(iii) The employer shall assure that contaminated protective clothing and equipment, when removed for laundering, cleaning, maintenance, or disposal, is placed and stored in sealed, impermeable bags or other closed, impermeable containers that are designed to prevent dispersion of cadmium dust.

(iv) The employer shall assure that bags or containers of contaminated protective clothing and equipment that are to be taken out of the change rooms or the workplace for laundering, cleaning, maintenance or disposal shall bear labels in accordance with paragraph (m)(3) of this section.

(3) Cleaning, replacement, and disposal.

(i) The employer shall provide the protective clothing and equipment required by paragraph (i)(1) of this section in a clean and dry condition as often as necessary to maintain its effectiveness, but in any event at least weekly. The employer is responsible for cleaning and laundering the protective clothing and equipment required by this paragraph to maintain its effectiveness and is also responsible for disposing of such clothing and equipment.

(ii) The employer also is responsible for repairing or replacing required protective clothing and equipment as needed to maintain its effectiveness. When rips or tears are detected while an employee is working they shall be immediately mended, or the worksuit shall be immediately replaced.

(iii) The employer shall prohibit the removal of cadmium from protective clothing and equipment by blowing, shaking, or any other means that disperses cadmium into the air.

(iv) The employer shall assure that any laundering of contaminated clothing or cleaning of contaminated equipment in the workplace is done in a manner that prevents the release of airborne cadmium in excess of the permissible exposure limit prescribed in paragraph (c) of this section.

(v) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with cadmium of the potentially harmful effects of exposure to cadmium and that the clothing and equipment should be laundered or cleaned in a manner to effectively prevent the release of airborne cadmium in excess of the PEL.

(j) Hygiene areas and practices

(1) General. For employees whose airborne exposure to cadmium is above the PEL, the employer shall provide clean change rooms, handwashing facilities, showers, and lunchroom facilities that comply with 29 CFR 1910.141.

(2) Change rooms. The employer shall assure that change rooms are equipped with separate

storage facilities for street clothes and for protective clothing and equipment, which are designed to prevent dispersion of cadmium and contamination of the employee's street clothes.

(3) Showers and handwashing facilities.

(i) The employer shall assure that employees who are exposed to cadmium above the PEL shower during the end of the work shift.

(ii) The employer shall assure that employees whose airborne exposure to cadmium is above the PEL wash their hands and faces prior to eating, drinking, smoking, chewing tobacco or gum, or applying cosmetics.

(4) Lunchroom facilities.

(i) The employer shall assure that the lunchroom facilities are readily accessible to employees, that tables for eating are maintained free of cadmium, and that no employee in a lunchroom facility is exposed at any time to cadmium at or above a concentration of 2.5 $\mu\text{g}/\text{m}$ (Footnote 3).

(ii) The employer shall assure that employees do not enter lunchroom facilities with protective work clothing or equipment unless surface cadmium has been removed from the clothing and equipment by HEPA vacuuming or some other method that removes cadmium dust without dispersing it.

(k) Housekeeping.

(1) All surfaces shall be maintained as free as practicable of accumulations of cadmium.

(2) All spills and sudden releases of material containing cadmium shall be cleaned up as soon as possible.

(3) Surfaces contaminated with cadmium shall, wherever possible, be cleaned by vacuuming or other methods that minimize the likelihood of cadmium becoming airborne.

(4) HEPA-filtered vacuuming equipment or equally effective filtration methods shall be used for vacuuming. The equipment shall be used and emptied in a manner that minimizes the reentry of cadmium into the workplace.

(5) Shoveling, dry or wet sweeping, and brushing may be used only where vacuuming or other methods that minimize the likelihood of cadmium becoming airborne have been tried and found not to be effective.

(6) Compressed air shall not be used to remove cadmium from any surface unless the compressed air is used in conjunction with a ventilation system designed to capture the dust

cloud created by the compressed air.

~~(7) Waste, scrap, debris, bags, containers, personal protective equipment, and clothing contaminated with cadmium and consigned for disposal shall be collected and disposed of in sealed impermeable bags or other closed, impermeable containers. These bags and containers shall be labeled in accordance with paragraph (m)(2) of this section. Waste, scrap, debris, bags, containers, personal protective equipment, and clothing contaminated with cadmium and consigned for disposal shall be collected and disposed of in sealed impermeable bags or other closed, impermeable containers. These bags and containers shall be labeled in accordance with paragraph (m) of this section.~~

(l) Medical surveillance

(1) General

(i) Scope.

(A) Currently exposed-The employer shall institute a medical surveillance program for all employees who are or may be exposed to cadmium at or above the action level unless the employer demonstrates that the employee is not, and will not be, exposed at or above the action level on 30 or more days per year (twelve consecutive months); and,

(B) Previously exposed-The employer shall also institute a medical surveillance program for all employees who prior to the effective date of this section might previously have been exposed to cadmium at or above the action level by the employer, unless the employer demonstrates that the employee did not prior to the effective date of this section work for the employer in jobs with exposure to cadmium for an aggregated total of more than 60 months.

(ii) To determine an employee's fitness for using a respirator, the employer shall provide the limited medical examination specified in paragraph (1)(6) of this section.

(iii) The employer shall assure that all medical examinations and procedures required by this standard are performed by or under the supervision of a licensed physician, who has read and is familiar with the health effects section of appendix A to this section, the regulatory text of this section, the protocol for sample handling and laboratory selection in appendix F to this section, and the questionnaire of appendix D to this section. These examinations and procedures shall be provided without cost to the employee and at a time and place that is reasonable and convenient to employees.

(iv) The employer shall assure that the collecting and handling of biological samples of cadmium in urine (CdU), cadmium in blood (CdB), and beta-2 microglobulin in urine (b2-M) taken from employees under this section is done in a manner that assures their reliability and that analysis of biological samples of cadmium in urine (CdU), cadmium in blood (CdB), and beta-2

microglobulin in urine (β 2-M) taken from employees under this section is performed in laboratories with demonstrated proficiency for that particular analyte. (See appendix F to this section.)

(2) Initial examination.

(i) The employer shall provide an initial (preplacement) examination to all employees covered by the medical surveillance program required in paragraph (1)(1)(i) of this section. The examination shall be provided to those employees within 30 days after initial assignment to a job with exposure to cadmium or no later than 90 days after the effective date of this section, whichever date is later.

(ii) The initial (preplacement) medical examination shall include:

(A) A detailed medical and work history, with emphasis on: Past, present, and anticipated future exposure to cadmium; any history of renal, cardiovascular, respiratory, hematopoietic, reproductive, and/or musculo-skeletal system dysfunction; current usage of medication with potential nephrotoxic side-effects; and smoking history and current status; and

(B) Biological monitoring that includes the following tests:

(1) Cadmium in urine (CdU), standardized to grams of creatinine (g/Cr);

(2) Beta-2 microglobulin in urine (β 2-M), standardized to grams of creatinine (g/Cr), with pH specified, as described in appendix F to this section; and

(3) Cadmium in blood (CdB), standardized to liters of whole blood (lwb).

(iii) Recent Examination: An initial examination is not required to be provided if adequate records show that the employee has been examined in accordance with the requirements of paragraph (1)(2)(ii) of this section within the past 12 months. In that case, such records shall be maintained as part of the employee's medical record and the prior exam shall be treated as if it were an initial examination for the purposes of paragraphs (1)(3) and (4) of this section.

(3) Actions triggered by initial biological monitoring:

(i) If the results of the initial biological monitoring tests show the employee's CdU level to be at or below 3 μ g/g Cr, β 2-M level to be at or below 300 μ g/g Cr and CdB level to be at or below 5 μ g/lwb, then:

(A) For currently exposed employees, who are subject to medical surveillance under paragraph (1)(1)(i)(A) of this section, the employer shall provide the minimum level of periodic medical surveillance in accordance with the requirements in paragraph (1)(4)(i) of this section;

and

(B) For previously exposed employees, who are subject to medical surveillance under paragraph (1)(1)(i)(B) of this section, the employer shall provide biological monitoring for CdU, β 2-M, and CdB one year after the initial biological monitoring and then the employer shall comply with the requirements of paragraph (1)(4)(v) of this section.

(ii) For all employees who are subject to medical surveillance under paragraph (1)(1)(i) of this section, if the results of the initial biological monitoring tests show the level of CdU to exceed 3 $\mu\text{g/g Cr}$, the level of β 2-M to exceed 300 $\mu\text{g/g Cr}$, or the level of CdB to exceed 5 $\mu\text{g/lwb}$, the employer shall:

(A) Within two weeks after receipt of biological monitoring results, reassess the employee's occupational exposure to cadmium as follows:

- (1) Reassess the employee's work practices and personal hygiene;
- (2) Reevaluate the employee's respirator use, if any, and the respirator program;
- (3) Review the hygiene facilities;
- (4) Reevaluate the maintenance and effectiveness of the relevant engineering controls;
- (5) Assess the employee's smoking history and status;

(B) Within 30 days after the exposure reassessment, specified in paragraph (1)(3)(ii)(A) of this section, take reasonable steps to correct any deficiencies found in the reassessment that may be responsible for the employee's excess exposure to cadmium; and,

(C) Within 90 days after receipt of biological monitoring results, provide a full medical examination to the employee in accordance with the requirements of paragraph (1)(4)(ii) of this section. After completing the medical examination, the examining physician shall determine in a written medical opinion whether to medically remove the employee. If the physician determines that medical removal is not necessary, then until the employee's CdU level falls to or below 3 $\mu\text{g/g Cr}$, β 2-M level falls to or below 300 $\mu\text{g/g Cr}$ and CdB level falls to or below 5 $\mu\text{g/lwb}$, the employer shall:

(1) Provide biological monitoring in accordance with paragraph (1)(2)(ii)(B) of this section on a semiannual basis; and

(2) Provide annual medical examinations in accordance with paragraph (1)(4)(ii) of this section.

(iii) For all employees who are subject to medical surveillance under paragraph (1)(1)(i) of this section, if the results of the initial biological monitoring tests show the level of CdU to be in excess of 15 µg/g Cr, or the level of CdB to be in excess of 15 µg/lwb, or the level of β2-M to be in excess of 1,500 µg/g Cr, the employer shall comply with the requirements of paragraphs (1)(3)(ii)(A)-(B) of this section. Within 90 days after receipt of biological monitoring results, the employer shall provide a full medical examination to the employee in accordance with the requirements of paragraph (1)(4)(ii) of this section. After completing the medical examination, the examining physician shall determine in a written medical opinion whether to medically remove the employee. However, if the initial biological monitoring results and the biological monitoring results obtained during the medical examination both show that: CdU exceeds 15 µg/g Cr; or CdB exceeds 15 µg/lwb; or β2-M exceeds 1500 µg/g Cr, and in addition CdU exceeds 3 µg/g Cr or CdB exceeds 5 µg/liter of whole blood, then the physician shall medically remove the employee from exposure to cadmium at or above the action level. If the second set of biological monitoring results obtained during the medical examination does not show that a mandatory removal trigger level has been exceeded, then the employee is not required to be removed by the mandatory provisions of this paragraph. If the employee is not required to be removed by the mandatory provisions of this paragraph or by the physician's determination, then until the employee's CdU level falls to or below 3 µg/g Cr, β2-M level falls to or below 300 µg/g Cr and CdB level falls to or below 5 µg/lwb, the employer shall:

(A) Periodically reassess the employee's occupational exposure to cadmium;

(B) Provide biological monitoring in accordance with paragraph (1)(2)(ii)(B) of this section on a quarterly basis; and

(C) Provide semiannual medical examinations in accordance with paragraph (1)(4)(ii) of this section.

(iv) For all employees to whom medical surveillance is provided, beginning on January 1, 1999, and in lieu of paragraphs (1)(3)(i)-(iii) of this section:

(A) If the results of the initial biological monitoring tests show the employee's CdU level to be at or below 3 µg/g Cr, β2-M level to be at or below 300 µg/g Cr and CdB level to be at or below 5 µg/lwb, then for currently exposed employees, the employer shall comply with the requirements of paragraph (1)(3)(i)(A) of this section, and for previously exposed employees, the employer shall comply with the requirements of paragraph (1)(3)(i)(B) of this section;

(B) If the results of the initial biological monitoring tests show the level of CdU to exceed 3 µg/g Cr, the level of β2-M to exceed 300 µg/g Cr, or the level of CdB to exceed 5 µg/lwb, the employer shall comply with the requirements of paragraphs (1)(3)(ii)(A)-(C) of this section; and,

(C) If the results of the initial biological monitoring tests show the level of CdU to be in

excess of 7 µg/g Cr, or the level of CdB to be in excess of 10 µg/lwb, or the level of β2-M to be in excess of 750 µg/g Cr, the employer shall: Comply with the requirements of paragraphs (1)(3)(ii)(A)-(B) of this section; and, within 90 days after receipt of biological monitoring results, provide a full medical examination to the employee in accordance with the requirements of paragraph (1)(4)(ii) of this section. After completing the medical examination, the examining physician shall determine in a written medical opinion whether to medically remove the employee. However, if the initial biological monitoring results and the biological monitoring results obtained during the medical examination both show that: CdU exceeds 7 µg/g Cr; or CdB exceeds 10 µg/lwb; or β2-M exceeds 750 µg/g Cr, and in addition CdU exceeds 3 µg/g Cr or CdB exceeds 5 µg/liter of whole blood, then the physician shall medically remove the employee from exposure to cadmium at or above the action level. If the second set of biological monitoring results obtained during the medical examination does not show that a mandatory removal trigger level has been exceeded, then the employee is not required to be removed by the mandatory provisions of this paragraph. If the employee is not required to be removed by the mandatory provisions of this paragraph or by the physician's determination, then until the employee's CdU level falls to or below 3 µg/g Cr, β2-M level falls to or below 300 µg/g Cr and CdB level falls to or below 5 µg/lwb, the employer shall: periodically reassess the employee's occupational exposure to cadmium; provide biological monitoring in accordance with paragraph (1)(2)(ii)(B) of this section on a quarterly basis; and provide semiannual medical examinations in accordance with paragraph (1)(4)(ii) of this section.

(4) Periodic medical surveillance.

(i) For each employee who is covered under paragraph (1)(1)(i)(A) of this section, the employer shall provide at least the minimum level of periodic medical surveillance, which consists of periodic medical examinations and periodic biological monitoring. A periodic medical examination shall be provided within one year after the initial examination required by paragraph (1)(2) of this section and thereafter at least biennially. Biological sampling shall be provided at least annually, either as part of a periodic medical examination or separately as periodic biological monitoring.

(ii) The periodic medical examination shall include:

(A) A detailed medical and work history, or update thereof, with emphasis on: Past, present and anticipated future exposure to cadmium; smoking history and current status; reproductive history; current use of medications with potential nephrotoxic side-effects; any history of renal, cardiovascular, respiratory, hematopoietic, and/or musculo-skeletal system dysfunction; and as part of the medical and work history, for employees who wear respirators, questions 3-11 and 25-32 in Appendix D to this section;

(B) A complete physical examination with emphasis on: Blood pressure, the respiratory system, and the urinary system;

(C) A 14 inch by 17 inch, or a reasonably standard sized posterior-anterior chest X-ray (after the initial X-ray, the frequency of chest X-rays is to be determined by the examining physician);

(D) Pulmonary function tests, including forced vital capacity (FVC) and forced expiratory volume at 1 second (FEV1);

(E) Biological monitoring, as required in paragraph (1)(2)(ii)(B) of this section;

(F) Blood analysis, in addition to the analysis required under paragraph (1)(2)(ii)(B) of this section, including blood urea nitrogen, complete blood count, and serum creatinine;

(G) Urinalysis, in addition to the analysis required under paragraph (1)(2)(ii)(B) of this section, including the determination of albumin, glucose, and total and low molecular weight proteins;

(H) For males over 40 years old, prostate palpation, or other at least as effective diagnostic test(s); and

(I) Any additional tests deemed appropriate by the examining physician.

(iii) Periodic biological monitoring shall be provided in accordance with paragraph (1)(2)(ii)(B) of this section.

(iv) If the results of periodic biological monitoring or the results of biological monitoring performed as part of the periodic medical examination show the level of the employee's CdU, β 2-M, or CdB to be in excess of the levels specified in paragraphs (1)(3)(ii) or (iii); or, beginning on January 1, 1999, in excess of the levels specified in paragraphs (1)(3)(ii) or (iv) of this section, the employer shall take the appropriate actions specified in paragraphs (1)(3)(ii)-(iv) of this section.

(v) For previously exposed employees under paragraph (1)(1)(i)(B) of this section:

(A) If the employee's levels of CdU did not exceed 3 μ g/g Cr, CdB did not exceed 5 μ g/lwb, and β 2-M did not exceed 300 μ g/g Cr in the initial biological monitoring tests, and if the results of the followup biological monitoring required by paragraph (1)(3)(i)(B) of this section one year after the initial examination confirm the previous results, the employer may discontinue all periodic medical surveillance for that employee.

(B) If the initial biological monitoring results for CdU, CdB, or β 2-M were in excess of the levels specified in paragraph (1)(3)(i) of this section, but subsequent biological monitoring results required by paragraph (1)(3)(ii)-(iv) of this section show that the employee's CdU levels no longer exceed 3 μ g/g Cr, CdB levels no longer exceed 5 μ g/lwb, and β 2-M levels no longer

exceed 300 µg/g Cr, the employer shall provide biological monitoring for CdU, CdB, and β2-M one year after these most recent biological monitoring results. If the results of the followup biological monitoring, specified in this paragraph, confirm the previous results, the employer may discontinue all periodic medical surveillance for that employee.

(C) However, if the results of the follow-up tests specified in paragraph (1)(4)(v)(A) or (B) of this section indicate that the level of the employee's CdU, β2-M, or CdB exceeds these same levels, the employer is required to provide annual medical examinations in accordance with the provisions of paragraph (1)(4)(ii) of this section until the results of biological monitoring are consistently below these levels or the examining physician determines in a written medical opinion that further medical surveillance is not required to protect the employee's health.

(vi) A routine, biennial medical examination is not required to be provided in accordance with paragraphs (1)(3)(i) and (1)(4) of this section if adequate medical records show that the employee has been examined in accordance with the requirements of paragraph (1)(4)(ii) of this section within the past 12 months. In that case, such records shall be maintained by the employer as part of the employee's medical record, and the next routine, periodic medical examination shall be made available to the employee within two years of the previous examination.

(5) Actions triggered by medical examinations.

(i) If the results of a medical examination carried out in accordance with this section indicate any laboratory or clinical finding consistent with cadmium toxicity that does not require employer action under paragraph (1)(2), (3) or (4) of this section, the employer, within 30 days, shall reassess the employee's occupational exposure to cadmium and take the following corrective action until the physician determines they are no longer necessary:

(A) Periodically reassess: The employee's work practices and personal hygiene; the employee's respirator use, if any; the employee's smoking history and status; the respiratory protection program; the hygiene facilities; and the maintenance and effectiveness of the relevant engineering controls;

(B) Within 30 days after the reassessment, take all reasonable steps to correct the deficiencies found in the reassessment that may be responsible for the employee's excess exposure to cadmium;

(C) Provide semiannual medical reexaminations to evaluate the abnormal clinical sign(s) of cadmium toxicity until the results are normal or the employee is medically removed; and

(D) Where the results of tests for total proteins in urine are abnormal, provide a more detailed medical evaluation of the toxic effects of cadmium on the employee's renal system.

(6) Examination for respirator use.

(i) To determine an employee's fitness for respirator use, the employer shall provide a medical examination that includes the elements specified in paragraph (1)(6)(i)(A)-(D) of this section. This examination shall be provided prior to the employee's being assigned to a job that requires the use of a respirator or no later than 90 days after this section goes into effect, whichever date is later, to any employee without a medical examination within the preceding 12 months that satisfies the requirements of this paragraph.

(A) A detailed medical and work history, or update thereof, with emphasis on: Past exposure to cadmium; smoking history and current status; any history of renal, cardiovascular, respiratory, hematopoietic, and/or musculoskeletal system dysfunction; a description of the job for which the respirator is required; and questions 3-11 and 25-32 in appendix D to this section;

(B) A blood pressure test;

(C) Biological monitoring of the employee's levels of CdU, CdB and β 2-M in accordance with the requirements of paragraph (1)(2)(ii)(B) of this section, unless such results already have been obtained within the previous 12 months; and

(D) Any other test or procedure that the examining physician deems appropriate.

(ii) After reviewing all the information obtained from the medical examination required in paragraph (1)(6)(i) of this section, the physician shall determine whether the employee is fit to wear a respirator.

(iii) Whenever an employee has exhibited difficulty in breathing during a respirator fit test or during use of a respirator, the employer, as soon as possible, shall provide the employee with a periodic medical examination in accordance with paragraph (1)(4)(ii) of this section to determine the employee's fitness to wear a respirator.

(iv) Where the results of the examination required under paragraph (1)(6)(i), (ii), or (iii) of this section are abnormal, medical limitation or prohibition of respirator use shall be considered. If the employee is allowed to wear a respirator, the employee's ability to continue to do so shall be periodically evaluated by a physician.

(7) Emergency examinations.

(i) In addition to the medical surveillance required in paragraphs (1)(2)-(6) of this section, the employer shall provide a medical examination as soon as possible to any employee who may have been acutely exposed to cadmium because of an emergency.

(ii) The examination shall include the requirements of paragraph (1)(4)(ii) of this section, with emphasis on the respiratory system, other organ systems considered appropriate by the examining physician, and symptoms of acute overexposure, as identified in paragraphs II

(B)(1)-(2) and IV of appendix A to this section.

(8) Termination of employment examination.

(i) At termination of employment, the employer shall provide a medical examination in accordance with paragraph (1)(4)(ii) of this section, including a chest X-ray, to any employee to whom at any prior time the employer was required to provide medical surveillance under paragraphs (1)(1)(i) or (1)(7) of this section. However, if the last examination satisfied the requirements of paragraph (1)(4)(ii) of this section and was less than six months prior to the date of termination, no further examination is required unless otherwise specified in paragraphs (1)(3) or (1)(5) of this section;

(ii) However, for employees covered by paragraph (1)(1)(i)(B) of this section, if the employer has discontinued all periodic medical surveillance under paragraph (1)(4)(v) of this section, no termination of employment medical examination is required.

(9) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this standard and appendices;

(ii) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to cadmium;

(iii) The employee's former, current, and anticipated future levels of occupational exposure to cadmium;

(iv) A description of any personal protective equipment, including respirators, used or to be used by the employee, including when and for how long the employee has used that equipment; and

(v) relevant results of previous biological monitoring and medical examinations.

(10) Physician's written medical opinion.

(i) The employer shall promptly obtain a written, medical opinion from the examining physician for each medical examination performed on each employee. This written opinion shall contain:

(A) The physician's diagnosis for the employee;

(B) The physician's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to cadmium, including any indications of potential cadmium toxicity;

(C) The results of any biological or other testing or related evaluations that directly assess the employee's absorption of cadmium;

(D) Any recommended removal from, or limitation on the activities or duties of the employee or on the employee's use of personal protective equipment, such as respirators;

(E) A statement that the physician has clearly and carefully explained to the employee the results of the medical examination, including all biological monitoring results and any medical conditions related to cadmium exposure that require further evaluation or treatment, and any limitation on the employee's diet or use of medications.

(ii) The employer promptly shall obtain a copy of the results of any biological monitoring provided by an employer to an employee independently of a medical examination under paragraphs (1)(2) and (1)(4) of this section, and, in lieu of a written medical opinion, an explanation sheet explaining those results.

(iii) The employer shall instruct the physician not to reveal orally or in the written medical opinion given to the employer specific findings or diagnoses unrelated to occupational exposure to cadmium.

(11) Medical Removal Protection (MRP)

(i) General.

(A) The employer shall temporarily remove an employee from work where there is excess exposure to cadmium on each occasion that medical removal is required under paragraph (1)(3), (1)(4), or (1)(6) of this section and on each occasion that a physician determines in a written medical opinion that the employee should be removed from such exposure. The physician's determination may be based on biological monitoring results, inability to wear a respirator, evidence of illness, other signs or symptoms of cadmium-related dysfunction or disease, or any other reason deemed medically sufficient by the physician.

(B) The employer shall medically remove an employee in accordance with paragraph (1)(11) of this section regardless of whether at the time of removal a job is available into which the removed employee may be transferred.

(C) Whenever an employee is medically removed under paragraph (1)(11) of this section, the employer shall transfer the removed employee to a job where the exposure to cadmium is within the permissible levels specified in that paragraph as soon as one becomes available.

(D) For any employee who is medically removed under the provisions of paragraph (1)(11)(i) of this section, the employer shall provide follow-up biological monitoring in accordance with (1)(2)(ii)(B) of this section at least every three months and follow-up medical

examinations semi-annually at least every six months until in a written medical opinion the examining physician determines that either the employee may be returned to his/her former job status as specified under paragraph (1)(11)(iv)-(v) of this section or the employee must be permanently removed from excess cadmium exposure.

(E) The employer may not return an employee who has been medically removed for any reason to his/her former job status until a physician determines in a written medical opinion that continued medical removal is no longer necessary to protect the employee's health.

(ii) Where an employee is found unfit to wear a respirator under paragraph (1)(6)(ii) of this section, the employer shall remove the employee from work where exposure to cadmium is above the PEL.

(iii) Where removal is based on any reason other than the employee's inability to wear a respirator, the employer shall remove the employee from work where exposure to cadmium is at or above the action level.

(iv) Except as specified in paragraph (1)(11)(v) of this section, no employee who was removed because his/her level of CdU, CdB and/or β 2-M exceeded the medical removal trigger levels in paragraph (1)(3) or (1)(4) of this section may be returned to work with exposure to cadmium at or above the action level until the employee's levels of CdU fall to or below 3 μ g/g Cr, CdB falls to or below 5 μ g/lwb, and β 2-M falls to or below 300 μ g/g Cr.

(v) However, when in the examining physician's opinion continued exposure to cadmium will not pose an increased risk to the employee's health and there are special circumstances that make continued medical removal an inappropriate remedy, the physician shall fully discuss these matters with the employee, and then in a written determination may return a worker to his/her former job status despite what would otherwise be unacceptably high biological monitoring results. Thereafter, the returned employee shall continue to be provided with medical surveillance as if he/she were still on medical removal until the employee's levels of CdU fall to or below 3 μ g/g Cr, CdB falls to or below 5 μ g/lwb, and β 2-M falls to or below 300 μ g/g Cr.

(vi) Where an employer, although not required by paragraph (1)(11)(i)-(iii) of this section to do so, removes an employee from exposure to cadmium or otherwise places limitations on an employee due to the effects of cadmium exposure on the employee's medical condition, the employer shall provide the same medical removal protection benefits to that employee under paragraph (1)(12) of this section as would have been provided had the removal been required under paragraph (1)(11)(i)-(iii) of this section.

(12) Medical Removal Protection Benefits (MRPB).

(i) The employer shall provide MRPB for up to a maximum of 18 months to an employee each time and while the employee is temporarily medically removed under paragraph (1)(11) of

this section.

(ii) For purposes of this section, the requirement that the employer provide MRPB means that the employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits of the removed employee, including the employee's right to his/her former job status, as if the employee had not been removed from the employee's job or otherwise medically limited.

(iii) Where, after 18 months on medical removal because of elevated biological monitoring results, the employee's monitoring results have not declined to a low enough level to permit the employee to be returned to his/her former job status:

(A) The employer shall make available to the employee a medical examination pursuant to this section in order to obtain a final medical determination as to whether the employee may be returned to his/her former job status or must be permanently removed from excess cadmium exposure; and

(B) The employer shall assure that the final medical determination indicates whether the employee may be returned to his/her former job status and what s, if any, should be taken to protect the employee's health.

(iv) The employer may condition the provision of MRPB upon the employee's participation in medical surveillance provided in accordance with this section.

(13) Multiple physician review.

(i) If the employer selects the initial physician to conduct any medical examination or consultation provided to an employee under this section, the employee may designate a second physician to:

(A) Review any findings, determinations, or recommendations of the initial physician; and

(ii) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician provided by the employer conducts a medical examination or consultation pursuant to this section. The employer may condition its participation in, and payment for, multiple physician review upon the employee doing the following within fifteen (15) days after receipt of this notice, or receipt of the initial physician's written opinion, whichever is later:

(A) Informing the employer that he or she intends to seek a medical opinion; and

(B) Initiating s to make an appointment with a second physician.

(iii) If the findings, determinations, or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve any disagreement.

(iv) If the two physicians have been unable to quickly resolve their disagreement, then the employer and the employee, through their respective physicians, shall designate a third physician to:

(A) Review any findings, determinations, or recommendations of the other two physicians; and

(B) Conduct such examinations, consultations, laboratory tests, and discussions with the other two physicians as the third physician deems necessary to resolve the disagreement among them.

(v) The employer shall act consistently with the findings, determinations, and recommendations of the third physician, unless the employer and the employee reach an agreement that is consistent with the recommendations of at least one of the other two physicians.

(14) Alternate physician determination. The employer and an employee or designated employee representative may agree upon the use of any alternate form of physician determination in lieu of the multiple physician review provided by paragraph (l)(13) of this section, so long as the alternative is expeditious and at least as protective of the employee.

(15) Information the employer must provide the employee.

(i) The employer shall provide a copy of the physician's written medical opinion to the examined employee within two weeks after receipt thereof.

(ii) The employer shall provide the employee with a copy of the employee's biological monitoring results and an explanation sheet explaining the results within two weeks after receipt thereof.

(iii) Within 30 days after a request by an employee, the employer shall provide the employee with the information the employer is required to provide the examining physician under paragraph (l)(9) of this section.

(16) Reporting. In addition to other medical events that are required to be reported on the OSHA Form No. 200, the employer shall report any abnormal condition or disorder caused by occupational exposure to cadmium associated with employment as specified in Chapter (V)(E) of the Reporting Guidelines for Occupational Injuries and Illnesses.

(m) Communication of cadmium hazards to employees

(1) ~~General. In communications concerning cadmium hazards, employers shall comply with the requirements of OSHA's Hazard Communication Standard, 29 CFR 1910.1200, including but not limited to the requirements concerning warning signs and labels, material safety data sheets (MSDS), and employee information and training. In addition, employers shall comply with the following requirements: Hazard communication.—general.~~

(i) Warning signs shall be provided and displayed in regulated areas. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective steps before entering the area.

(2) Warning signs.

(i) Warning signs shall be provided and displayed in regulated areas. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective s before entering the area.

~~(ii) Warning signs required by paragraph (m)(2)(i) of this section shall bear the following information:~~ Warning signs required by paragraph (m)(2)(i) of this section shall bear the following legend:

~~————— DANGER
————— CADMIUM
————— CANCER HAZARD
————— CAN CAUSE LUNG AND KIDNEY DISEASE
————— AUTHORIZED PERSONNEL ONLY
————— RESPIRATORS REQUIRED IN THIS AREA~~
DANGER
CADMIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS AND KIDNEYS
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

~~(iii) The employer shall assure that signs required by this paragraph are illuminated, cleaned, and maintained as necessary so that the legend is readily visible. The employer shall ensure that signs required by this paragraph (m)(2) are illuminated, cleaned, and maintained as necessary so that the legend is readily visible.~~

(iv) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in

paragraph (m)(2)(ii) of this section:

DANGER
CADMIUM
CANCER HAZARD
CAN CAUSE LUNG AND KIDNEY DISEASE
AUTHORIZED PERSONNEL ONLY
RESPIRATORS REQUIRED IN THIS AREA

(3) Warning labels.

(i) ~~Shipping and storage containers containing cadmium, cadmium compounds, or cadmium contaminated clothing, equipment, waste, scrap, or debris shall bear appropriate warning labels, as specified in paragraph (m)(3)(ii) of this section.~~

(ii) ~~The warning labels shall include at least the following information:~~ The warning labels for containers of contaminated protective clothing, equipment, waste, scrap, or debris shall include at least the following information:

~~_____ DANGER~~
~~_____ CONTAINS CADMIUM~~
~~_____ CANCER HAZARD~~
~~_____ AVOID CREATING DUST~~
~~_____ CAN CAUSE LUNG AND KIDNEY DISEASE~~

DANGER
CONTAINS CADMIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS AND KIDNEYS
AVOID CREATING DUST

(iii) ~~Where feasible, installed cadmium products shall have a visible label or other indication that cadmium is present. Prior to June 1, 2015, employers may include the following information on shipping and storage containers containing cadmium, cadmium compounds, or cadmium contaminated clothing, equipment, waste, scrap, or debris in lieu of the labeling requirements specified in paragraphs (m)(1)(i) and (m)(3)(ii) of this section:~~

DANGER
CONTAINS CADMIUM
CANCER HAZARD
AVOID CREATING DUST
CAN CAUSE LUNG AND KIDNEY DISEASE

(iv) Where feasible, installed cadmium products shall have a visible label or other indication

that cadmium is present

(4) Employee information and training.

(i) The employer shall train each employee who is potentially exposed to cadmium in accordance with the requirements of this section. The employer shall institute a training program, ensure employee participation in the program, and maintain a record of the contents of such program.

(ii) Training shall be provided prior to or at the time of initial assignment to a job involving potential exposure to cadmium and at least annually thereafter.

(iii) The employer shall make the training program understandable to the employee and shall assure that each employee is informed of the following:

(A) The health hazards associated with cadmium exposure, with special attention to the information incorporated in appendix A to this section:

(B) The quantity, location, manner of use, release, and storage of cadmium in the workplace and the specific nature of operations that could result in exposure to cadmium, especially exposures above the PEL;

(C) The engineering controls and work practices associated with the employee's job assignment;

(D) The measures employees can take to protect themselves from exposure to cadmium, including modification of such habits as smoking and personal hygiene, and specific procedures the employer has implemented to protect employees from exposure to cadmium such as appropriate work practices, emergency procedures, and the provision of personal protective equipment;

(E) The purpose, proper selection, fitting, proper use, and limitations of respirators and protective clothing;

(F) The purpose and a description of the medical surveillance program required by paragraph (l) of this section;

(G) The contents of this section and its appendices; and

(H) The employee's rights of access to records under 1910.1020(e) and (g).

(iv) Additional access to information and training program and materials.

(A) The employer shall make a copy of this section and its appendices readily available without cost to all affected employees and shall provide a copy if requested.

(B) The employer shall provide to the Assistant Secretary or the Director, upon request, all materials relating to the employee information and the training program.

(n) Recordkeeping

(1) Exposure monitoring.

(i) The employer shall establish and keep an accurate record of all air monitoring for cadmium in the workplace.

(ii) This record shall include at least the following information:

(A) The monitoring date, duration, and results in terms of an 8-hour TWA of each sample taken;

(B) The name, social security number, and job classification of the employees monitored and of all other employees whose exposures the monitoring is intended to represent;

(C) A description of the sampling and analytical methods used and evidence of their accuracy;

(D) The type of respiratory protective device, if any, worn by the monitored employee;

(E) A notation of any other conditions that might have affected the monitoring results.

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.1020.

(2) Objective data for exemption from requirement for initial monitoring. (i) For purposes of this section, objective data are information demonstrating that a particular product or material containing cadmium or a specific process, operation, or activity involving cadmium cannot release dust or fumes in concentrations at or above the action level even under the worst-case release conditions. Objective data can be obtained from an industry-wide study or from laboratory product test results from manufacturers of cadmium-containing products or materials. The data the employer uses from an industry-wide survey must be obtained under workplace conditions closely resembling the processes, types of material, control methods, work practices and environmental conditions in the employer's current operations.

(ii) The employer shall establish and maintain a record of the objective data for at least 30 years.

(3) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (1)(1)(i) of this section.

(ii) The record shall include at least the following information about the employee:

(A) Name, social security number, and description of the duties;

(B) A copy of the physician's written opinions and an explanation sheet for biological monitoring results;

(C) A copy of the medical history, and the results of any physical examination and all test results that are required to be provided by this section, including biological tests, X-rays, pulmonary function tests, etc., or that have been obtained to further evaluate any condition that might be related to cadmium exposure;

(D) The employee's medical symptoms that might be related to exposure to cadmium; and

(E) A copy of the information provided to the physician as required by paragraph (1)(9)(ii)-(v) of this section.

(iii) The employer shall assure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

(4) Availability.

(i) Except as otherwise provided for in this section, access to all records required to be maintained by paragraphs (n)(1) through (3) of this section shall be in accordance with the provisions of 29 CFR 1910.1020.

(ii) Within 15 days after a request, the employer shall make an employee's medical records required to be kept by paragraph (n)(3) of this section available for examination and copying to the subject employee, to designated representatives, to anyone having the specific written consent of the subject employee, and after the employee's death or incapacitation, to the employee's family members.

(5) Transfer of records. Whenever an employer ceases to do business and there is no successor employer to receive and retain records for the prescribed period or the employer intends to dispose of any records required to be preserved for at least 30 years, the employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020 (h).

(o) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to cadmium.

(2) Observation procedures. When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with that clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures.

(p) Dates

(1) Effective date. This section shall become effective December 14, 1992.

(2) Start-up dates. All obligations of this section commence on the effective date except as follows:

(i) Exposure monitoring. Except for small businesses (nineteen (19) or fewer employees), initial monitoring required by paragraph (d)(2) of this section shall be completed as soon as possible and in any event no later than 60 days after the effective date of this standard. For small businesses, initial monitoring required by paragraph (d)(2) of this section shall be completed as soon as possible and in any event no later than 120 days after the effective date of this standard.

(ii) Regulated areas. Except for small business, defined under paragraph (p)(2)(i) of this section, regulated areas required to be established by paragraph (e) of this section shall be set up as soon as possible after the results of exposure monitoring are known and in any event no later than 90 days after the effective date of this section. For small businesses, regulated areas required to be established by paragraph (e) of this section shall be set up as soon as possible after the results of exposure monitoring are known and in any event no later than 150 days after the effective date of this section.

(iii) Respiratory protection. Except for small businesses, defined under paragraph (p)(2)(i) of this section, respiratory protection required by paragraph (g) of this section shall be provided as soon as possible and in any event no later than 90 days after the effective date of this section. For small businesses, respiratory protection required by paragraph (g) of this section shall be provided as soon as possible and in any event no later than 150 days after the effective date of this section.

(iv) Compliance program. Written compliance programs required by paragraph (f)(2) of this section shall be completed and available for inspection and copying as soon as possible and in any event no later than 1 year after the effective date of this section.

(v) Methods of compliance. The engineering controls required by paragraph (f)(1) of this

section shall be implemented as soon as possible and in any event no later than two (2) years after the effective date of this section. Work practice controls shall be implemented as soon as possible. Work practice controls that are directly related to engineering controls to be implemented in accordance with the compliance plan shall be implemented as soon as possible after such engineering controls are implemented.

(vi) Hygiene and lunchroom facilities.

(A) Handwashing facilities, permanent or temporary, shall be provided in accordance with 29 CFR 1910.141 (d)(1) and (2) as soon as possible and in any event no later than 60 days after the effective date of this section.

(B) Change rooms, showers, and lunchroom facilities shall be completed as soon as possible and in any event no later than 1 year after the effective date of this section.

(vii) Employee information and training. Except for small businesses, defined under paragraph (p)(2)(i) of this section, employee information and training required by paragraph (m)(4) of this section shall be provided as soon as possible and in any event no later than 90 days after the effective date of this standard. For small businesses, employee information and training required by paragraph (m)(4) of this standard shall be provided as soon as possible and in any event no later than 180 days after the effective date of this standard.

(viii) Medical surveillance. Except for small businesses, defined under paragraph (p)(2)(i) of this section, initial medical examinations required by paragraph (l) of this section shall be provided as soon as possible and in any event no later than 90 days after the effective date of this standard. For small businesses, initial medical examinations required by paragraph (l) of this section shall be provided as soon as possible and in any event no later than 180 days after the effective date of this standard.

(q) Appendices.

Except where portions of appendices A, B, D, E, and F to this section are expressly incorporated in requirements of this section, these appendices are purely informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

1910.1027 Appendix A Substance Safety Data Sheet - Cadmium

I. Substance Identification

A. Substance: Cadmium.

B. 8-Hour, Time-weighted-average, Permissible Exposure Limit (TWA PEL):

1. TWA PEL: Five micrograms of cadmium per cubic meter of air 5 ug/m(3), time-weighted average (TWA) for an 8-hour workday.

C. Appearance: Cadmium metal-soft, blue-white, malleable, lustrous metal or grayish-white powder. Some cadmium compounds may also appear as a brown, yellow, or red powdery substance.

II. Health Hazard Data

A. Routes of Exposure. Cadmium can cause local skin or eye irritation. Cadmium can affect your health if you inhale it or if you swallow it.

B. Effects of Overexposure.

1. Short-term (acute) exposure: Cadmium is much more dangerous by inhalation than by ingestion. High exposures to cadmium that may be immediately dangerous to life or health occur in jobs where workers handle large quantities of cadmium dust or fume; heat cadmium-containing compounds or cadmium-coated surfaces; weld with cadmium solders or cut cadmium-containing materials such as bolts.

2. Severe exposure may occur before symptoms appear. Early symptoms may include mild irritation of the upper respiratory tract, a sensation of constriction of the throat, a metallic taste and/or a cough. A period of 1-10 hours may precede the onset of rapidly progressing shortness of breath, chest pain, and flu-like symptoms with weakness, fever, headache, chills, sweating and muscular pain. Acute pulmonary edema usually develops within 24 hours and reaches a maximum by three days. If death from asphyxia does not occur, symptoms may resolve within a week.

3. Long-term (chronic) exposure. Repeated or long-term exposure to cadmium, even at relatively low concentrations, may result in kidney damage and an increased risk of cancer of the lung and of the prostate.

C. Emergency First Aid Procedures.

1. Eye exposure: Direct contact may cause redness or pain. Wash eyes immediately with large amounts of water, lifting the upper and lower eyelids. Get medical attention immediately.

2. Skin exposure: Direct contact may result in irritation. Remove contaminated clothing and shoes immediately. Wash affected area with soap or mild detergent and large amounts of water. Get medical attention immediately.

3. Ingestion: Ingestion may result in vomiting, abdominal pain, nausea, diarrhea, headache and sore throat. Treatment for symptoms must be administered by medical personnel. Under no circumstances should the employer allow any person whom he retains, employs, supervises or controls to engage in therapeutic chelation. Such treatment is likely to translocate cadmium from pulmonary or other tissue to renal tissue. Get medical attention immediately.

4. Inhalation: If large amounts of cadmium are inhaled, the exposed person must be moved to fresh air at once. If breathing has stopped, perform cardiopulmonary resuscitation. Administer oxygen if available. Keep the affected person warm and at rest. Get medical attention immediately.

5. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, attempt rescue only after notifying at least one other person of the emergency and putting into effect established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the emergency equipment before the need arises.

III. Employee Information

A. Protective Clothing and Equipment.

1. Respirators: You may be required to wear a respirator for non-routine activities; in emergencies; while your employer is in the process of reducing cadmium exposures through engineering controls; and where engineering controls are not feasible. If respirators are worn in the future, they must have a joint Mine Safety and Health Administration (MSHA) and National Institute for Occupational Safety and Health (NIOSH) label of approval. Cadmium does not have a detectable odor except at levels well above the permissible exposure limits. If you can smell cadmium while wearing a respirator, proceed immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

2. Protective Clothing: You may be required to wear impermeable clothing, gloves, foot gear, a face shield, or other appropriate protective clothing to prevent skin contact with cadmium. Where protective clothing is required, your employer must provide clean garments to you as necessary to assure that the clothing protects you adequately. The employer must replace or repair protective clothing that has become torn or otherwise damaged.

3. Eye Protection: You may be required to wear splash-proof or dust resistant goggles to prevent eye contact with cadmium.

B. Employer Requirements.

1. Medical: If you are exposed to cadmium at or above the action level, your employer is required to provide a medical examination, laboratory tests and a medical history according to the medical surveillance provisions under paragraph (I) of this standard. (See summary chart and tables in this Appendix A.) These tests shall be provided without cost to you. In addition, if you are accidentally exposed to cadmium under conditions known or suspected to constitute toxic exposure to cadmium, your employer is required to make special tests available to you.

2. Access to Records: All medical records are kept strictly confidential. You or your representative are entitled to see the records of measurements of your exposure to cadmium. Your medical examination records can be furnished to your personal physician or designated representative upon request by you to your employer.

3. Observation of Monitoring: Your employer is required to perform measurements that are representative of your exposure to cadmium and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear the protective clothing and equipment.

C. Employee Requirements. You will not be able to smoke, eat, drink, chew gum or tobacco, or apply cosmetics while working with cadmium in regulated areas. You will also not be able to carry or store tobacco products, gum, food, drinks or cosmetics in regulated areas because these products easily become contaminated with cadmium from the workplace and can therefore create another source of unnecessary cadmium exposure.

Some workers will have to change out of work clothes and shower at the end of the day, as part of their workday, in order to wash cadmium from skin and hair. Handwashing and cadmium-free eating facilities shall be provided by the employer and proper hygiene should always be performed before eating. It is also recommended that you do not smoke or use tobacco products, because among other things, they naturally contain cadmium. For further information, read the labeling on such products.

IV. Physician Information

A. Introduction.

The medical surveillance provisions of paragraph (l) generally are aimed at accomplishing three main interrelated purposes: First, identifying employees at higher risk of adverse health effects from excess, chronic exposure to cadmium; second, preventing cadmium-induced disease; and third, detecting and minimizing existing cadmium-induced disease. The core of medical surveillance in this standard is the early and periodic monitoring of the employee's biological indicators of: (a) recent exposure to cadmium; (b) cadmium body burden; and (c) potential and actual kidney damage associated with exposure to cadmium.

The main adverse health effects associated with cadmium overexposure are lung cancer and kidney dysfunction. It is not yet known how to adequately biologically monitor human beings to specifically prevent cadmium-induced lung cancer. By contrast, the kidney can be monitored to provide prevention and early detection of cadmium-induced kidney damage. Since, for non-carcinogenic effects, the kidney is considered the primary target organ of chronic exposure to cadmium, the medical surveillance provisions of this standard effectively focus on cadmium-induced kidney disease. Within that focus, the aim, where possible, is to prevent the onset of such disease and, where necessary, to minimize such disease as may already exist. The by-products of successful prevention of kidney disease are anticipated to be the reduction and prevention of other cadmium-induced diseases.

B. Health Effects.

The major health effects associated with cadmium overexposure are described below.

1. Kidney. The most prevalent non-malignant disease observed among workers chronically exposed to cadmium is kidney dysfunction. Initially, such dysfunction is manifested as proteinuria. The proteinuria associated with cadmium exposure is most commonly characterized by excretion of low-molecular weight proteins (15,000 to 40,000 MW) accompanied by loss of electrolytes, uric acid, calcium, amino acids, and phosphate. The compounds commonly excreted include: beta-2-microglobulin (B(2)-M), retinol binding protein (RBP), immunoglobulin light chains, and lysozyme. Excretion of low molecular weight proteins are characteristic of damage to the proximal tubules of the kidney (Iwao et al., 1980).

It has also been observed that exposure to cadmium may lead to urinary excretion of high-molecular weight proteins such as albumin, immunoglobulin G, and glycoproteins (Ex. 29). Excretion of high-molecular weight proteins is typically indicative of damage to the glomeruli of the kidney. Bernard et al., (1979) suggest that damage to the glomeruli and damage to the proximal tubules of the kidney may both be linked to cadmium exposure but they may occur independently of each other.

Several studies indicate that the onset of low-molecular weight proteinuria is a sign of irreversible kidney damage (Friberg et al., 1974; Roels et al., 1982; Piscator 1984; Elinder et al., 1985; Smith et al., 1986). Above specific levels of B(2)-M associated with cadmium exposure it is unlikely that B(2)-M levels return to normal even when cadmium exposure is eliminated by removal of the individual from the cadmium work environment (Friberg, Ex. 29, 1990).

Some studies indicate that such proteinuria may be progressive; levels of B(2)-M observed in the urine increase with time even after cadmium exposure has ceased. See, for example, Elinder et al., 1985. Such observations, however, are not universal, and it has been suggested that studies in which proteinuria has not been observed to progress may not have tracked patients for a sufficiently long time interval (Jarup, Ex. 8-661).

When cadmium exposure continues after the onset of proteinuria, chronic nephrotoxicity may occur (Friberg, Ex. 29). Uremia results from the inability of the glomerulus to adequately filter blood. This leads to severe disturbance of electrolyte concentrations and may lead to various clinical complications including kidney stones (L-140-50).

After prolonged exposure to cadmium, glomerular proteinuria, glucosuria, aminoaciduria, phosphaturia, and hypercalciuria may develop (Exs. 8-86, 4-28, 14-18). Phosphate, calcium, glucose, and amino acids are essential to life, and under normal conditions, their excretion should be regulated by the kidney. Once low molecular weight proteinuria has developed, these elements dissipate from the human body. Loss of glomerular function may also occur, manifested by decreased glomerular filtration rate and increased serum creatinine. Severe cadmium-induced renal damage may eventually develop into chronic renal failure and uremia (Ex. 55).

Studies in which animals are chronically exposed to cadmium confirm the renal effects observed in humans (Friberg et al., 1986). Animal studies also confirm problems with calcium metabolism

and related skeletal effects which have been observed among humans exposed to cadmium in addition to the renal effects. Other effects commonly reported in chronic animal studies include anemia, changes in liver morphology, immunosuppression and hypertension. Some of these effects may be associated with co-factors. Hypertension, for example, appears to be associated with diet as well as cadmium exposure. Animals injected with cadmium have also shown testicular necrosis (Ex. 8-86B).

2. Biological Markers

It is universally recognized that the best measures of cadmium exposures and its effects are measurements of cadmium in biological fluids, especially urine and blood. Of the two, CdU is conventionally used to determine body burden of cadmium in workers without kidney disease. CdB is conventionally used to monitor for recent exposure to cadmium. In addition, levels of CdU and CdB historically have been used to predict the percent of the population likely to develop kidney disease (Thun et al., Ex. L-140-50; WHO, Ex. 8-674; ACGIH, Exs. 8-667, 140-50).

The third biological parameter upon which OSHA relies for medical surveillance is Beta-2-microglobulin in urine (B(2)-M), a low molecular weight protein. Excess B(2)-M has been widely accepted by physicians and scientists as a reliable indicator of functional damage to the proximal tubule of the kidney (Exs. 8-447, 144-3-C, 4-47, L-140-45, 19-43-A).

Excess B(2)-M is found when the proximal tubules can no longer reabsorb this protein in a normal manner. This failure of the proximal tubules is an early stage of a kind of kidney disease that commonly occurs among workers with excessive cadmium exposure. Used in conjunction with biological test results indicating abnormal levels of CdU and CdB, the finding of excess B(2)-M can establish for an examining physician that any existing kidney disease is probably cadmium-related (Trs. 6/6/90, pp. 82-86, 122, 134). The upper limits of normal levels for cadmium in urine and cadmium in blood are 3 ug Cd/gram creatinine in urine and 5 ug Cd/liter whole blood, respectively. These levels were derived from broad-based population studies.

Three issues confront the physicians in the use of B(2)-M as a marker of kidney dysfunction and material impairment. First, there are a few other causes of elevated levels of B(2)-M not related to cadmium exposures, some of which may be rather common diseases and some of which are serious diseases (e.g., myeloma or transient flu, Exs. 29 and 8-086). These can be medically evaluated as alternative causes (Friberg, Ex. 29). Also, there are other factors that can cause B(2)-M to degrade so that low levels would result in workers with tubular dysfunction. For example, regarding the degradation of B(2)-M, workers with acidic urine (pH > 6) might have B(2)-M levels that are within the "normal" range when in fact kidney dysfunction has occurred (Ex. L-140-1) and the low molecular weight proteins are degraded in acid urine. Thus, it is very important that the pH of urine be measured, that urine samples be buffered as necessary (See Appendix F.), and that urine samples be handled correctly, i.e., measure the pH of freshly voided urine samples, then if necessary, buffer to pH > 6 (or above for shipping purposes), measure pH again and then, perhaps, freeze the sample for storage and shipping. (See also Appendix F.) Second, there is debate over the pathological significance of proteinuria, however, most world

experts believe that B(2)-M levels greater than 300 ug/g Cr are abnormal (Elinder, Ex. 55, Friberg, Ex. 29). Such levels signify kidney dysfunction that constitutes material impairment of health. Finally, detection of B(2)-M at low levels has often been considered difficult, however, many laboratories have the capability of detecting excess B(2)-M using simple kits, such as the Phadebas Delphia test, that are accurate to levels of 100 ug B(2)-M/g Cr U (Ex. L-140-1).

Specific recommendations for ways to measure B(2)-M and proper handling of urine samples to prevent degradation of B(2)-M have been addressed by OSHA in Appendix F, in the section on laboratory standardization. All biological samples must be analyzed in a laboratory that is proficient in the analysis of that particular analyte, under paragraph (l)(1)(iv). (See Appendix F). Specifically, under paragraph (l)(1)(iv), the employer is to assure that the collecting and handling of biological samples of cadmium in urine (CdU), cadmium in blood (CdB), and beta-2 microglobulin in urine (B(2)-M) taken from employees is collected in a manner that assures reliability. The employer must also assure that analysis of biological samples of cadmium in urine (CdU), cadmium in blood (CdB), and beta-2 microglobulin in urine (B(2)-M) taken from employees is performed in laboratories with demonstrated proficiency for that particular analyte. (See Appendix F.)

3. Lung and Prostrate Cancer

The primary sites for cadmium-associated cancer appear to be the lung and the prostate (L-140-50). Evidence for an association between cancer and cadmium exposure derives from both epidemiological studies and animal experiments. Mortality from prostate cancer associated with cadmium is slightly elevated in several industrial cohorts, but the number of cases is small and there is not clear dose-response relationship. More substantive evidence exists for lung cancer.

The major epidemiological study of lung cancer was conducted by Thun et al., (Ex. 4-68). Adequate data on cadmium exposures were available to allow evaluation of dose-response relationships between cadmium exposure and lung cancer. A statistically significant excess of lung cancer attributed to cadmium exposure was observed in this study even when confounding variables such as co-exposure to arsenic and smoking habits were taken into consideration (Ex. L-140-50).

The primary evidence for quantifying a link between lung cancer and cadmium exposure from animal studies derives from two rat bioassay studies; one by Takenaka et al., (1983), which is a study of cadmium chloride and a second study by Oldiges and Glaser (1990) of four cadmium compounds.

Based on the above cited studies, the U.S. Environmental Protection Agency (EPA) classified cadmium as "B1", a probable human carcinogen, in 1985 (Ex. 4-4). The International Agency for Research on Cancer (IARC) in 1987 also recommended that cadmium be listed as "2A", a probable human carcinogen (Ex. 4-15). The American Conference of Governmental Industrial Hygienists (ACGIH) has recently recommended that cadmium be labeled as a carcinogen. Since 1984, NIOSH has concluded that cadmium is possibly a human carcinogen and has recommended that exposures be controlled to the lowest level feasible.

4. Non-carcinogenic Effects

Acute pneumonitis occurs 10 to 24 hours after initial acute inhalation of high levels of cadmium fumes with symptoms such as fever and chest pain (Exs. 30, 8-86B). In extreme exposure cases pulmonary edema may develop and cause death several days after exposure. Little actual exposure measurement data is available on the level of airborne cadmium exposure that causes such immediate adverse lung effects, nonetheless, it is reasonable to believe a cadmium concentration of approximately 1 mg/m³ over an eight hour period is "immediately dangerous" (55 FR 4052, ANSI; Ex. 8-86B).

In addition to acute lung effects and chronic renal effects, long term exposure to cadmium may cause other severe effects on the respiratory system. Reduced pulmonary function and chronic lung disease indicative of emphysema have been observed in workers who have had prolonged exposure to cadmium dust or fumes (Exs. 4-29, 4-22, 4-42, 4-50, 4-63). In a study of workers conducted by Kazantzis et al., a statistically significant excess of worker deaths due to chronic bronchitis was found, which in his opinion was directly related to high cadmium exposures of 1 mg/m³ or more (Tr. 6/8/90, pp. 156-157).

Cadmium need not be respirable to constitute a hazard. Inspirable cadmium particles that are too large to be respirable but small enough to enter the tracheobronchial region of the lung can lead to bronchoconstriction, chronic pulmonary disease, and cancer of that portion of the lung. All of these diseases have been associated with occupational exposure to cadmium (Ex. 8-86B).

Particles that are constrained by their size to the extra-thoracic regions of the respiratory system such as the nose and maxillary sinuses can be swallowed through mucociliary clearance and be absorbed into the body (ACGIH, Ex. 8-692). The impaction of these particles in the upper airways can lead to anosmia, or loss of sense of smell, which is an early indication of overexposure among workers exposed to heavy metals. This condition is commonly reported among cadmium-exposed workers (Ex. 8-86-B).

C. Medical Surveillance

In general, the main provisions of the medical surveillance section of the standard, under paragraphs (l)(1)-(17) of the regulatory text, are as follows:

1. Workers exposed above the action level are covered;
2. Workers with intermittent exposures are not covered;
3. Past workers who are covered receive biological monitoring for at least one year;
4. Initial examinations include a medical questionnaire and biological monitoring of cadmium in blood (CdB), cadmium in urine (CdU), and Beta-2-microglobulin in urine (B(2)-M);
5. Biological monitoring of these three analytes is performed at least annually; full medical examinations are performed biennially;

6. Until five years from the effective date of the standard, medical removal is required when CdU is greater than 15 ug/gram creatinine (g Cr), or CdB is greater than 15 ug/liter whole blood (lwb), or B(2)-M is greater than 1500 ug/g Cr, and CdB is greater than 5 ug/lwb or CdU is greater than 3 ug/g Cr;

7. Beginning five years after the standard is in effect, medical removal triggers will be reduced;

8. Medical removal protection benefits are to be provided for up to 18 months;

9. Limited initial medical examinations are required for respirator usage;

10. Major provisions are fully described under section (l) of the regulatory text; they are outlined here as follows:

A. Eligibility

B. Biological monitoring

C. Actions triggered by levels of CdU, CdB, and B(2)-M (See Summary Charts and Tables in Attachment 1.)

D. Periodic medical surveillance

E. Actions triggered by periodic medical surveillance (See appendix A Summary Chart and Tables in Attachment 1.)

F. Respirator usage

G. Emergency medical examinations

H. Termination examination

I. Information to physician

J. Physician's medical opinion

K. Medical removal protection

L. Medical removal protection benefits

M. Multiple physician review

N. Alternate physician review

O. Information employer gives to employee

P. Recordkeeping

Q. Reporting on OSHA form 200

11. The above mentioned summary of the medical surveillance provisions, the summary chart, and tables for the actions triggered at different levels of CdU, CdB and B(2)-M (in Appendix A Attachment-1) are included only for the purpose of facilitating understanding of the provisions of paragraphs (1)(3) of the final cadmium standard. The summary of the provisions, the summary chart, and the tables do not add to or reduce the requirements in paragraph (1)(3).

D. Recommendations to Physicians

1. It is strongly recommended that patients with tubular proteinuria are counseled on: the hazards of smoking; avoidance of nephrotoxins and certain prescriptions and over-the-counter medications that may exacerbate kidney symptoms; how to control diabetes and/or blood pressure; proper hydration, diet, and exercise (Ex. 19-2). A list of prominent or common nephrotoxins is attached. (See Appendix A Attachment-2.)

2. DO NOT CHELATE; KNOW WHICH DRUGS ARE NEPHROTOXINS OR ARE ASSOCIATED WITH NEPHRITIS.

3. The gravity of cadmium-induced renal damage is compounded by the fact there is no medical treatment to prevent or reduce the accumulation of cadmium in the kidney (Ex. 8-619). Dr. Friberg, a leading world expert on cadmium toxicity, indicated in 1992, that there is no form of chelating agent that could be used without substantial risk. He stated that tubular proteinuria has to be treated in the same way as other kidney disorders (Ex. 29).

4. After the results of a workers' biological monitoring or medical examination are received the employer is required to provide an information sheet to the patient, briefly explaining the significance of the results. (See Attachment 3 of this Appendix A.)

5. For additional information the physician is referred to the following additional resources:

a. The physician can always obtain a copy of the preamble, with its full discussion of the health effects, from OSHA's Computerized Information System (OCIS).

b. The Docket Officer maintains a record of the rulemaking. The Cadmium Docket (H-057A), is located at 200 Constitution Ave. N.W., Room N-2625, Washington, D.C. 20210; telephone: 202-219-7894.

c. The following articles and exhibits in particular from that docket (H-057A):

| Exhibit number | Author and paper title |
|----------------|---|
| 8-447 | Lauwerys et. al., Guide for physicians, "Health Maintenance of Workers Exposed to Cadmium," published by the Cadmium Council. |
| 4-67 | Takenaka, S., H. Oldiges, H. Konig, D. Hochrainer, |

| | |
|----------------|---|
| | G. Oberdorster. "Carcinogenicity of Cadmium Chloride Aerosols in Wistar Rats". JNCI 70:367-373, 1983. (32) |
| 4-68 | Thun, M.J., T.M. Schnoor, A.B. Smith, W.E. Halperin, R.A. Lemen. "Mortality Among a Cohort of U.S. Cadmium Production Workers - An Update." JNCI 74(2):325-33, 1985. (8) |
| 4-25 | Elinder, C.G., Kjellstrom, T., Hogstedt, C., et al., "Cancer Mortality of Cadmium Workers." Brit. J. Ind. Med. 42:651-655, 1985. (14) |
| 4-26 | Ellis, K.J. et al., "Critical Concentrations of Cadmium in Human Renal Cortex: Dose Effect Studies to Cadmium Smelter Workers." J. Toxicol. Environ. Health 7:691-703, 1981. (76) |
| 4-27 | Ellis, K.J., S.H. Cohn and T.J. Smith. "Cadmium Inhalation Exposure Estimates: Their Significance with Respect to Kidney and Liver Cadmium Burden." J. Toxicol. Environ. Health 15:173-187, 1985. |
| 4-28 | Falck, F.Y., Jr., Fine, L.J., Smith, R.G., McClatchey, K.D., Annesley, T., England, B., and Schork, A.M. "Occupational Cadmium Exposure and Renal Status." Am J.Ind.Med. 4:541, 1983. (64) |
| 8-86A | Friberg, L., C.G. Elinder, et al., "Cadmium and Health a Toxicological and Epidemiological Appraisal Volume I Exposure, Dose, and Metabolism." CRC Press, Inc., Boca Raton, FL, 1986. (Available from the OSHA Technical Data Center) |
| 8-86B | Friberg, L., C.G. Elinder, et al. "Cadmium and Health: A Toxicological and Epidemiological Appraisal Volume II Effects and Response." CRC Press, Inc., Boca Raton, FL, 1986. (Available from the OSHA Technical Data Center) |
| L-140-45 | Elinder, C.G., "Cancer Morality of Cadmium Workers", Brit. J. Ind. Med., 42, 651-655, 1985. |
| L-140-50 | Thun, M., Elinder, C.G., Friberg, L, "Scientific Basis for an Occupational Standard for Cadmium, Am. J. Ind. Med., 20; 629-642, 1991. |

V. Information Sheet

The information sheet (Appendix A Attachment-3.) or an equally explanatory one should be provided to you after any biological monitoring results are reviewed by the physician, or where applicable, after any medical examination.

Appendix A

Attachment 1: Appendix A Summary Chart and Tables A and B of Actions Triggered by Biological Monitoring

Appendix A - Summary Chart: Section (1)(3) Medical Surveillance

Categorizing Biological Monitoring Results

(A) Biological monitoring results categories are set forth in Appendix A Table A for the periods ending December 31, 1998 and for the period beginning January 1, 1999.

(B) The results of the biological monitoring for the initial medical exam and the subsequent exams shall determine an employee's biological monitoring result category.

Actions Triggered by Biological Monitoring

(A)(i) The actions triggered by biological monitoring for an employee are set forth in Appendix A Table B.

(ii) The biological monitoring results for each employee under section (1)(3) shall determine the actions required for that employee. That is, for any employee in biological monitoring category C, the employer will perform all of the actions for which there is an X in column C of Appendix A Table B.

(iii) An employee is assigned the alphabetical category ("A" being the lowest) depending upon the test results of the three biological markers.

(iv) An employee is assigned category A if monitoring results for all three biological markers fall at or below the levels indicated in the table listed for category A.

(v) An employee is assigned category B if any monitoring result for any of the three biological markers fall within the range of levels indicated in the table listed for category B, providing no result exceeds the levels listed for category B.

(vi) An employee is assigned category C if any monitoring result for any of the three biological markers are above the levels listed for category C.

(B) The user of Appendix A Tables A and B should know that these tables are provided only to facilitate understanding of the relevant provisions of paragraph (1)(3) of this section. Appendix A Tables A and B are not meant to add to or subtract from the requirements of those provisions.

Appendix A - Table A

Categorization of Biological Monitoring Results

APPLICABLE THROUGH 1998 ONLY

| Biological Marker | Monitoring result categorie | | |
|---|-----------------------------|-------------------|----------|
| | A | B | C |
| Cadmium in urine (CdU) (ug/g creatinine)..... | < = 3 | >3 and < = 15 | >15 |
| B(2)-microglobulin (B(2)-M) (ug/g creatinine)..... | < = 300 | >300 and < = 1500 | >1500(1) |
| Cadmium in blood (CdB) | | | |

| (ug/liter whole blood)..... | < = 5 | >5 and < = 15 | >15 |
|---|-------|---------------|-----|
| Footnote(1) If an employee's B(2)-M levels are above 1,500 ug/g creatinine, in order for mandatory medical removal to be required (See Appendix A Table B.), either the employee's CdU level must also be >3 ug/g creatinine or CdB level must also be >5 ug/liter whole blood. | | | |

APPLICABLE BEGINNING JANUARY 1, 1999

| Biological Marker | Monitoring result categorie | | |
|---|-----------------------------|------------------|---------|
| | A | B | C |
| Cadmium in urine (CdU) (ug/g creatinine)..... | < = 3 | >3 and < = 7 | >7 |
| B(2)-microglobulin (B(2)-M) (ug/g creatinine)..... | < = 300 | >300 and < = 750 | >750(1) |
| Cadmium in blood (CdB) (ug/liter whole blood)..... | < = 5 | >5 and < = 10 | >10 |

Footnote(1) If an employee's B(2)-M levels are above 750 ug/g creatinine, in order for mandatory medical removal to be required (See Appendix A Table B.), either the employee's CdU level must also be >3 ug/g creatinine or CdB level must also be >5 ug/liter whole blood.

Appendix A - Table B - Actions Determined by Biological Monitoring

This table presents the actions required based on the monitoring result in Appendix A Table A. Each item is a separate requirement in citing non-compliance. For example, a medical examination within 90 days for an employee in category B is separate from the requirement to administer a periodic medical examination for category B employees on an annual basis.

| Required Actions | Monitoring result category | | |
|----------------------------------|----------------------------|------|------|
| | A(1) | B(1) | C(1) |
| (1) Biological Monitoring: | | | |
| (a) Annual..... | X | | |
| (b) Semiannual..... | | X | |
| (c) Quarterly..... | | | X |
| (2) Medical Examination: | | | |
| (a) Biennial..... | X | | |
| (b) Annual..... | | X | |
| (c) Semiannual..... | | | X |
| (d) Within 90 Days..... | | X | X |
| (3) Assess within two weeks: | | | |
| (a) Excess cadmium exposure..... | | X | X |
| (b) Work practices..... | | X | X |
| (c) Personal hygiene..... | | X | X |

| | | | |
|--|---|---|------|
| (d) Respirator usage..... | | X | X |
| (e) Smoking history..... | | X | X |
| (f) Hygiene facilities..... | | X | X |
| (g) Engineering controls..... | | X | X |
| (h) Correct within 30 days..... | | X | X |
| (i) Periodically Assess Exposures... | | | X |
| (4) Discretionary Medical Removal..... | X | | X |
| (5) Mandatory Medical Removal..... | | | X(2) |

Footnote(1) For all employees covered by medical surveillance exclusively because of exposures prior to the effective date of this standard, if they are in Category A, the employer shall follow the requirements of paragraphs (1)(3)(i)(B) and (1)(4)(v)(A). If they are in Category B or C, the employer shall follow the requirements of paragraphs (1)(4)(v)(B)-(C).

Footnote(2) See footnote Appendix A Table A.

Appendix A - Attachment - 2: List of Medications

A list of the more common medications that a physician, and the employee, may wish to review is likely to include some of the following: (1) anticonvulsants: paramethadione, phenytoin, trimethadone; (2) antihypertensive drugs: captopril, methyldopa; (3) antimicrobials: aminoglycosides, amphotericin B, cephalosporins, ethambutol; (4) antineoplastic agents: cisplatin, methotrexate, mitomycin-C, nitrosoureas, radiation; (5) sulfonamide diuretics: acetazolamide, chlorthalidone, furosemide, thiazides; (6) halogenated alkanes, hydrocarbons, and solvents that may occur in some settings: carbon tetrachloride, ethylene glycol, toluene; iodinated radiographic contrast media; nonsteroidal anti-inflammatory drugs; and, (7) other miscellaneous compounds: acetaminophen, allopurinol, amphetamines, azathioprine, cimetidine, cyclosporine, lithium, methoxyflurane, methysergide, D-penicillamine, phenacetin, phenindione. A list of drugs associated with acute interstitial nephritis includes: (1) antimicrobial drugs: cephalosporins, chloramphenicol, colistin, erythromycin, ethambutol, isoniazid, paraaminosalicylic acid, penicillins, polymyxin B, rifampin, sulfonamides, tetracyclines, and vancomycin; (2) other miscellaneous drugs: allopurinol, antipyrene, azathioprine, captopril, cimetidine, clofibrate, methyldopa, phenindione, phenylpropanolamine, phenytoin, probenecid, sulfapyrazone, sulfonamid diuretics, triamterene; and, (3) metals: bismuth, gold.

This list has been derived from commonly available medical textbooks (e.g., Ex. 14-18). The list has been included merely to facilitate the physician's, employer's, and employee's understanding. The list does not represent an official OSHA opinion or policy regarding the use of these medications for particular employees. The use of such medications should be under physician discretion.

Appendix A - Attachment 3

Biological Monitoring and Medical Examination Results

Employee _____
 Testing Date _____
 Cadmium in Urine _____ ug/g Cr
 Cadmium in Blood _____ ug/lwb
 Beta-2-microglobulin in Urine _____ ug/g Cr

Normal Levels: < = 3 ug/g Cr, < = 5 ug/lwb, < = 300 ug/g Cr

Physical Examination Results: N/A _____
Satisfactory _____
Unsatisfactory _____
(see physician again)

Physician's Review of Pulmonary Function

Test: N/A _____ Normal _____ Abnormal _____

Next biological monitoring or medical examination scheduled for _____

The biological monitoring program has been designed for three main purposes: 1) to identify employees at risk of adverse health effects from excess, chronic exposure to cadmium; 2) to prevent cadmium-induced disease(s); and 3) to detect and minimize existing cadmium-induced disease(s).

The levels of cadmium in the urine and blood provide an estimate of the total amount of cadmium in the body. The amount of a specific protein in the urine (beta-2-microglobulin) indicates changes in kidney function. All three tests must be evaluated together. A single mildly elevated result may not be important if testing at a later time indicates that the results are normal and the workplace has been evaluated to decrease possible sources of cadmium exposure. The levels of cadmium or beta-2-microglobulin may change over a period of days to months and the time needed for those changes to occur is different for each worker.

If the results for biological monitoring are above specific "high levels" [cadmium urine greater than 10 micrograms per gram of creatinine (ug/g Cr), cadmium blood greater than 10 micrograms per liter of whole blood (ug/lwb), or beta-2-microglobulin greater than 1000 micrograms per gram of creatinine (ug/g Cr)], the worker has a much greater chance of developing other kidney diseases.

One way to measure for kidney function is by measuring beta-2-microglobulin in the urine. Beta-2-microglobulin is a protein which is normally found in the blood as it is being filtered in the kidney, and the kidney reabsorbs or returns almost all of the beta-2-microglobulin to the blood. A very small amount (less than 300 ug/g Cr in the urine) of beta-2-microglobulin is not reabsorbed into the blood, but is released in the urine. If cadmium damages the kidney, the amount of beta-2-microglobulin in the urine increases because the kidney cells are unable to reabsorb the beta-2-microglobulin normally. An increase in the amount of beta-2-microglobulin in the urine is a very early sign of kidney dysfunction. A small increase in beta-2-microglobulin in the urine will serve as an early warning sign that the worker may be absorbing cadmium from the air, cigarettes contaminated in the workplace, or eating in areas that are cadmium contaminated.

Even if cadmium causes permanent changes in the kidney's ability to reabsorb beta-2-microglobulin, and the beta-2-microglobulin is above the "high levels", the loss of kidney function may not lead to any serious health problems. Also, renal function naturally declines as people age. The risk for changes in kidney function for workers who have biological monitoring results between the "normal values" and the "high levels" is not well known. Some people are more cadmium-tolerant, while others are more cadmium-susceptible.

For anyone with even a slight increase of beta-2-microglobulin, cadmium in the urine, or cadmium in the blood, it is very important to protect the kidney from further damage. Kidney damage can come from other sources than excess cadmium-exposure so it is also recommended that if a worker's levels are "high" he/she should receive counseling about drinking more water; avoiding cadmium-tainted tobacco and certain medications (nephrotoxins, acetaminophen); controlling diet, vitamin intake, blood pressure and diabetes; etc.

1910.1027 Appendix B to Substances Technical Guidelines for Cadmium

I. CADMIUM METAL

A. Physical and Chemical Data.

1. Substance Identification.

Chemical name: Cadmium.

Formula: Cd.

Molecular Weight: 112.4.

Chemical Abstracts Service (CAS) Registry No.: 7740-43-9.

Other Identifiers: RETCS EU9800000; EPA D006; DOT 2570 53.

Synonyms: Colloidal Cadmium: Kadmium (German): CI77180.

2. Physical data.

Boiling point: (760 mm Hg): 765 degrees C.

Melting point: 321 degrees C.

Specific Gravity: (H₂O at 20 deg. C): 8.64.

Solubility: Insoluble in water; soluble in dilute nitric acid and in sulfuric acid.

Appearance: Soft, blue-white, malleable, lustrous metal or grayish-white powder.

B. Fire, Explosion and Reactivity Data.

1. Fire.

Fire and Explosion Hazards: The finely divided metal is pyrophoric, that is the dust is a severe fire hazard and moderate explosion hazard when exposed to heat or flame. Burning material reacts violently with extinguishing agents such as water, foam, carbon dioxide, and halons.

Flash point: Flammable (dust).

Extinguishing media: Dry sand, dry dolomite, dry graphite, or sodium chloride.

2. Reactivity.

Conditions contributing to instability: Stable when kept in sealed containers under normal temperatures and pressure, but dust may ignite upon contact with air. Metal tarnishes in moist air.

Incompatibilities: Ammonium nitrate, fused: Reacts violently or explosively with cadmium dust below 20 degrees C. Hydrozoic acid: Violent explosion occurs after 30 minutes. Acids: reacts violently, forms hydrogen gas. Oxidizing agents or metals: strong reaction with

cadmium dust. Nitryl fluoride at slightly elevated temperature: glowing or white incandescence occurs. Selenium: reacts exothermically. Ammonia: corrosive reaction. Sulfur dioxide: corrosive reaction. Fire extinguishing agents (water, foam, carbon dioxide, and halons): reacts violently. Tellurium: incandescent reaction in hydrogen atmosphere.

Hazardous decomposition products: The heated metal rapidly forms highly toxic, brownish fumes of oxides of cadmium.

C. Spill, Leak and Disposal Procedures.

1. Steps to be taken if the materials is released or spilled

Do not touch spilled material. Stop leak if you can do it without risk. Do not get water inside container. For large spills, dike spill for later disposal. Keep unnecessary people away. Isolate hazard area and deny entry. The Superfund Amendments and Reauthorization Act of 1986 Section 304 requires that a release equal to or greater than the reportable quantity for this substance (1 pound) must be immediately reported to the local emergency planning committee, the state emergency response commission, and the National Response Center (800) 424-8802; in Washington, D.C. metropolitan area (202) 426-2675.

II. CADMIUM OXIDE

A. Physical and Chemical Data

1. Substance identification

Chemical name: Cadmium Oxide.

Formula: CdO.

Molecular Weight: 128.4.

CAS No.: 1306-19-0.

Other Identifiers: RTECS EV1929500.

Synonyms: Kadmu tlenek (Polish).

2. Physical data.

Boiling point (760 mm Hg): 950 degrees C decomposes.

Melting point: 1500 deg. C.

Specific Gravity: (H₂O = 1 at 200 deg. C): 7.0.

Solubility: Insoluble in water; soluble in acids and alkalines.

Appearance: Red or brown crystals.

B. Fire, Explosion and Reactivity Data.

1. Fire.

Fire and Explosion Hazards: Negligible fire hazard when exposed to heat or flame.

Flash point: Nonflammable.

Extinguishing media: Dry chemical, carbon dioxide, water spray or foam.

2. Reactivity.

Conditions contributing to instability: Stable under normal temperatures and pressures.

Incompatibilities: Magnesium may reduce CdO(2) explosively on heating.

Hazardous decomposition products: Toxic fumes of cadmium.

C. Spill Leak and Disposal Procedures

1. Steps to be taken if the material is released or spilled

Do not touch spilled material. Stop leak if you can do it without risk. For small spills, take up with sand or other absorbent material and place into containers for later disposal. For small dry spills, use a clean shovel to place material into clean, dry container and then cover. Move containers from spill area. For larger spills, dike far ahead of spill for later disposal. Keep unnecessary people away. Isolate hazard area and deny entry. The Superfund Amendments and Reauthorization Act of 1986 Section 304 requires that a release equal to or greater than the reportable quantity for this substance (1 pound) must be immediately reported to the local emergency planning committee, the state emergency response commission, and the National Response Center (800) 424-8802; in Washington, D.C. metropolitan area (202) 426-2675.

III. CADMIUM SULFIDE

A. Physical and Chemical Data

1. Substance Identification.

Chemical name: Cadmium sulfide.

Formula: CdS.

Molecular weight: 144.5.

CAS No. 1306-23-6.

Other Identifiers: RTECS EV3150000.

Synonyms: Aurora yellow; Cadmium Golden 366; Cadmium Lemon Yellow 527; Cadmium Orange; Cadmium Primrose 819; Cadmium Sulphide; Cadmium Yellow; Cadmium Yellow 000; Cadmium Yellow Conc. Deep; Cadmium Yellow Conc. Golden; Cadmium Yellow Conc. Lemon; Cadmium Yellow Conc. Primrose; Cadmium Yellow Oz. Dark; Cadmium Yellow Primrose 47-1400; Cadmium Yellow 10G Conc.; Cadmium Yellow 892; Cadmopur Golden Yellow N; Cadmopur Yellow: Capsebon; C.I. 77199; C.I. Pigment Orange 20; CI Pigment Yellow 37; Ferro Lemon Yellow; Ferro Orange Yellow; Ferro Yellow; Greenockite; NCI-C02711.

2. Physical data.

Boiling point (760 mm. Hg): sublimes in N(2) at 980 deg. C.

Melting point: 1750 degrees C (100 atm).

Specific Gravity: (H(2)O= 1 at 20 deg. C): 4.82.

Solubility: Slightly soluble in water; soluble in acid.

Appearance: Light yellow or yellow-orange crystals.

B. Fire, Explosion and Reactivity Data.

1. Fire.

Fire and Explosion Hazards: Negligible fire hazard when exposed to heat or flame.

Flash point: Nonflammable.

Extinguishing media: Dry chemical, carbon dioxide, water spray or foam.

2. Reactivity.

Conditions contributing to instability: Generally non-reactive under normal conditions.

Reacts with acids to form toxic hydrogen sulfide gas.

Incompatibilities: Reacts vigorously with iodine monochloride.

Hazardous decomposition products: Toxic fumes of cadmium and sulfur oxides.

C. Spill Leak and Disposal Procedures.

1. Steps to be taken if the material is released or spilled.

Do not touch spilled material. Stop leak if you can do it without risk. For small, dry spills, with a clean shovel place material into clean, dry container and cover. Move containers from spill area. For larger spills, dike far ahead of spill for later disposal. Keep unnecessary people away. Isolate hazard and deny entry.

IV. CADMIUM CHLORIDE

A. Physical and Chemical Data.

1. Substance Identification.

Chemical name: Cadmium chloride.

Formula: $CdCl_2$.

Molecular weight: 183.3.

CAS No. 10108-64-2.

Other Identifiers: RTECS EY0175000.

Synonyms: Caddy; Cadmium dichloride; NA 2570 (DOT); UI-CAD; dichlorocadmium.

2. Physical data.

Boiling point (760 mm Hg): 960 degrees C.

Melting point: 568 degrees C.

Specific Gravity: (H₂O = 1 at 20 deg. C): 4.05.

Solubility: Soluble in water (140 g/100 cc); soluble in acetone.

Appearance: small, white crystals.

B. Fire, Explosion and Reactivity Data.

1. Fire.

Fire and Explosion Hazards: Negligible fire and negligible explosion hazard in dust form when exposed to heat or flame.

Flash point: Nonflammable.

Extinguishing media: Dry chemical, carbon dioxide, water spray or foam.

2. Reactivity.

Conditions contributing to instability:

Generally stable under normal temperatures and pressures.

Incompatibilities: Bromine trifluoride rapidly attacks cadmium chloride. A mixture of potassium and cadmium chloride may produce a strong explosion on impact.

Hazardous decomposition products:

Thermal decomposition may release toxic fumes of hydrogen chloride, chloride, chlorine or oxides of cadmium.

C. Spill Leak and Disposal Procedures.

1. Steps to be taken if the materials is released or spilled.

Do not touch spilled material. Stop leak if you can do it without risk. For small, dry spills, with a clean shovel place material into clean, dry container and cover. Move containers from spill area. For larger spills, dike far ahead of spill for later disposal. Keep unnecessary people away. Isolate hazard and deny entry. The Superfund Amendments and Reauthorization Act of 1986 Section 304 requires that a release equal to or greater than the reportable quantity for this substance (100 pounds) must be immediately reported to the local emergency planning committee, the state emergency response commission, and the National Response Center (800) 424-8802; in Washington, D.C. Metropolitan area (202) 426-2675.

Appendix C to 1910.1027 - Qualitative and Quantitative Fit Testing Procedures [Reserved]

Appendix D to 1910.1027 -Occupational Health History Interview With Reference to Cadmium Exposure

Directions

(To be read by employee and signed prior to the interview)

Please answer the questions you will be asked as completely and carefully as you can. These questions are asked of everyone who works with cadmium. You will also be asked to give blood and urine samples. The doctor will give your employer a written opinion on whether you are physically capable of working with cadmium. Legally, the doctor cannot share personal information you may tell him/her with your employer. The following information is considered strictly confidential. The results of the tests will go to you, your doctor and your employer. You will also receive an information sheet explaining the results of any biological monitoring or physical examinations performed.

If you are just being hired, the results of this interview and examination will be used to:

- (1) Establish your health status and see if working with cadmium might be expected to cause unusual problems,
- (2) Determine your health status today and see if there are changes over time,
- (3) See if you can wear a respirator safely.

If you are not a new hire:

OSHA says that everyone who works with cadmium can have periodic medical examinations performed by a doctor. The reasons for this are:

- (a) If there are changes in your health, either because of cadmium or some other reason, to find them early,
- (b) to prevent kidney damage.

Please sign below.

I have read these directions and understand them:

Employee signature

Date

Thank you for answering these questions.
(Suggested Format)

Name _____
 Age _____
 Social Security # _____
 Company _____
 Job _____

Type of Preplacement Exam:

- Periodic
- Termination
- Initial
- Other

Blood Pressure _____

Pulse Rate _____

- 1. How long have you worked at the job listed above?
 Not yet hired
 Number of months
 Number of years

2. JOB DUTIES ETC.

- 3. Have you ever been told by a doctor that you had bronchitis?
 Yes
 No

If yes, how long ago?

Number of months

Number of years

4. Have you ever been told by a doctor that you had emphysema?

Yes

No

If yes, how long ago?

Number of years

Number of months

5. Have you ever been told by a doctor that you had other lung problems?

Yes

No

If yes, please describe type of lung problems and when you had these problems.

6. In the past year, have you had a cough?

Yes

No

If yes, did you cough up sputum?

Yes

No

If yes, how long did the cough with sputum production last?

Less than 3 months

3 months or longer

If yes, for how many years have you had episodes of cough with sputum production lasting this long?

Less than one

1

2

Longer than 2

7. Have you ever smoked cigarettes?

Yes

No

8. Do you now smoke cigarettes?

Yes

No

9. If you smoke or have smoked cigarettes, for how many years have you smoked, or did you smoke?

Less than 1 year

Number of years

What is or was the greatest number of packs per day that you have smoked?

Number of packs

If you quit smoking cigarettes, how many years ago did you quit?

- Less than 1 year
- Number of years

How many packs a day do you now smoke?
 Number of packs per day

10. Have you ever been told by a doctor that you had a kidney or urinary tract disease or disorder?
 Yes
 No

11. Have you ever had any of these disorders?

- Kidney stones..... Yes No
- Protein in urine..... Yes No
- Blood in urine..... Yes No
- Difficulty urinating..... Yes No
- Other kidney/Urinary disorders..... Yes No

Please describe problems, age, treatment, and follow up for any kidney or urinary problems you have had:

12. Have you ever been told by a doctor or other health care provider who took your blood pressure that your blood pressure was high?
 Yes
 No

13. Have you ever been advised to take any blood pressure medication?
 Yes
 No

14. Are you presently taking any blood pressure medication?
 Yes
 No

15. Are you presently taking any other medication?
 Yes
 No

16. Please list any blood pressure or other medications and describe how long you have been taking each one:

| Medicine | How Long Taken |
|----------|----------------|
| | |
| | |
| | |
| | |

17. Have you ever been told by a doctor that you have diabetes? (sugar in your blood or urine)
 Yes
 No

If yes, do you presently see a doctor about your diabetes?
 Yes
 No

If yes, how do you control your blood sugar?

Diet alone
 Diet plus oral medicine
 Diet plus insulin (injection)

18. Have you ever been told by a doctor that you had:

Anemia Yes No
A low blood count? Yes No

19. Do you presently feel that you tire or run out of energy sooner than normal or sooner than other people your age?

Yes
 No

If yes, for how long have you felt that you tire easily?

Less than 1 year
 Number of years

20. Have you given blood within the last year?

Yes
 No

If yes, how many times?

Number of times

How long ago was the last time you gave blood?

Less than 1 month
 Number of months

21. Within the last year have you had any injuries with heavy bleeding?

Yes
 No

If yes, how long ago?

Less than 1 month
 Number of months

Describe: _____

22. Have you recently had any surgery?

Yes
 No

If yes, please describe: _____

23. Have you seen any blood lately in your stool or after a bowel movement?

- Yes
- No

24. Have you ever had a test for blood in your stool?

- Yes
- No

If yes, did the test show any blood in the stool?

- Yes
- No

What further evaluation and treatment were done? _____

The following questions pertain to the ability to wear a respirator. Additional information for the physician can be found in The Respiratory Protective Devices Manual.

25. Have you ever been told by a doctor that you have asthma?

- Yes
- No

If yes, are you presently taking any medication for asthma? Mark all that apply.

- Shots
- Pills
- Inhaler

26. Have you ever had a heart attack?

- Yes
- No

If yes, how long ago?

- Number of years
- Number of months

27. Have you ever had pains in your chest?

- Yes
- No

If yes, when did it usually happen?

- While resting
- While working
- While exercising
- Activity didn't matter

28. Have you ever had a thyroid problem?

- Yes
- No

29. Have you ever had a seizure or fits?

- Yes
- No

30. Have you ever had a stroke (cerebrovascular accident)?

- Yes
- No

31. Have you ever had a ruptured eardrum or a serious hearing problem?
 Yes
 No
32. Do you now have a claustrophobia, meaning fear of crowded or closed in spaces or any psychological problems that would make it hard for you to wear a respirator?
 Yes
 No

The following questions pertain to reproductive history.

33. Have you or your partner had a problem conceiving a child?
 Yes
 No

If yes, specify:

- Self
 Present mate
 Previous mate

34. Have you or your partner consulted a physician for a fertility or other reproductive problem?
 Yes
 No

If yes, specify who consulted the physician:

- Self
 Spouse/partner
 Self and partner

If yes, specify diagnosis made: _____

35. Have you or your partner ever conceived a child resulting in a miscarriage, still birth or deformed offspring?
 Yes
 No

If yes, specify:

- Miscarriage
 Still birth
 Deformed offspring

If outcome was a deformed offspring, please specify type:

36. Was this outcome a result of a pregnancy of:
 Yours with present partner
 Yours with a previous partner

37. Did the timing of any abnormal pregnancy outcome coincide with present employment?
 Yes
 No

List dates of occurrences: _____

38. What is the occupation of your spouse or partner?

For Women Only

39. Do you have menstrual periods?

- Yes
 No

Have you had menstrual irregularities?

- Yes
 No

If yes, specify type: _____

If yes, what was the approximated date this problem began? _____

Approximate date problem stopped? _____

For Men Only

40. Have you ever been diagnosed by a physician as having prostate gland problem(s)?

- Yes
 No

If yes, please describe type of problem(s) and what was done to evaluate and treat the problem(s) : _____

Appendix E to 1910.1027 Cadmium in Workplace Atmospheres

Method Number: ID-189

Matrix: Air

OSHA Permissible Exposure Limits: 5 ug/m(3) (TWA), 2.5 ug/m(3) (Action Level TWA)

Collection Procedure: A known volume of air is drawn through a 37-mm diameter filter cassette containing a 0.8-um mixed cellulose ester membrane filter (MCEF).

Recommended Air Volume: 960 L

Recommended Sampling Rate: 2.0 L/min

Analytical Procedure: Air filter samples are digested with nitric acid. After digestion, a small amount of hydrochloric acid is added. The samples are then diluted to volume with deionized water and analyzed by either flame atomic absorption spectroscopy (AAS) or flameless atomic absorption spectroscopy using a heated graphite furnace

atomizer (AAS-HGA).
Detection Limits:
Qualitative: 0.2 ug/m(3) for a 200 L sample by Flame AAS, 0.007 ug/m(3)
for a 60 L sample by AAS-HGA
Quantitative: 0.70 ug/m(3) for a 200 L sample by Flame AAS, 0.025 ug/m(3)
for a 60 L sample by AAS-HGA
Precision and Accuracy: (Flame AAS Analysis and AAS-HGA Analysis):

Validation Level: 2.5 to 10 ug/m(3) for a 400 L air vol. 1.25 to
5.0 ug/m(3) for a 60 L air vol.
CV(1)(pooled): 0.010, 0.043
Analytical Bias: +4.0%, -5.8%
Overall Analytical Error: + or - 6.0%, + or - 14.2%
Method Classification: Validated
Date: June, 1992

Inorganic Service Branch II, OSHA Salt Lake Technical Center, Salt Lake City, Utah

Commercial manufacturers and products mentioned in this method are for descriptive use only and do not constitute endorsements by USDOL-OSHA. Similar products from other sources can be substituted.

1. Introduction

1.1. Scope

This method describes the collection of airborne elemental cadmium and cadmium compounds on 0.8-um mixed cellulose ester membrane filters and their subsequent analysis by either flame atomic absorption spectroscopy (AAS) or flameless atomic absorption spectroscopy using a heated graphite furnace atomizer (AAS-HGA). It is applicable for both TWA and Action Level TWA Permissible Exposure Level (PEL) measurements. The two atomic absorption analytical techniques included in the method do not differentiate between cadmium fume and cadmium dust samples. They also do not differentiate between elemental cadmium and its compounds.

1.2. Principle

Airborne elemental cadmium and cadmium compounds are collected on a 0.8-um mixed cellulose ester membrane filter (MCEF). The air filter samples are digested with concentrated nitric acid to destroy the organic matrix and dissolve the cadmium analytes. After digestion, a small amount of concentrated hydrochloric acid is added to help dissolve other metals which may be present. The samples are diluted to volume with deionized water and then aspirated into the oxidizing air/acetylene flame of an atomic absorption spectrophotometer for analysis of elemental cadmium. If the concentration of cadmium in a sample solution is too low for quantitation by this flame AAS analytical technique, and the sample is to be averaged with other samples for TWA calculations, aliquots of the sample and a matrix modifier are later injected onto a L'vov platform in a pyrolytically-coated graphite tube of a Zeeman atomic absorption spectrophotometer/graphite furnace assembly for analysis of elemental cadmium. The matrix modifier is added to stabilize the cadmium metal and minimize sodium chloride as an interference during the high temperature charring step of the analysis (5.1., 5.2.).

1.3. History

Previously, two OSHA sampling and analytical methods for cadmium were used concurrently (5.3., 5.4.). Both of these methods also required 0.8-um mixed cellulose ester membrane filters for the collection of air samples. These cadmium air filter samples were analyzed by either flame atomic absorption spectroscopy (5.3.) or inductively coupled plasma/atomic emission spectroscopy (ICP-AES) (5.4.). Neither of these two analytical methods have adequate sensitivity for measuring workplace exposure to airborne cadmium at the new lower TWA and Action Level TWA PEL levels when consecutive samples are taken on one employee and the sample results need to be averaged with other samples to determine a single TWA.

The inclusion of two atomic absorption analytical techniques in the new sampling and analysis method for airborne cadmium permits quantitation of sample results over a broad range of exposure levels and sampling periods. The flame AAS analytical technique included in this method is similar to the previous procedure given in the General Metals Method ID-121 (5.3.) with some modifications. The sensitivity of the AAS-HGA analytical technique included in this method is adequate to measure exposure levels at 1/10 the Action Level TWA, or lower, when less than full-shift samples need to be averaged together.

1.4. Properties (5.5.)

Elemental cadmium is a silver-white, blue-tinged, lustrous metal which is easily cut with a knife. It is slowly oxidized by moist air to form cadmium oxide. It is insoluble in water, but reacts readily with dilute nitric acid. Some of the physical properties and other descriptive information of elemental cadmium are given below:

| | |
|---------------------|-----------------------|
| CAS No ----- | 7440-43-9 |
| Atomic Number ----- | 48 |
| Atomic Symbol ----- | Cd |
| Atomic Weight ----- | 112.41 |
| Melting Point ----- | 321 Deg. C |
| Boiling Point ----- | 765 Deg. C |
| Density ----- | 8.65 g/mL (25 Deg. C) |

The properties of specific cadmium compounds are described in reference 5.5.

1.5. Method Performance

A synopsis of method performance is presented below. Further information can be found in Section 4.

1.5.1. The qualitative and quantitative detection limits for the flame AAS analytical technique are 0.04 ug (0.004 ug/mL) and 0.14 ug (0.014 ug/mL) cadmium, respectively, for a 10 mL solution volume. These correspond, respectively, to 0.2 ug/m(3) and 0.70 ug/m(3) for a 200 L air volume.

1.5.2. The qualitative and quantitative detection limits for the AAS-HGA analytical technique are 0.44 ng (0.044 ng/mL) and 1.5 ng (0.15 ng/mL) cadmium, respectively, for a 10 mL solution

volume. These correspond, respectively, to 0.007 ug/m³ and 0.025 ug/m³ for a 60 L air volume.

1.5.3. The average recovery by the flame AAS analytical technique of 17 spiked MCEF samples containing cadmium in the range of 0.5 to 2.0 times the TWA target concentration of 5 ug/m³ (assuming a 400 L air volume) was 104.0% with a pooled coefficient of variation (CV(1)) of 0.010. The flame analytical technique exhibited a positive bias of +4.0% for the validated concentration range. The overall analytical error (OAE) for the flame AAS analytical technique was + or - 6.0%.

1.5.4. The average recovery by the AAS-HGA analytical technique of 18 spiked MCEF samples containing cadmium in the range of 0.5 to 2.0 times the Action Level TWA target concentration of 2.5 ug/m³ (assuming a 60 L air volume) was 94.2% with a pooled coefficient of variation (CV(1)) of 0.043. The AAS-HGA analytical technique exhibited a negative bias of -5.8% for the validated concentration range. The overall analytical error (OAE) for the AAS-HGA analytical technique was + or - 14.2%.

1.5.5. Sensitivity in flame atomic absorption is defined as the characteristic concentration of an element required to produce a signal of 1% absorbance (0.0044 absorbance units). Sensitivity values are listed for each element by the atomic absorption spectrophotometer manufacturer and have proved to be a very valuable diagnostic tool to determine if instrumental parameters are optimized and if the instrument is performing up to specification. The sensitivity of the spectrophotometer used in the validation of the flame AAS analytical technique agreed with the manufacturer specifications (5.6.); the 2 ug/mL cadmium standard gave an absorbance reading of 0.350 abs. units.

1.5.6. Sensitivity in graphite furnace atomic absorption is defined in terms of the characteristic mass, the number of picograms required to give an integrated absorbance value of 0.0044 absorbance-second (5.7.). Data suggests that under Stabilized Temperature Platform Furnace (STPF) conditions (see Section 1.6.2.), characteristic mass values are transferable between properly functioning instruments to an accuracy of about 20% (5.2.). The characteristic mass for STPF analysis of cadmium with Zeeman background correction listed by the manufacturer of the instrument used in the validation of the AAS-HGA analytical technique was 0.35 pg. The experimental characteristic mass value observed during the determination of the working range and detection limits of the AAS-HGA analytical technique was 0.41 pg.

1.6. Interferences

1.6.1. High concentrations of silicate interfere in determining cadmium by flame AAS (5.6.). However, silicates are not significantly soluble in the acid matrix used to prepare the samples.

1.6.2. Interferences, such as background absorption, are reduced to a minimum in the AAS-HGA analytical technique by taking full advantage of the Stabilized Temperature Platform Furnace (STPF) concept. STPF includes all of the following parameters (5.2.):

- a. Integrated Absorbance,
- b. Fast Instrument Electronics and Sampling Frequency,

- c. Background Correction,
- d. Maximum Power Heating,
- e. Atomization off the L'vov platform in a pyrolytically coated graphite tube,
- f. Gas Stop during Atomization,
- g. Use of Matrix Modifiers.

1.7. Toxicology (5.14.)

Information listed within this section is synopsis of current knowledge of the physiological effects of cadmium and is not intended to be used as the basis for OSHA policy. IARC classifies cadmium and certain of its compounds as Group 2A carcinogens (probably carcinogenic to humans). Cadmium fume is intensely irritating to the respiratory tract. Workplace exposure to cadmium can cause both chronic and acute effects. Acute effects include tracheobronchitis, pneumonitis, and pulmonary edema. Chronic effects include anemia, rhinitis/anosmia, pulmonary emphysema, proteinuria and lung cancer. The primary target organs for chronic disease are the kidneys (non-carcinogenic) and the lungs (carcinogenic).

2. Sampling

2.1. Apparatus

2.1.1. Filter cassette unit for air sampling: A 37-mm diameter mixed cellulose ester membrane filter with a pore size of 0.8-um contained in a 37-mm polystyrene two- or three-piece cassette filter holder (part no. MAWP 037 A0, Millipore Corp., Bedford, MA). The filter is supported with a cellulose backup pad. The cassette is sealed prior to use with a shrinkable gel band.

2.1.2. A calibrated personal sampling pump whose flow is determined to an accuracy of + or - 5% at the recommended flow rate with the filter cassette unit in line.

2.2. Procedure

2.2.1. Attach the prepared cassette to the calibrated sampling pump (the backup pad should face the pump) using flexible tubing. Place the sampling device on the employee such that air is sampled from the breathing zone.

2.2.2. Collect air samples at a flow rate of 2.0 L/min. If the filter does not become overloaded, a full-shift (at least seven hours) sample is strongly recommended for TWA and Action Level TWA measurements with a maximum air volume of 960 L. If overloading occurs, collect consecutive air samples for shorter sampling periods to cover the full workshift.

2.2.3. Replace the end plugs into the filter cassettes immediately after sampling. Record the sampling conditions.

2.2.4. Securely wrap each sample filter cassette end-to-end with an OSHA Form 21 sample seal.

2.2.5. Submit at least one blank sample with each set of air samples. The blank sample should be handled the same as the other samples except that no air is drawn through it.

2.2.6. Ship the samples to the laboratory for analysis as soon as possible in a suitable container designed to prevent damage in transit.

3. Analysis

3.1. Safety Precautions

3.1.1. Wear safety glasses, protective clothing and gloves at all times.

3.1.2. Handle acid solutions with care. Handle all cadmium samples and solutions with extra care (see Sect. 1.7.). Avoid their direct contact with work area surfaces, eyes, skin and clothes. Flush acid solutions which contact the skin or eyes with copious amounts of water.

3.1.3. Perform all acid digestions and acid dilutions in an exhaust hood while wearing a face shield. To avoid exposure to acid vapors, do not remove beakers containing concentrated acid solutions from the exhaust hood until they have returned to room temperature and have been diluted or emptied.

3.1.4. Exercise care when using laboratory glassware. Do not use chipped pipets, volumetric flasks, beakers or any glassware with sharp edges exposed in order to avoid the possibility of cuts or abrasions.

3.1.5. Never pipet by mouth.

3.1.6. Refer to the instrument instruction manuals and SOPs (5.8., 5.9.) for proper and safe operation of the atomic absorption spectrophotometer, graphite furnace atomizer and associated equipment.

3.1.7. Because metallic elements and other toxic substances are vaporized during AAS flame or graphite furnace atomizer operation, it is imperative that an exhaust vent be used. Always ensure that the exhaust system is operating properly during instrument use.

3.2. Apparatus for Sample and Standard Preparation

3.2.1. Hot plate, capable of reaching 150 deg. C, installed in an exhaust hood.

3.2.2. Phillips beakers, 125 mL.

3.2.3. Bottles, narrow-mouth, polyethylene or glass with leakproof caps: used for storage of standards and matrix modifier.

3.2.4. Volumetric flasks, volumetric pipets, beakers and other associated general laboratory glassware.

3.2.5. Forceps and other associated general laboratory equipment.

3.3. Apparatus for Flame AAS Analysis

3.3.1. Atomic absorption spectrophotometer consisting of a(an):

Nebulizer and burner head. Pressure regulating devices capable of maintaining constant oxidant and

fuel pressures. Optical system capable of isolating the desired wavelength of radiation

(228.8 nm). Adjustable slit. Light measuring and amplifying device. Display, strip chart, or computer interface for indicating the amount of

absorbed radiation. Cadmium hollow cathode lamp or electrodeless discharge lamp (EDL) and power supply.

3.3.2. Oxidant: compressed air, filtered to remove water, oil and other foreign substances.

3.3.3. Fuel: standard commercially available tanks of acetylene dissolved in acetone; tanks should be equipped with flash arresters.

CAUTION: Do not use grades of acetylene containing solvents other than acetone because they may damage the PVC tubing used in some instruments.

3.3.4. Pressure-reducing valves: two gauge, two-stage pressure regulators to maintain fuel and oxidant pressures somewhat higher than the controlled operating pressures of the instrument.

3.3.5. Exhaust vent installed directly above the spectrophotometer burner head.

3.4. Apparatus for AAS-HGA Analysis

3.4.1. Atomic absorption spectrophotometer consisting of a(an):

Heated graphite furnace atomizer (HGA) with argon purge system.

Pressure-regulating devices capable of maintaining constant argon purge pressure.

Optical system capable of isolating the desired wavelength of radiation (228.8 nm).

Adjustable slit.

Light measuring and amplifying device.

Display, strip chart, or computer interface for indicating the amount of absorbed radiation (as integrated absorbance, peak area).

Background corrector: Zeeman or deuterium arc. The Zeeman background corrector is recommended.

Cadmium hollow cathode lamp or electrodeless discharge lamp (EDL) and power supply.

Autosampler capable of accurately injecting 5 to 20 μ L sample aliquots onto the L'vov Platform in a graphite tube.

3.4.2. Pyrolytically-coated graphite tubes containing solid, pyrolytic L'vov platforms.

3.4.3. Polyethylene sample cups, 2.0 to 2.5 mL, for use with the autosampler.

3.4.4. Inert purge gas for graphite furnace atomizer: compressed gas cylinder of purified argon.

3.4.5. Two gauge, two-stage pressure regulator for the argon gas cylinder.

3.4.6. Cooling water supply for graphite furnace atomizer.

3.4.7. Exhaust vent installed directly above the graphite furnace atomizer.

3.5. Reagents

All reagents should be ACS analytical reagent grade or better.

3.5.1. Deionized water with a specific conductance of less than 10 uS.

3.5.2. Concentrated nitric acid, HNO₃.

3.5.3. Concentrated hydrochloric acid, HCl.

3.5.4. Ammonium phosphate, monobasic, NH₄H₂PO₄.

3.5.5. Magnesium nitrate, Mg(NO₃)₂·6H₂O.

3.5.6. Diluting solution (4% HNO₃, 0.4% HCl): Add 40 mL HNO₃ and 4 mL HCl carefully to approximately 500 mL deionized water and dilute to 1 L with deionized water.

3.5.7. Cadmium standard stock solution, 1,000 ug/mL: Use a commercially available certified 1,000 ug/mL cadmium standard or, alternatively, dissolve 1.0000 g of cadmium metal in a minimum volume of 1:1 HCl and dilute to 1 L with 4% HNO₃. Observe expiration dates of commercial standards. Properly dispose of commercial standards with no expiration dates or prepared standards one year after their receipt or preparation date.

3.5.8. Matrix modifier for AAS-HGA analysis: Dissolve 1.0 g NH₄H₂PO₄ and 0.15 g Mg(NO₃)₂·6H₂O in approximately 200 mL deionized water. Add 1 mL HNO₃ and dilute to 500 mL with deionized water.

3.5.9. Nitric Acid, 1:1 HNO₃/DI H₂O mixture: Carefully add a measured volume of concentrated HNO₃ to an equal volume of DI H₂O.

3.5.10. Nitric acid, 10% v/v: Carefully add 100 mL of concentrated HNO₃ to 500 mL of DI H₂O and dilute to 1 L.

3.6. Glassware Preparation

3.6.1. Clean Phillips beakers by refluxing with 1:1 nitric acid on a hot plate in a fume hood. Thoroughly rinse with deionized water and invert the beakers to allow them to drain dry.

3.6.2. Rinse volumetric flasks and all other glassware with 10% nitric acid and deionized water prior to use.

3.7. Standard Preparation for Flame AAS Analysis

3.7.1. Dilute stock solutions: Prepare 1, 5, 10 and 100 ug/mL cadmium standard stock solutions by making appropriate serial dilutions of 1,000 ug/mL cadmium standard stock solution with the diluting solution described in Section 3.5.6.

3.7.2. Working standards: Prepare cadmium working standards in the range of 0.02 to 2.0 ug/mL by making appropriate serial dilutions of the dilute stock solutions with the same diluting solution. A suggested method of preparation of the working standards is given below.

| Working Standard (ug/mL) | Std Solution (ug/mL) | Aliquot (mL) | Final Vol. (mL) |
|-----------------------------|-------------------------|-----------------|--------------------|
| 0.02..... | 1 | 10 | 500 |
| 0.05..... | 5 | 5 | 500 |
| 0.1..... | 10 | 5 | 500 |
| 0.2..... | 10 | 10 | 500 |
| 0.5..... | 10 | 25 | 500 |
| 1..... | 100 | 5 | 500 |
| 2..... | 100 | 10 | 500 |

Store the working standards in 500-mL, narrow-mouth polyethylene or glass bottles with leak proof caps. Prepare every twelve months.

3.8. Standard Preparation for AAS-HGA Analysis

3.8.1. Dilute stock solutions: Prepare 10, 100 and 1,000 ng/mL cadmium standard stock solutions by making appropriate ten-fold serial dilutions of the 1,000 ug/mL cadmium standard stock solution with the diluting solution described in Section 3.5.6.

3.8.2. Working standards: Prepare cadmium working standards in the range of 0.2 to 20 ng/mL by making appropriate serial dilutions of the dilute stock solutions with the same diluting solution. A suggested method of preparation of the working standards is given below.

| Working Standard (ng/mL) | Std Solution (ng/mL) | Aliquot (mL) | Final Vol (mL) |
|-----------------------------|-------------------------|-----------------|-------------------|
| 0.2..... | 10 | 2 | 100 |
| 0.5..... | 10 | 5 | 100 |
| 1..... | 10 | 10 | 100 |
| 2..... | 100 | 2 | 100 |
| 5..... | 100 | 5 | 100 |
| 10..... | 100 | 10 | 100 |
| 20..... | 1,000 | 2 | 100 |

Store the working standards in narrow-mouth polyethylene or glass bottles with leakproof caps. Prepare monthly.

3.9. Sample Preparation

3.9.1. Carefully transfer each sample filter with forceps from its filter cassette unit to a clean, separate 125-mL Phillips beaker along with any loose dust found in the cassette. Label each Phillips beaker with the appropriate sample number.

3.9.2. Digest the sample by adding 5 mL of concentrated nitric acid (HNO₃) to each Phillips beaker containing an air filter sample. Place the Phillips beakers on a hot plate in an exhaust hood and heat the samples until approximately 0.5 mL remains. The sample solution in each Phillips beaker should become clear. If it is not clear, digest the sample with another portion of concentrated nitric acid.

3.9.3. After completing the HNO₃ digestion and cooling the samples, add 40 μ L (2 drops) of concentrated HCl to each air sample solution and then swirl the contents. Carefully add about 5 mL of deionized water by pouring it down the inside of each beaker.

3.9.4. Quantitatively transfer each cooled air sample solution from each Phillips beaker to a clean 10-mL volumetric flask. Dilute each flask to volume with deionized water and mix well.

3.10. Flame AAS Analysis

Analyze all of the air samples for their cadmium content by flame atomic absorption spectroscopy (AAS) according to the instructions given below.

3.10.1. Set up the atomic absorption spectrophotometer for the air/acetylene flame analysis of cadmium according to the SOP (5.8.) or the manufacturer's operational instructions. For the source lamp, use the cadmium hollow cathode or electrodeless discharge lamp operated at the manufacturer's recommended rating for continuous operation. Allow the lamp to warm up 10 to 20 min or until the energy output stabilizes. Optimize conditions such as lamp position, burner head alignment, fuel and oxidant flow rates, etc. See the SOP or specific instrument manuals for details. Instrumental parameters for the Perkin-Elmer Model 603 used in the validation of this method are given in Attachment 1.

3.10.2. Aspirate and measure the absorbance of a standard solution of cadmium. The standard concentration should be within the linear range. For the instrumentation used in the validation of this method a 2 μ g/mL cadmium standard gives a net absorbance reading of about 0.350 abs. units (see Section 1.5.5.) when the instrument and the source lamp are performing to manufacturer specifications.

3.10.3. To increase instrument response, scale expand the absorbance reading of the aspirated 2 μ g/mL working standard approximately four times. Increase the integration time to at least 3 seconds to reduce signal noise.

3.10.4. Autozero the instrument while aspirating a deionized water blank. Monitor the variation in the baseline absorbance reading (baseline noise) for a few minutes to insure that the instrument, source lamp and associated equipment are in good operating condition.

3.10.5. Aspirate the working standards and samples directly into the flame and record their absorbance readings. Aspirate the deionized water blank immediately after every standard or sample to correct for and monitor any baseline drift and noise. Record the baseline absorbance reading of each deionized water blank. Label each standard and sample reading and its accompanying baseline reading.

3.10.6. It is recommended that the entire series of working standards be analyzed at the beginning and end of the analysis of a set of samples to establish a concentration-response curve, ensure that the standard readings agree with each other and are reproducible. Also, analyze a working standard after every five or six samples to monitor the performance of the spectrophotometer. Standard readings should agree within + or - 10 to 15% of the readings obtained at the beginning of the analysis.

3.10.7. Bracket the sample readings with standards during the analysis. If the absorbance reading of a sample is above the absorbance reading of the highest working standard, dilute the sample with diluting solution and reanalyze. Use the appropriate dilution factor in the calculations.

3.10.8. Repeat the analysis of approximately 10% of the samples for a check of precision.

3.10.9. If possible, analyze quality control samples from an independent source as a check on analytical recovery and precision.

3.10.10. Record the final instrument settings at the end of the analysis. Date and label the output.

3.11. AAS-HGA Analysis

Initially analyze all of the air samples for their cadmium content by flame atomic absorption spectroscopy (AAS) according to the instructions given in Section 3.10. If the concentration of cadmium in a sample solution is less than three times the quantitative detection limit [0.04 ug/mL (40 ng/mL) for the instrumentation used in the validation] and the sample results are to be averaged with other samples for TWA calculations, proceed with the AAS-HGA analysis of the sample as described below.

3.11.1. Set up the atomic absorption spectrophotometer and HGA for flameless atomic absorption analysis of cadmium according to the SOP (5.9.) or the manufacturer's operational instructions and allow the instrument to stabilize. The graphite furnace atomizer is equipped with a pyrolytically coated graphite tube containing a pyrolytic platform. For the source lamp, use a cadmium hollow cathode or electrodeless discharge lamp operated at the manufacturer's recommended setting for graphite furnace operation. The Zeeman background corrector and EDL are recommended for use with the L'vov platform. Instrumental parameters for the Perkin-Elmer Model 5100 spectrophotometer and Zeeman HGA-600 graphite furnace used in the validation of this method are given in Attachment 2.

- 3.11.2. Optimize the energy reading of the spectrophotometer at 228.8 nm by adjusting the lamp position and the wavelength according to the manufacturer's instructions.
- 3.11.3. Set up the autosampler to inject a 5-uL aliquot of the working standard, sample or reagent blank solution onto the L'vov platform along with a 10-uL overlay of the matrix modifier.
- 3.11.4. Analyze the reagent blank (diluting solution, Section 3.5.6.) and then autozero the instrument before starting the analysis of a set of samples. It is recommended that the reagent blank be analyzed several times during the analysis to assure the integrated absorbance (peak area) reading remains at or near zero.
- 3.11.5. Analyze a working standard approximately midway in the linear portion of the working standard range two or three times to check for reproducibility and sensitivity (see sections 1.5.5. and 1.5.6.) before starting the analysis of samples. Calculate the experimental characteristic mass value from the average integrated absorbance reading and injection volume of the analyzed working standard. Compare this value to the manufacturer's suggested value as a check of proper instrument operation.
- 3.11.6. Analyze the reagent blank, working standard, and sample solutions. Record and label the peak area (abs-sec) readings and the peak and background peak profiles on the printer/plotter.
- 3.11.7. It is recommended the entire series of working standards be analyzed at the beginning and end of the analysis of a set of samples. Establish a concentration-response curve and ensure standard readings agree with each other and are reproducible. Also, analyze a working standard after every five or six samples to monitor the performance of the system. Standard readings should agree within + or - 15% of the readings obtained at the beginning of the analysis.
- 3.11.8. Bracket the sample readings with standards during the analysis. If the peak area reading of a sample is above the peak area reading of the highest working standard, dilute the sample with the diluting solution and reanalyze. Use the appropriate dilution factor in the calculations.
- 3.11.9. Repeat the analysis of approximately 10% of the samples for a check of precision.
- 3.11.10. If possible, analyze quality control samples from an independent source as a check of analytical recovery and precision.
- 3.11.11. Record the final instrument settings at the end of the analysis. Date and label the output.

3.12. Calculations

Note: Standards used for HGA analysis are in ng/mL. Total amounts of cadmium from calculations will be in ug (not ug) unless a prior conversion is made.

- 3.12.1. Correct for baseline drift and noise in flame AAS analysis by subtracting each baseline absorbance reading from its corresponding working standard or sample absorbance reading to obtain the net absorbance reading for each standard and sample.

3.12.2. Use a least squares regression program to plot a concentration- response curve of net absorbance reading (or peak area for HGA analysis) versus concentration (ug/mL or ng/mL) of cadmium in each working standard.

3.12.3. Determine the concentration (ug/mL or ng/mL) of cadmium in each sample from the resulting concentration-response curve. If the concentration of cadmium in a sample solution is less than three times the quantitative detection limit [0.04 ug/mL (40 ng/mL) for the instrumentation used in the validation of the method] and if consecutive samples were taken on one employee and the sample results are to be averaged with other samples to determine a single TWA, reanalyze the sample by AAS-HGA as described in Section 3.11. and report the AAS-HGA analytical results.

3.12.4. Calculate the total amount (ug or ng) of cadmium in each sample from the sample solution volume (mL):

$$W = (C)(\text{sample vol, mL})(DF)$$

Where:

W = Total cadmium in sample
C = Calculated concentration of cadmium
DF = Dilution Factor (if applicable)

3.12.5. Make a blank correction for each air sample by subtracting the total amount of cadmium in the corresponding blank sample from the total amount of cadmium in the sample.

3.12.6. Calculate the concentration of cadmium in an air sample (mg/m³) or ug/m³) by using one of the following equations:

$$\text{mg/m}^3 = W(\text{bc})/(\text{Air vol sampled, L})$$

or

$$\text{ug/m}^3 = (W(\text{bc}))(1,000 \text{ ng/ug})/(\text{Air vol sampled, L})$$

Where:

W(bc) = blank corrected total ug cadmium in the sample.
(1 ug = 1,000 ng)

4. Backup Data

4.1. Introduction

4.1.1. The purpose of this evaluation is to determine the analytical method recovery, working standard range, and qualitative and quantitative detection limits of the two atomic absorption analytical techniques included in this method. The evaluation consisted of the following experiments:

1. An analysis of 24 samples (six samples each at 0.1, 0.5, 1 and 2 times the TWA-PEL) for the analytical method recovery study of the flame AAS analytical technique.

2. An analysis of 18 samples (six samples each at 0.5, 1 and 2 times the Action Level TWA-PEL) for the analytical method recovery study of the AAS-HGA analytical technique.

3. Multiple analyses of the reagent blank and a series of standard solutions to determine the working standard range and the qualitative and quantitative detection limits for both atomic absorption analytical techniques.

4.1.2. The analytical method recovery results at all test levels were calculated from concentration-response curves and statistically examined for outliers at the 99% confidence level. Possible outliers were determined using the Treatment of Outliers test (5.10.). In addition, the sample results of the two analytical techniques, at 0.5, 1.0 and 2.0 times their target concentrations, were tested for homogeneity of variances also at the 99% confidence level. Homogeneity of the coefficients of variation was determined using the Bartlett's test (5.11.). The overall analytical error (OAE) at the 95% confidence level was calculated using the equation (5.12.):

$$\text{OAE} = + \text{ or } - [|\text{Bias}| + (1.96)(\text{CV}(1)(\text{pooled}))(100\%)]$$

4.1.3. A derivation of the International Union of Pure and Applied Chemistry (IUPAC) detection limit equation (5.13.) was used to determine the qualitative and quantitative detection limits for both atomic absorption analytical techniques:

$$C(\text{ld}) = k(\text{sd})/m \quad (\text{Equation 1})$$

Where:

- C(ld) = the smallest reliable detectable concentration an analytical instrument can determine at a given confidence level.
- k = 3 for the Qualitative Detection Limit at the 99.86% Confidence Level
- = 10 for the Quantitative Detection Limit at the 99.99% Confidence Level.
- sd = standard deviation of the reagent blank (Rbl) readings.
- m = analytical sensitivity or slope as calculated by linear regression.

4.1.4. Collection efficiencies of metallic fume and dust atmospheres on 0.8-um mixed cellulose ester membrane filters are well documented and have been shown to be excellent (5.11.). Since elemental cadmium and the cadmium component of cadmium compounds are nonvolatile, stability studies of cadmium spiked MCEF samples were not performed.

4.2. Equipment

4.2.1. A Perkin-Elmer (PE) Model 603 spectrophotometer equipped with a manual gas control system, a stainless steel nebulizer, a burner mixing chamber, a flow spoiler and a 10 cm. (one-slot) burner head was used in the experimental validation of the flame AAS analytical technique. A PE cadmium hollow cathode lamp, operated at the manufacturer's recommended current setting for continuous operation (4 mA), was used as the source lamp. Instrument parameters are listed in Attachment 1.

4.2.2. A PE Model 5100 spectrophotometer, Zeeman HGA-600 graphite furnace atomizer and AS-60 HGA autosampler were used in the experimental validation of the AAS-HGA analytical technique. The spectrophotometer was equipped with a PE Series 7700 professional computer and Model PR-310 printer. A PE System 2 cadmium electrodeless discharge lamp, operated at the manufacturer's recommended current setting for modulated operation (170 mA), was used as the source lamp. Instrument parameters are listed in Attachment 2.

4.3. Reagents

4.3.1 J.T. Baker Chem. Co. (Analyzed grade) concentrated nitric acid, 69.0-71.0%, and concentrated hydrochloric acid, 36.5-38.0%, were used to prepare the samples and standards.

4.3.2. Ammonium phosphate, monobasic, $\text{NH}_4\text{H}_2\text{PO}_4$ and magnesium nitrate, $\text{Mg}(\text{NO}_3)_2 \cdot 6\text{H}_2\text{O}$, both manufactured by the Mallinckrodt Chem. Co., were used to prepare the matrix modifier for AAS-HGA analysis.

4.4. Standard Preparation for Flame AAS Analysis

4.4.1. Dilute stock solutions: Prepared 0.01, 0.1, 1, 10 and 100 $\mu\text{g}/\text{mL}$ cadmium standard stock solutions by making appropriate serial dilutions of a commercially available 1,000 $\mu\text{g}/\text{mL}$ cadmium standard stock solution (RICCA Chemical Co., Lot # A102) with the diluting solution (4% HNO_3 , 0.4% HCl).

4.4.2. Analyzed Standards: Prepared cadmium standards in the range of 0.001 to 2.0 $\mu\text{g}/\text{mL}$ by pipetting 2 to 10 mL of the appropriate dilute cadmium stock solution into a 100-mL volumetric flask and diluting to volume with the diluting solution. (See Section 3.7.2.)

4.5. Standard Preparation for AAS-HGA Analysis

4.5.1. Dilute stock solutions: Prepared 1, 10, 100 and 1,000 ng/mL cadmium standard stock solutions by making appropriate serial dilutions of a commercially available 1,000 $\mu\text{g}/\text{mL}$ cadmium standard stock solution (J.T. Baker Chemical Co., Intra-analyzed, Lot # D22642) with the diluting solution (4% HNO_3 , 0.4% HCl).

4.5.2. Analyzed Standards: Prepared cadmium standards in the range of 0.1 to 40 ng/mL by pipetting 2 to 10 mL of the appropriate dilute cadmium stock solution into a 100-mL volumetric flask and diluting to volume with the diluting solution. (See Section 3.8.2.)

4.6. Detection Limits and Standard Working Range for Flame AAS Analysis

4.6.1. Analyzed the reagent blank solution and the entire series of cadmium standards in the range of 0.001 to 2.0 $\mu\text{g}/\text{mL}$ three to six times according to the instructions given in Section 3.10. The diluting solution (4% HNO_3 , 0.4% HCl) was used as the reagent blank. The integration time on the PE 603 spectrophotometer was set to 3.0 seconds and a four-fold expansion of the absorbance reading of the 2.0 $\mu\text{g}/\text{mL}$ cadmium standard was made prior to analysis. The 2.0

ug/mL standard gave a net absorbance reading of 0.350 abs. units prior to expansion in agreement with the manufacturer's specifications (5.6.).

4.6.2. The net absorbance readings of the reagent blank and the low concentration Cd standards from 0.001 to 0.1 ug/mL and the statistical analysis of the results are shown in Table I. The standard deviation, sd, of the six net absorbance readings of the reagent blank is 1.05 abs. units. The slope, m, as calculated by a linear regression plot of the net absorbance readings (shown in Table II) of the 0.02 to 1.0 ug/mL cadmium standards versus their concentration is 772.7 abs. units/(ug/mL).

4.6.3. If these values for sd and the slope, m, are used in Eqn. 1 (Sect. 4.1.3.), the qualitative and quantitative detection limits as determined by the IUPAC Method are:

$$\begin{aligned} C(ld) &= (3)(1.05 \text{ abs. units})/(772.7 \text{ abs. units}/(\text{ug/mL})) \\ &= 0.0041 \text{ ug/mL for the qualitative detection limit.} \\ C(ld) &= (10)(1.05 \text{ abs. units})/(772.7 \text{ abs. units}/(\text{ug/mL})) \\ &= 0.014 \text{ ug/mL for the quantitative detection limit.} \end{aligned}$$

The qualitative and quantitative detection limits for the flame AAS analytical technique are 0.041 ug and 0.14 ug cadmium, respectively, for a 10 mL solution volume. These correspond, respectively, to 0.2 ug/m³ and 0.70 ug/m³ for a 200 L air volume.

4.6.4. The recommended Cd standard working range for flame AAS analysis is 0.02 to 2.0 ug/mL. The net absorbance readings of the reagent blank and the recommended working range standards and the statistical analysis of the results are shown in Table II. The standard of lowest concentration in the working range, 0.02 ug/mL, is slightly greater than the calculated quantitative detection limit, 0.014 ug/mL. The standard of highest concentration in the working range, 2.0 ug/mL, is at the upper end of the linear working range suggested by the manufacturer (5.6.). Although the standard net absorbance readings are not strictly linear at concentrations above 0.5 ug/mL, the deviation from linearity is only about 10% at the upper end of the recommended standard working range. The deviation from linearity is probably caused by the four-fold expansion of the signal suggested in the method. As shown in Table II, the precision of the standard net absorbance readings are excellent throughout the recommended working range; the relative standard deviations of the readings range from 0.009 to 0.064.

4.7. Detection Limits and Standard Working Range for AAS-HGA Analysis

4.7.1. Analyzed the reagent blank solution and the entire series of cadmium standards in the range of 0.1 to 40 ng/mL according to the instructions given in Section 3.11. The diluting solution (4% HNO₃, 0.4% HCl) was used as the reagent blank. A fresh aliquot of the reagent blank and of each standard was used for every analysis. The experimental characteristic mass value was 0.41 pg, calculated from the average peak area (abs-sec) reading of the 5 ng/mL standard which is approximately midway in the linear portion of the working standard range. This agreed within 20% with the characteristic mass value, 0.35 pg, listed by the manufacturer of the instrument (5.2.).

4.7.2. The peak area (abs-sec) readings of the reagent blank and the low concentration Cd standards from 0.1 to 2.0 ng/mL and statistical analysis of the results are shown in Table III. Five of the reagent blank peak area readings were zero and the sixth reading was 1 and was an outlier. The near lack of a blank signal does not satisfy a strict interpretation of the IUPAC method for determining the detection limits. Therefore, the standard deviation of the six peak area readings of the 0.2 ng/mL cadmium standard, 0.75 abs-sec, was used to calculate the detection limits by the IUPAC method. The slope, m , as calculated by a linear regression plot of the peak area (abs-sec) readings (shown in Table IV) of the 0.2 to 10 ng/mL cadmium standards versus their concentration is 51.5 abs-sec/(ng/mL).

4.7.3. If 0.75 abs-sec (sd) and 51.5 abs-sec/(ng/mL) (m) are used in Eqn. 1 (Sect. 4.1.3.), the qualitative and quantitative detection limits as determined by the IUPAC method are:

$$C(1d) = (3)(0.75 \text{ abs-sec}) / (51.5 \text{ abs-sec}/(\text{ng/mL})) \\ = 0.044 \text{ ng/mL for the qualitative detection limit.}$$

$$C(1d) = (10)(0.75 \text{ abs-sec}) / (51.5 \text{ abs-sec}/(\text{ng/mL})) \\ = 0.15 \text{ ng/mL for the quantitative detection limit.}$$

The qualitative and quantitative detection limits for the AAS-HGA analytical technique are 0.44 ng and 1.5 ng cadmium, respectively, for a 10 mL solution volume. These correspond, respectively, to 0.007 ug/m³ and 0.025 ug/m³ for a 60 L air volume.

4.7.4. The peak area (abs-sec) readings of the Cd standards from 0.2 to 40 ng/mL and the statistical analysis of the results are given in Table IV. The recommended standard working range for AAS-HGA analysis is 0.2 to 20 ng/mL. The standard of lowest concentration in the recommended working range is slightly greater than the calculated quantitative detection limit, 0.15 ng/mL. The deviation from linearity of the peak area readings of the 20 ng/mL standard, the highest concentration standard in the recommended working range, is approximately 10%. The deviations from linearity of the peak area readings of the 30 and 40 ng/mL standards are significantly greater than 10%. As shown in Table IV, the precision of the peak area readings are satisfactory throughout the recommended working range; the relative standard deviations of the readings range from 0.025 to 0.083.

4.8. Analytical Method Recovery for Flame AAS Analysis

4.8.1. Four sets of spiked MCEF samples were prepared by injecting 20 uL of 10, 50, 100 and 200 ug/mL dilute cadmium stock solutions on 37 mm diameter filters (part no. AAWP 037 00, Millipore Corp., Bedford, MA) with a calibrated micropipet. The dilute stock solutions were prepared by making appropriate serial dilutions of a commercially available 1,000 ug/mL cadmium standard stock solution (RICCA Chemical Co., Lot # A102) with the diluting solution (4% HNO₃, 0.4% HCl). Each set contained six samples and a sample blank. The amount of cadmium in the prepared sets were equivalent to 0.1, 0.5, 1.0 and 2.0 times the TWA PEL target concentration of 5 ug/m³ for a 400 L air volume.

4.8.2. The air-dried spiked filters were digested and analyzed for their cadmium content by flame atomic absorption spectroscopy (AAS) following the procedure described in Section 3. The 0.02

to 2.0 ug/mL cadmium standards (the suggested working range) were used in the analysis of the spiked filters.

4.8.3. The results of the analysis are given in Table V. One result at 0.5 times the TWA PEL target concentration was an outlier and was excluded from statistical analysis. Experimental justification for rejecting it is that the outlier value was probably due to a spiking error. The coefficients of variation for the three test levels at 0.5 to 2.0 times the TWA PEL target concentration passed the Bartlett's test and were pooled.

4.8.4. The average recovery of the six spiked filter samples at 0.1 times the TWA PEL target concentration was 118.2% with a coefficient of variation (CV(1)) of 0.128. The average recovery of the spiked filter samples in the range of 0.5 to 2.0 times the TWA target concentration was 104.0% with a pooled coefficient of variation (CV(1)) of 0.010. Consequently, the analytical bias found in these spiked sample results over the tested concentration range was + 4.0% and the OAE was + or - 6.0%.

4.9. Analytical Method Recovery for AAS-HGA Analysis

4.9.1. Three sets of spiked MCEF samples were prepared by injecting 15 uL of 5, 10 and 20 ug/mL dilute cadmium stock solutions on 37 mm diameter filters (part no. AAWP 037 00, Millipore Corp., Bedford, MA) with a calibrated micropipet. The dilute stock solutions were prepared by making appropriate serial dilutions of a commercially available certified 1,000 ug/mL cadmium standard stock solution (Fisher Chemical Co., Lot # 913438-24) with the diluting solution (4% HNO₃, 0.4% HCl). Each set contained six samples and a sample blank. The amount of cadmium in the prepared sets were equivalent to 0.5, 1 and 2 times the Action Level TWA target concentration of 2.5 ug/m³ for a 60 L air volume.

4.9.2. The air-dried spiked filters were digested and analyzed for their cadmium content by flameless atomic absorption spectroscopy using a heated graphite furnace atomizer following the procedure described in Section 3. A five-fold dilution of the spiked filter samples at 2 times the Action Level TWA was made prior to their analysis. The 0.05 to 20 ng/mL cadmium standards were used in the analysis of the spiked filters.

4.9.3. The results of the analysis are given in Table VI. There were no outliers. The coefficients of variation for the three test levels at 0.5 to 2.0 times the Action Level TWA PEL passed the Bartlett's test and were pooled. The average recovery of the spiked filter samples was 94.2% with a pooled coefficient of variation (CV(1)) of 0.043. Consequently, the analytical bias was - 5.8% and the OAE was + or - 14.2%.

4.10. Conclusions

The experiments performed in this evaluation show the two atomic absorption analytical techniques included in this method to be precise and accurate and have sufficient sensitivity to measure airborne cadmium over a broad range of exposure levels and sampling periods.

5. References:

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TABLE I. -- CD DETECTION LIMIT STUDY
[Flame AAS Analysis]

| STD (ug/mL) | Absorbance reading at 228.8 nm | | Statistical analysis |
|--------------------|--------------------------------|----|----------------------|
| Reagent blank..... | 5 | 2 | n = 6 |
| | 4 | 3 | mean = 3.50 |
| | 4 | 3 | std dev = 1.05 |
| | | | CV = 0.30 |
| 0.001..... | 6 | 6 | n = 6 |
| | 2 | 4 | mean = 5.00 |
| | 6 | 6 | std dev = 1.67 |
| | | | CV = 0.335 |
| 0.002..... | 5 | 7 | n = 6 |
| | 7 | 3 | mean = 5.50 |
| | 7 | 4 | std dev = 1.76 |
| | | | CV = 0.320 |
| 0.005..... | 7 | 7 | n = 6 |
| | 8 | 8 | mean = 7.33 |
| | 8 | 6 | std dev = 0.817 |
| | | | CV = 0.111 |
| 0.010..... | 10 | 9 | n = 6 |
| | 10 | 13 | mean = 10.3 |
| | 10 | 10 | std dev = 1.37 |
| | | | CV = 0.133 |
| 0.020..... | 20 | 23 | n = 6 |
| | 20 | 22 | mean = 20.8 |
| | 20 | 20 | std dev = 1.33 |
| | | | CV = 0.064 |
| 0.050..... | 42 | 42 | n = 6 |
| | 42 | 42 | mean = 42.5 |
| | 42 | 45 | std dev = 1.22 |
| | | | CV = 0.029 |
| 0.10..... | | 84 | n = 3 |
| | | 80 | mean = 82.3 |
| | | 83 | std dev = 2.08 |
| | | | CV = 0.025 |

TABLE II. -- CD STANDARD WORKING RANGE STUDY
[Flame AAS Analysis]

| STD (ug/mL) | Absorbance reading at 228.8 nm | | Statistical analysis |
|--------------------|--------------------------------|---|----------------------|
| Reagent blank..... | 5 | 2 | n = 6 |

| | | | |
|------------|----|------|----------------|
| | 4 | 3 | mean = 3.50 |
| | 4 | 3 | std dev = 1.05 |
| | | | CV = 0.30 |
| 0.020..... | 20 | 23 | n = 6 |
| | 20 | 22 | mean = 20.8 |
| | 20 | 20 | std dev = 1.33 |
| | | | CV = 0.064 |
| 0.050..... | 42 | 42 | n = 6 |
| | 42 | 42 | mean = 42.5 |
| | 42 | 45 | std dev = 1.22 |
| | | | CV = 0.029 |
| 0.10..... | | 84 | n = 3 |
| | | 80 | mean = 82.3 |
| | | 83 | std dev = 2.08 |
| | | | CV = 0.025 |
| 0.20..... | | 161 | n = 3 |
| | | 161 | mean = 160.0 |
| | | 158 | std dev = 1.73 |
| | | | CV = 0.011 |
| 0.50..... | | 391 | n = 3 |
| | | 389 | mean = 391.0 |
| | | 393 | std dev = 2.00 |
| | | | CV = 0.005 |
| 1.00..... | | 760 | n = 3 |
| | | 748 | mean = 753.3 |
| | | 752 | std dev = 6.11 |
| | | | CV = 0.008 |
| 2.00..... | | 1416 | n = 3 |
| | | 1426 | mean = 1414.3 |
| | | 1401 | std dev = 12.6 |
| | | | CV = 0.009 |

Table III. -- CD DETECTION LIMIT STUDY
(AAS-HGA Analysis)

| STD (ng/mL) | Peak area readings X 10(3) at 228.8 nm | | Statistical analysis |
|------------------|--|----|----------------------|
| Reagent blank... | 0 | 0 | n = 6 |
| | 0 | 1 | mean = 0.167 |
| | 0 | 0 | std dev = 0.41 |
| | | | CV = 2.45 |
| 0.1..... | 8 | 6 | n = 6 |
| | 5 | 7 | mean = 7.7 |
| | 13 | 7 | std dev = 2.8 |
| | | | CV = 0.366 |
| 0.2..... | 11 | 13 | n = 6 |
| | 11 | 12 | mean = 11.8 |
| | 12 | 12 | std dev = 0.75 |
| | | | CV = 0.064 |
| 0.5..... | 28 | 33 | n = 6 |

| | | | |
|----------|-----|-----|---------------|
| | 26 | 28 | mean = 28.8 |
| | 28 | 30 | std dev = 2.4 |
| | | | CV = 0.083 |
| 1.0..... | 52 | 55 | n = 6 |
| | 56 | 58 | mean = 54.8 |
| | 54 | 54 | std dev = 2.0 |
| | | | CV = 0.037 |
| 2.0..... | 101 | 112 | n = 6 |
| | 110 | 110 | mean = 108.8 |
| | 110 | 110 | std dev = 3.9 |
| | | | CV = 0.036 |

Table IV. -- CD STANDARD WORKING RANGE STUDY
(AAS-HGA Analysis)

| STD (ng/mL) | Peak area readings X 10(3) at 228.8 nm | | Statistical analysis |
|-------------|--|------|----------------------|
| 0.2..... | 11 | 13 | n = 6 |
| | 11 | 12 | mean = 11.8 |
| | 12 | 12 | std dev = 0.75 |
| | | | CV = 0.064 |
| 0.5..... | 28 | 33 | n = 6 |
| | 26 | 28 | mean = 28.8 |
| | 28 | 30 | std dev = 2.4 |
| | | | CV = 0.083 |
| 1.0..... | 52 | 55 | n = 6 |
| | 56 | 58 | mean = 54.8 |
| | 54 | 54 | std dev = 2.0 |
| | | | CV = 0.037 |
| 2.0..... | 101 | 112 | n = 6 |
| | 110 | 110 | mean = 108.8 |
| | 110 | 110 | std dev = 3.9 |
| | | | CV = 0.036 |
| 5.0..... | 247 | 265 | n = 6 |
| | 268 | 275 | mean = 265.5 |
| | 259 | 279 | std dev = 11.5 |
| | | | CV = 0.044 |
| 10.0..... | 495 | 520 | n = 6 |
| | 523 | 513 | mean = 516.7 |
| | 516 | 533 | std dev = 12.7 |
| | | | CV = 0.025 |
| 20.0..... | 950 | 953 | n = 6 |
| | 951 | 958 | mean = 941.8 |
| | 949 | 890 | std dev = 25.6 |
| | | | CV = 0.027 |
| 30.0..... | 1269 | 1291 | n = 6 |
| | 1303 | 1307 | mean = 1293 |
| | 1295 | 1290 | std dev = 13.3 |
| | | | CV = 0.010 |
| 40.0..... | 1505 | 1567 | n = 6 |
| | 1535 | 1567 | mean = 1552 |

| | | | |
|--|------|------|----------------|
| | 1566 | 1572 | std dev = 26.6 |
| | | | CV = 0.017 |

TABLE V. -- ANALYTICAL METHOD RECOVERY
(Flame AAS Analysis)

| Test Level | 0.5X | Percent rec. | ug taken | 1.0X | Percent rec. | ug taken | 2.0X | Percent rec |
|------------|-----------------------|--------------|----------|----------|--------------|----------|----------|-------------|
| ug taken | ug found | | | ug found | | | ug found | |
| 1.00 | 1.0715 | 107.2 | 2.00 | 2.0688 | 103.4 | 4.00 | 4.1504 | 103.8 |
| 1.00 | 1.0842 | 108.4 | 2.00 | 2.0174 | 100.9 | 4.00 | 4.1108 | 102.8 |
| 1.00 | 1.0842 | 108.4 | 2.00 | 2.0431 | 102.2 | 4.00 | 4.0581 | 101.5 |
| 1.00 | (*)1.0081 | (*)100.8 | 2.00 | 2.0431 | 102.2 | 4.00 | 4.0844 | 102.1 |
| 1.00 | 1.0715 | 107.2 | 2.00 | 2.0174 | 100.9 | 4.00 | 4.1504 | 103.8 |
| 1.00 | 1.0842 | 108.4 | 2.00 | 2.0045 | 100.2 | 4.00 | 4.1899 | 104.7 |
| n = | 5 | | | 6 | | | 6 | |
| mean = | 107.9 | | | 101.6 | | | 103.1 | |
| std dev = | 0.657 | | | 1.174 | | | 1.199 | |
| CV(1) = | 0.006 | | | 0.011 | | | 0.012 | |
| | CV(1)(pooled) = 0.010 | | | | | | | |

Footnote(*) Rejected as an outlier - this value did not pass the outlier T-test at the 99% confidence level.

| Test Level | 0.1X | Percent Rec. |
|---------------|----------|--------------|
| ug taken | ug found | |
| 0.200 | 0.2509 | 125.5 |
| 0.200 | 0.2509 | 125.5 |
| 0.200 | 0.2761 | 138.1 |
| 0.200 | 0.2258 | 112.9 |
| 0.200 | 0.2258 | 112.9 |
| 0.200 | 0.1881 | 94.1 |
| n = ... | 6 | |
| mean = ... | 118.2 | |
| std dev = ... | 15.1 | |
| CV(1) = ... | 0.128 | |

TABLE VI. -- ANALYTICAL METHOD RECOVERY

(AAS-HGA Analysis)

| Test Level | 0.5X | Percent rec. | ng taken | 1.0X | Percent rec. | ng taken | 2.0X | Percent rec. |
|------------|----------|-----------------------|----------|----------|--------------|----------|----------|--------------|
| ng taken | ng found | | | ng found | | | ng found | |
| 75 | 71.23 | 95.0 | 150 | 138.00 | 92.0 | 300 | 258.43 | 86.1 |
| 75 | 71.47 | 95.3 | 150 | 138.29 | 92.2 | 300 | 258.46 | 86.2 |
| 75 | 70.02 | 93.4 | 150 | 136.30 | 90.9 | 300 | 280.55 | 93.5 |
| 75 | 77.34 | 103.1 | 150 | 146.62 | 97.7 | 300 | 288.34 | 96.1 |
| 75 | 78.32 | 104.4 | 150 | 145.17 | 96.8 | 300 | 261.74 | 87.2 |
| 75 | 71.96 | 95.9 | 150 | 144.88 | 96.6 | 300 | 277.22 | 92.4 |
| n = | | 6 | | | 6 | | | 6 |
| mean = | | 97.9 | | | 94.4 | | | 90.3 |
| std dev = | | 4.66 | | | 2.98 | | | 4.30 |
| CV(1) = | | 0.048 | | | 0.03 | | | 0.048 |
| | | CV(1)(pooled) = 0.043 | | | | | | |

Attachment 1

Instrumental Parameters for Flame AAS Analysis

Atomic Absorption Spectrophotometer
(Perkin-Elmer Model 603)

Flame: Air/Acetylene -- lean, blue
Oxidant Flow: 55
Fuel Flow: 32
Wavelength: 228.8 nm
Slit: 4 (0.7 nm)
Range: UV
Signal: Concentration (4 exp)
Integration Time: 3 sec

Attachment 2

Instrumental Parameters for HGA Analysis

Atomic Absorption Spectrophotometer
(Perkin-Elmer Model 5100)

Signal Type: Zeeman AA
Slitwidth: 0.7 nm
Wavelength: 228.8 nm
Measurement: Peak Area
Integration Time: 6.0 sec
BOC Time: 5 sec
BOC = Background Offset Correction

ZEEMAN GRAPHITE FURNACE

(PERKIN-ELMER MODEL HGA-600)

| Step | Ramp time (sec) | Hold time (sec) | Temp. (Deg. C) | Argon flow (mL/min) | Read (sec) |
|-----------------|--------------------|--------------------|-------------------|------------------------|---------------|
| (1)Predry..... | 5 | 10 | 90 | 300 | ----- |
| (2)Dry..... | 30 | 10 | 140 | 300 | ----- |
| (3)Char..... | 10 | 20 | 900 | 300 | ----- |
| (4)Cool Down... | 1 | 8 | 30 | 300 | ----- |
| (5)Atomize..... | 0 | 5 | 1600 | 0 | -1 |
| (6)Burnout..... | 1 | 8 | 2500 | 300 | ----- |

Appendix F to 1910.1027: Nonmandatory Protocol for Biological Monitoring

1.0 Introduction

Under the final OSHA cadmium rule (29 CFR 1910), monitoring of biological specimens and several periodic medical examinations are required for eligible employees. These medical examinations are to be conducted regularly, and medical monitoring is to include the periodic analysis of cadmium in blood (CDB), cadmium in urine (CDU) and beta-2-microglobulin in urine (B(2)MU). As CDU and B(2)MU are to be normalized to the concentration of creatinine in urine (CRTU), then CRTU must be analyzed in conjunction with CDU and B(2)MU analyses.

The purpose of this protocol is to provide procedures for establishing and maintaining the quality of the results obtained from the analyses of CDB, CDU and B(2)MU by commercial laboratories. Laboratories conforming to the provisions of this nonmandatory protocol shall be known as "participating laboratories." The biological monitoring data from these laboratories will be evaluated by physicians responsible for biological monitoring to determine the conditions under which employees may continue to work in locations exhibiting airborne-cadmium concentrations at or above defined actions levels (see paragraphs (1)(3) and (1)(4) of the final rule). These results also may be used to support a decision to remove workers from such locations.

Under the medical monitoring program for cadmium, blood and urine samples must be collected at defined intervals from workers by physicians responsible for medical monitoring; these samples are sent to commercial laboratories that perform the required analyses and report results of these analyses to the responsible physicians. To ensure the accuracy and reliability of these laboratory analyses, the laboratories to which samples are submitted should participate in an ongoing and efficacious proficiency testing program. Availability of proficiency testing programs may vary with the analyses performed.

To test proficiency in the analysis of CDB, CDU and B(2)MU, a laboratory should participate either in the interlaboratory comparison program operated by the Centre de Toxicologie du Quebec (CTQ) or an equivalent program. (Currently, no laboratory in the U.S. performs proficiency testing on CDB, CDU or B(2)MU.) Under this program, CTQ sends participating laboratories 18 samples of each analyte (CDB, CDU and/or B(2)MU) annually for analysis.

Participating laboratories must return the results of these analyses to CTQ within four to five weeks after receiving the samples.

The CTQ program pools analytical results from many participating laboratories to derive consensus mean values for each of the samples distributed. Results reported by each laboratory then are compared against these consensus means for the analyzed samples to determine the relative performance of each laboratory. The proficiency of a participating laboratory is a function of the extent of agreement between results submitted by the participating laboratory and the consensus values for the set of samples analyzed.

Proficiency testing for CRTU analysis (which should be performed with CDU and B(2)MU analyses to evaluate the results properly) also is recommended. In the U.S., only the College of American Pathologists (CAP) currently conducts CRTU proficiency testing; participating laboratories should be accredited for CRTU analysis by the CAP.

Results of the proficiency evaluations will be forwarded to the participating laboratory by the proficiency-testing laboratory, as well as to physicians designated by the participating laboratory to receive this information. In addition, the participating laboratory should, on request, submit the results of their internal Quality Assurance/Quality Control (QA/QC) program for each analytic procedure (i.e., CDB, CDU and/or B(2)MU) to physicians designated to receive the proficiency results. For participating laboratories offering CDU and/or B(2)MU analyses, QA/QC documentation also should be provided for CRTU analysis. (Laboratories should provide QA/QC information regarding CRTU analysis directly to the requesting physician if they perform the analysis in-house; if CRTU analysis is performed by another laboratory under contract, this information should be provided to the physician by the contract laboratory.)

QA/QC information, along with the actual biological specimen measurements, should be provided to the responsible physician using standard formats. These physicians then may collate the QA/QC information with proficiency test results to compare the relative performance of laboratories, as well as to facilitate evaluation of the worker monitoring data. This information supports decisions made by the physician with regard to the biological monitoring program, and for mandating medical removal.

This protocol describes procedures that may be used by the responsible physicians to identify laboratories most likely to be proficient in the analysis of samples used in the biological monitoring of cadmium; also provided are procedures for record keeping and reporting by laboratories participating in proficiency testing programs, and recommendations to assist these physicians in interpreting analytical results determined by participating laboratories. As the collection and handling of samples affects the quality of the data, recommendations are made for these tasks. Specifications for analytical methods to be used in the medical monitoring program are included in this protocol as well.

In conclusion, this document is intended as a supplement to characterize and maintain the quality of medical monitoring data collected under the final cadmium rule promulgated by OSHA (29 CFR 1910). OSHA has been granted authority under the Occupational Safety and Health Act of

1970 to protect workers from the effects of exposure to hazardous substances in the work place and to mandate adequate monitoring of workers to determine when adverse health effects may be occurring. This nonmandatory protocol is intended to provide guidelines and recommendations to improve the accuracy and reliability of the procedures used to analyze the biological samples collected as part of the medical monitoring program for cadmium.

2.0 Definitions

When the terms below appear in this protocol, use the following definitions.

Accuracy: A measure of the bias of a data set. Bias is a systematic error that is either inherent in a method or caused by some artifact or idiosyncrasy of the measurement system. Bias is characterized by a consistent deviation (positive or negative) in the results from an accepted reference value.

Arithmetic Mean: The sum of measurements in a set divided by the number of measurements in a set.

Blind Samples: A quality control procedure in which the concentration of analyte in the samples should be unknown to the analyst at the time that the analysis is performed.

Coefficient of Variation: The ratio of the standard deviation of a set of measurements to the mean (arithmetic or geometric) of the measurements.

Compliance Samples: Samples from exposed workers sent to a participating laboratory for analysis.

Control Charts: Graphic representations of the results for quality control samples being analyzed by a participating laboratory.

Control Limits: Statistical limits which define when an analytic procedure exceeds acceptable parameters; control limits provide a method of assessing the accuracy of analysts, laboratories, and discrete analytic runs.

Control Samples: Quality control samples.

F/T: The measured amount of an analyte divided by the theoretical value (defined below) for that analyte in the sample analyzed; this ratio is a measure of the recovery for a quality control sample.

Geometric Mean: The natural antilog of the mean of a set of natural log-transformed data.

Geometric Standard Deviation: The antilog of the standard deviation of a set of natural log-transformed data.

Limit of Detection: Using a predefined level of confidence, this is the lowest measured value at which some of the measured material is likely to have come from the sample.

Mean: A central tendency of a set of data; in this protocol, this mean is defined as the arithmetic mean (see definition of arithmetic mean above) unless stated otherwise.

Performance: A measure of the overall quality of data reported by a laboratory.

Pools: Groups of quality-control samples to be established for each target value (defined below) of an analyte. For the protocol provided in attachment 3, for example, the theoretical value of the quality control samples of the pool must be within a range defined as plus or minus (+ or -) 50% of the target value. Within each analyte pool, there must be quality control samples of at least 4 theoretical values.

Precision: The extent of agreement between repeated, independent measurements of the same quantity of an analyte.

Proficiency: The ability to satisfy a specified level of analyte performance.

Proficiency Samples: Specimens, the values of which are unknown to anyone at a participating laboratory, and which are submitted by a participating laboratory for proficiency testing.

Quality or Data Quality: A measure of the confidence in the measurement value.

Quality Control (QC) Samples: Specimens, the value of which is unknown to the analyst, but is known to the appropriate QA/QC personnel of a participating laboratory; when used as part of a laboratory QA/QC program, the theoretical values of these samples should not be known to the analyst until the analyses are complete. QC samples are to be run in sets consisting of one QC sample from each pool (see definition of "pools" above).

Sensitivity: For the purposes of this protocol, the limit of detection.

Standard Deviation: A measure of the distribution or spread of a data set about the mean; the standard deviation is equal to the positive square root of the variance, and is expressed in the same units as the original measurements in the data set.

Standards: Samples with values known by the analyst and used to calibrate equipment and to check calibration throughout an analytic run. In a laboratory QA/QC program, the values of the standards must exceed the values obtained for compliance samples such that the lowest standard value is near the limit of detection and the highest standard is higher than the highest compliance sample or QC sample. Standards of at least three different values are to be used for calibration, and should be constructed from at least 2 different sources.

Target Value: Those values of CDB, CDU or B(2)MU which trigger some action as prescribed in the medical surveillance section of the regulatory text of the final cadmium rule. For CDB, the target values are 5, 10, and 15 ug/l. For CDU, the target values are 3, 7, and 15 ug/g CRTU. For B(2)MU, the target values are 300, 750, and 1500 ug/g CRTU. (Note that target values may vary as a function of time.)

Theoretical Value (or Theoretical Amount): The reported concentration of a quality-control sample (or calibration standard) derived from prior characterizations of the sample.

Value or Measurement Value: The numerical result of a measurement.

Variance: A measure of the distribution or spread of a data set about the mean; the variance is the sum of the squares of the differences between the mean and each discrete measurement divided by one less than the number of measurements in the data set.

3.0 Protocol

This protocol provides procedures for characterizing and maintaining the quality of analytic results derived for the medical monitoring program mandated for workers under the final cadmium rule.

3.1 Overview

The goal of this protocol is to assure that medical monitoring data are of sufficient quality to facilitate proper interpretation. The data quality objectives (DQOs) defined for the medical monitoring program are summarized in Table 1. Based on available information, the DQOs presented in Table 1 should be achievable by the majority of laboratories offering the required analyses commercially; OSHA recommends that only laboratories meeting these DQOs be used for the analysis of biological samples collected for monitoring cadmium exposure.

TABLE 1 - RECOMMENDED DATA QUALITY OBJECTIVES (DQOs) FOR THE CADMIUM MEDICAL MONITORING PROGRAM

| Analyte/Concentration Pool | Limit of Detection | Precision (CV) | Accuracy |
|---|---------------------|----------------|----------------------------------|
| Cadmium in Blood | 0.5 ug/l . | | + or - 1 ug/l or 15% of the mean |
| Less than or = to 2 ug/l | | 40% | |
| Greater than 2 ug/l | | 20% | |
| Cadmium in Urine | 0.5 ug/g creatinine | | + or - 1 ug/l or 15% of the mean |
| Less than or = to 2 ug/l creatinine | | 40% | |
| Greater than 2 ug/l creatinine | | 20% | |
| B-2-Microglobulin in Urine | 100 ug/g creatinine | | + or - 15% of the mean |
| 100 ug/g creatinine | | 5% | |

To satisfy the DQOs presented in Table 1, OSHA provides the following guidelines:

1. Procedures for the collection and handling of blood and urine are specified (Section 3.4.1 of this protocol);
2. Preferred analytic methods for the analysis of CDB, CDU and B(2)MU are defined (and a method for the determination of CRTU also is specified since CDU and B(2)MU results are to be normalized to the level of CRTU).
3. Procedures are described for identifying laboratories likely to provide the required analyses in an accurate and reliable manner;
4. These guidelines (Sections 3.2.1 to 3.2.3, and Section 3.3) include recommendations regarding internal QA/QC programs for participating laboratories, as well as levels of proficiency through participation in an interlaboratory proficiency program;
5. Procedures for QA/QC record keeping (Section 3.3.2), and for reporting QC/QA results are described (Section 3.3.3); and,
6. Procedures for interpreting medical monitoring results are specified (Section 3.4.3).

Methods recommended for the biological monitoring of eligible workers are:

1. The method of Stoeppler and Brandt (1980) for CDB determinations (limit of detection: 0.5 ug/l);
2. The method of Pruszkowska et al. (1983) for CDU determinations (limit of detection: 0.5 ug/l of urine); and,
3. The Pharmacia Delphia test kit (Pharmacia 1990) for the determination of B(2)MU (limit of detection: 100 ug/l urine).

Because both CDU and B(2)MU should be reported in ug/g CRTU, an independent determination of CRTU is recommended. Thus, both the OSHA Salt Lake City Technical Center (OSLTC) method (OSHA, no date) and the Jaffe method (Du Pont, no date) for the determination of CRTU are specified under this protocol (i.e., either of these 2 methods may be used). Note that although detection limits are not reported for either of these CRTU methods, the range of measurements expected for CRTU (0.9-1.7 ug/l) are well above the likely limit of detection for either of these methods (Harrison, 1987).

Laboratories using alternate methods should submit sufficient data to the responsible physicians demonstrating that the alternate method is capable of satisfying the defined data quality objectives of the program. Such laboratories also should submit a QA/QC plan that documents the performance of the alternate method in a manner entirely equivalent to the QA/QC plans proposed in Section 3.3.1.

3.2 Duties of the Responsible Physician

The responsible physician will evaluate biological monitoring results provided by participating laboratories to determine whether such laboratories are proficient and have satisfied the QA/QC recommendations. In determining which laboratories to employ for this purpose, these physicians should review proficiency and QA/QC data submitted to them by the participating laboratories.

Participating laboratories should demonstrate proficiency for each analyte (CDU, CDB and B(2)MU) sampled under the biological monitoring program. Participating laboratories involved in analyzing CDU and B(2)MU also should demonstrate proficiency for CRTU analysis, or provide evidence of a contract with a laboratory proficient in CRTU analysis.

3.2.1 Recommendations for Selecting Among Existing Laboratories

OSHA recommends that existing laboratories providing commercial analyses for CDB, CDU and/or B(2)MU for the medical monitoring program satisfy the following criteria:

1. Should have performed commercial analyses for the appropriate analyte (CDB, CDU and/or B(2)MU) on a regular basis over the last 2 years;
2. Should provide the responsible physician with an internal QA/QC plan;
3. If performing CDU or B(2)MU analyses, the participating laboratory should be accredited by the CAP for CRTU analysis, and should be enrolled in the corresponding CAP survey (note that alternate credentials may be acceptable, but acceptability is to be determined by the responsible physician); and,
4. Should have enrolled in the CTQ interlaboratory comparison program for the appropriate analyte (CDB, CDU and/or B(2)MU).

Participating laboratories should submit appropriate documentation demonstrating compliance with the above criteria to the responsible physician. To demonstrate compliance with the first of the above criteria, participating laboratories should submit the following documentation for each analyte they plan to analyze (note that each document should cover a period of at least 8 consecutive quarters, and that the period designated by the term "regular analyses" is at least once a quarter):

1. Copies of laboratory reports providing results from regular analyses of the appropriate analyte (CDB, CDU and/or B(2)MU);
2. Copies of 1 or more signed and executed contracts for the provision of regular analyses of the appropriate analyte (CDB, CDU and/or B(2)MU); or,
3. Copies of invoices sent to 1 or more clients requesting payment for the provision of regular analyses of the appropriate analyte (CDB, CDU and/or B(2)MU). Whatever the form of documentation submitted, the specific analytic procedures conducted should be identified directly. The forms that are copied for submission to the responsible physician also should identify the laboratory which provided these analyses.

To demonstrate compliance with the second of the above criteria, a laboratory should submit to the responsible physician an internal QA/QC plan detailing the standard operating procedures to be adopted for satisfying the recommended QA/QC procedures for the analysis of each specific analyte (CDB, CDU and/or B(2)MU). Procedures for internal QA/QC programs are detailed in Section 3.3.1 below.

To satisfy the third of the above criteria, laboratories analyzing for CDU or B(2)MU also should submit a QA/QC plan for creatinine analysis (CRTU); the QA/QC plan and characterization analyses for CRTU must come from the laboratory performing the CRTU analysis, even if the CRTU analysis is being performed by a contract laboratory.

Laboratories enrolling in the CTQ program (to satisfy the last of the above criteria) must remit, with the enrollment application, an initial fee of approximately \$100 per analyte. (Note that this fee is only an estimate, and is subject to revision without notice.) Laboratories should indicate on the application that they agree to have proficiency test results sent by the CTQ directly to the physicians designated by participating laboratories.

Once a laboratory's application is processed by the CTQ, the laboratory will be assigned a code number which will be provided to the laboratory on the initial confirmation form, along with identification of the specific analytes for which the laboratory is participating. Confirmation of participation will be sent by the CTQ to physicians designated by the applicant laboratory.

3.2.2 Recommended Review of Laboratories Selected to Perform Analyses

Six months after being selected initially to perform analyte determinations, the status of participating laboratories should be reviewed by the responsible physicians. Such reviews should then be repeated every 6 months or whenever additional proficiency or QA/QC documentation is received (whichever occurs first).

As soon as the responsible physician has received the CTQ results from the first 3 rounds of proficiency testing (i.e., 3 sets of 3 samples each for CDB, CDU and/or B(2)MU) for a participating laboratory, the status of the laboratory's continued participation should be reviewed. Over the same initial 6-month period, participating laboratories also should provide responsible physicians the results of their internal QA/QC monitoring program used to assess performance for each analyte (CDB, CDU and/or B(2)MU) for which the laboratory performs determinations. This information should be submitted using appropriate forms and documentation.

The status of each participating laboratory should be determined for each analyte (i.e., whether the laboratory satisfies minimum proficiency guidelines based on the proficiency samples sent by the CTQ and the results of the laboratory's internal QA/QC program). To maintain competency for analysis of CDB, CDU and/or B(2)MU during the first review, the laboratory should satisfy performance requirements for at least 2 of the 3 proficiency samples provided in each of the 3 rounds completed over the 6-month period. Proficiency should be maintained for the analyte(s) for which the laboratory conducts determinations.

To continue participation for CDU and/or B(2)MU analyses, laboratories also should either maintain accreditation for CRTU analysis in the CAP program and participate in the CAP surveys, or they should contract the CDU and B(2)MU analyses to a laboratory which satisfies these requirements (or which can provide documentation of accreditation/participation in an equivalent program).

The performance requirement for CDB analysis is defined as an analytical result within + or - 1 ug/l blood or 15% of the consensus mean (whichever is greater). For samples exhibiting a consensus mean less than 1 ug/l, the performance requirement is defined as a concentration between the detection limit of the analysis and a maximum of 2 ug/l. The purpose for redefining the acceptable interval for low CDB values is to encourage proper reporting of the actual values obtained during measurement; laboratories, therefore, will not be penalized (in terms of a narrow range of acceptability) for reporting measured concentrations smaller than 1 ug/l.

The performance requirement for CDU analysis is defined as an analytical result within + or - 1 ug/l urine or 15% of the consensus mean (whichever is greater). For samples exhibiting a consensus mean less than 1 ug/l urine, the performance requirement is defined as a concentration between the detection limit of the analysis and a maximum of 2 ug/l urine. Laboratories also should demonstrate proficiency in creatinine analysis as defined by the CAP. Note that reporting CDU results, other than for the CTQ proficiency samples (i.e., compliance samples), should be accompanied with results of analyses for CRTU, and these 2 sets of results should be combined to provide a measure of CDU in units of ug/g CRTU.

The performance requirement for B(2)MU is defined as analytical results within + or - 15% of the consensus mean. Note that reporting B(2)MU results, other than for CTQ proficiency samples (i.e., compliance samples), should be accompanied with results of analyses for CRTU, and these 2 sets of results should be combined to provide a measure of B(2)MU in units of ug/g CRTU.

There are no recommended performance checks for CRTU analyses. As stated previously, laboratories performing CRTU analysis in support of CDU or B(2)MU analyses should be accredited by the CAP, and participating in the CAP's survey for CRTU.

Following the first review, the status of each participating laboratory should be reevaluated at regular intervals (i.e., corresponding to receipt of results from each succeeding round of proficiency testing and submission of reports from a participating laboratory's internal QA/QC program).

After a year of collecting proficiency test results, the following proficiency criterion should be added to the set of criteria used to determine the participating laboratory's status (for analyzing CDB, CDU and/or B(2)MU): A participating laboratory should not fail performance requirements for more than 4 samples from the 6 most recent consecutive rounds used to assess proficiency for CDB, CDU and/or B(2)MU separately (i.e., a total of 18 discrete proficiency samples for each analyte). Note that this requirement does not replace, but supplements, the recommendation that a laboratory should satisfy the performance criteria for at least 2 of the 3 samples tested for each round of the program.

3.2.3 Recommendations for Selecting Among Newly-Formed Laboratories (or Laboratories that Previously Failed to Meet the Protocol Guidelines)

OSHA recommends that laboratories that have not previously provided commercial analyses of CDB, CDU and/or B(2)MU (or have done so for a period less than 2 years), or which have provided these analyses for 2 or more years but have not conformed previously with these protocol guidelines, should satisfy the following provisions for each analyte for which determinations are to be made prior to being selected to analyze biological samples under the medical monitoring program:

1. Submit to the responsible physician an internal QA/QC plan detailing the standard operating procedures to be adopted for satisfying the QA/QC guidelines (guidelines for internal QA/QC programs are detailed in Section 3.3.1;
2. Submit to the responsible physician the results of the initial characterization analyses for each analyte for which determinations are to be made;
3. Submit to the responsible physician the results, for the initial 6-month period, of the internal QA/QC program for each analyte for which determinations are to be made (if no commercial analyses have been conducted previously, a minimum of 2 mock standardization trials for each analyte should be completed per month for a 6-month period;
4. Enroll in the CTQ program for the appropriate analyte for which determinations are to be made, and arrange to have the CTQ program submit the initial confirmation of participation and proficiency test results directly to the designated physicians. Note that the designated physician should receive results from 3 completed rounds from the CTQ program before approving a laboratory for participation in the biological monitoring program;
5. Laboratories seeking participation for CDU and/or B(2)MU analyses should submit to the responsible physician documentation of accreditation by the CAP for CRTU analyses performed in conjunction with CDU and/or B(2)MU determinations (if CRTU analyses are conducted by a contract laboratory, this laboratory should submit proof of CAP accreditation to the responsible physician); and,
6. Documentation should be submitted on an appropriate form.

To participate in CDB, CDU and/or B(2)MU analyses, the laboratory should satisfy the above criteria for a minimum of 2 of the 3 proficiency samples provided in each of the 3 rounds of the CTQ program over a 6-month period; this procedure should be completed for each appropriate analyte. Proficiency should be maintained for each analyte to continue participation. Note that laboratories seeking participation for CDU or B(2)MU also should address the performance requirements for CRTU, which involves providing evidence of accreditation by the CAP and participation in the CAP surveys (or an equivalent program).

The performance requirement for CDB analysis is defined as an analytical result within + or - 1 ug/l or 15% of the consensus mean (whichever is greater). For samples exhibiting a consensus

mean less than 1 ug/l, the performance requirement is defined as a concentration between the detection limit of the analysis and a maximum of 2 ug/l. The purpose of redefining the acceptable interval for low CDB values is to encourage proper reporting of the actual values obtained during measurement; laboratories, therefore, will not be penalized (in terms of a narrow range of acceptability) for reporting measured concentrations less than 1 ug/l.

The performance requirement for CDU analysis is defined as an analytical result within + or - 1 ug/l urine or 15% of the consensus mean (whichever is greater). For samples exhibiting a consensus mean less than 1 ug/l urine, the performance requirement is defined as a concentration that falls between the detection limit of the analysis and a maximum of 2 ug/l urine. Performance requirements for the companion CRTU analysis (defined by the CAP) also should be met. Note that reporting CDU results, other than for CTQ proficiency testing should be accompanied with results of CRTU analyses, and these 2 sets of results should be combined to provide a measure of CDU in units of ug/g CRTU.

The performance requirement for B(2)MU is defined as an analytical result within + or - 15% of the consensus mean. Note that reporting B(2)MU results, other than for CTQ proficiency testing should be accompanied with results of CRTU analysis, these 2 sets of results should be combined to provide a measure of B(2)MU in units of ug/g CRTU.

Once a new laboratory has been approved by the responsible physician for conducting analyte determinations, the status of this approval should be reviewed periodically by the responsible physician as per the criteria presented under Section 3.2.2.

Laboratories which have failed previously to gain approval of the responsible physician for conducting determinations of 1 or more analytes due to lack of compliance with the criteria defined above for existing laboratories (Section 3.2.1), may obtain approval by satisfying the criteria for newly-formed laboratories defined under this section; for these laboratories, the second of the above criteria may be satisfied by submitting a new set of characterization analyses for each analyte for which determinations are to be made.

Reevaluation of these laboratories is discretionary on the part of the responsible physician. Reevaluation, which normally takes about 6 months, may be expedited if the laboratory can achieve 100% compliance with the proficiency test criteria using the 6 samples of each analyte submitted to the CTQ program during the first 2 rounds of proficiency testing.

For laboratories seeking reevaluation for CDU or B(2)MU analysis, the guidelines for CRTU analyses also should be satisfied, including accreditation for CRTU analysis by the CAP, and participation in the CAP survey program (or accreditation/participation in an equivalent program).

3.2.4 Future Modifications to the Protocol Guidelines

As participating laboratories gain experience with analyses for CDB, CDU and B(2)MU, it is anticipated that the performance achievable by the majority of laboratories should improve until it approaches that reported by the research groups which developed each method. OSHA,

therefore, may choose to recommend stricter performance guidelines in the future as the overall performance of participating laboratories improves.

3.3 Guidelines for Record Keeping and Reporting

To comply with these guidelines, participating laboratories should satisfy the above-stated performance and proficiency recommendations, as well as the following internal QA/QC, record keeping, and reporting provisions.

If a participating laboratory fails to meet the provisions of these guidelines, it is recommended that the responsible physician disapprove further analyses of biological samples by that laboratory until it demonstrates compliance with these guidelines. On disapproval, biological samples should be sent to a laboratory that can demonstrate compliance with these guidelines, at least until the former laboratory is reevaluated by the responsible physician and found to be in compliance.

The following record keeping and reporting procedures should be practiced by participating laboratories.

3.3.1 Internal Quality Assurance/Quality Control Procedures

Laboratories participating in the cadmium monitoring program should develop and maintain an internal quality assurance/quality control (QA/QC) program that incorporates procedures for establishing and maintaining control for each of the analytic procedures (determinations of CDB, CDU and/or B(2)MU) for which the laboratory is seeking participation. For laboratories analyzing CDU and/or B(2)MU, a QA/QC program for CRTU also should be established.

Written documentation of QA/QC procedures should be described in a formal QA/QC plan; this plan should contain the following information: Sample acceptance and handling procedures (i.e., chain-of-custody); sample preparation procedures; instrument parameters; calibration procedures; and, calculations. Documentation of QA/QC procedures should be sufficient to identify analytical problems, define criteria under which analysis of compliance samples will be suspended, and describe procedures for corrective actions.

3.3.1.1 QA/QC procedures for establishing control of CDB and CDU analyses

The QA/QC program for CDB and CDU should address, at a minimum, procedures involved in calibration, establishment of control limits, internal QC analyses and maintaining control, and corrective-action protocols. Participating laboratory should develop and maintain procedures to assure that analyses of compliance samples are within control limits, and that these procedures are documented thoroughly in a QA/QC plan.

A nonmandatory QA/QC protocol is presented in Attachment 1. This attachment is illustrative of the procedures that should be addressed in a proper QA/QC program.

Calibration. Before any analytic runs are conducted, the analytic instrument should be calibrated. Calibration should be performed at the beginning of each day on which QC and/or compliance

samples are run. Once calibration is established, QC or compliance samples may be run. Regardless of the type of samples run, about every fifth sample should serve as a standard to assure that calibration is being maintained.

Calibration is being maintained if the standard is within + or - 15% of its theoretical value. If a standard is more than + or - 15% of its theoretical value, the run has exceeded control limits due to calibration error; the entire set of samples then should be reanalyzed after recalibrating or the results should be recalculated based on a statistical curve derived from that set of standards.

It is essential that the value of the highest standard analyzed be higher than the highest sample analyzed; it may be necessary, therefore, to run a high standard at the end of the run, which has been selected based on results obtained over the course of the run (i.e., higher than any standard analyzed to that point).

Standards should be kept fresh; as samples age, they should be compared with new standards and replaced if necessary.

Internal Quality Control Analyses. Internal QC samples should be determined interspersed with analyses of compliance samples. At a minimum, these samples should be run at a rate of 5% of the compliance samples or at least one set of QC samples per analysis of compliance samples, whichever is greater. If only 2 samples are run, they should contain different levels of cadmium.

Internal QC samples may be obtained as commercially-available reference materials and/or they may be internally prepared. Internally-prepared samples should be well characterized and traced, or compared to a reference material for which a consensus value is available.

Levels of cadmium contained in QC samples should not be known to the analyst prior to reporting the results of the analysis.

Internal QC results should be plotted or charted in a manner which describes sample recovery and laboratory control limits.

Internal Control Limits. The laboratory protocol for evaluating internal QC analyses per control limits should be clearly defined. Limits may be based on statistical methods (e.g., as 2 unbiased standard deviation from the laboratory mean recovery), or on proficiency testing limits (e.g., + or - 1 ug or 15% of the mean, whichever is greater). Statistical limits that exceed + or - 40% should be reevaluated to determine the source error in the analysis.

When laboratory limits are exceeded, analytic work should terminate until the source of error is determined and corrected; compliance samples affected by the error should be reanalyzed. In addition, the laboratory protocol should address any unusual trends that develop which may be biasing the results. Numerous, consecutive results above or below laboratory mean recoveries, or outside laboratory statistical limits, indicate that problems may have developed.

Corrective Actions. The QA/QC plan should document in detail specific actions taken if control limits are exceeded or unusual trends develop. Corrective actions should be noted on an appropriate form, accompanied by supporting documentation.

In addition to these actions, laboratories should include whatever additional actions are necessary to assure that accurate data are reported to the responsible physicians.

Reference Materials. The following reference materials may be available:

Cadmium in Blood (CDB)

1. Centre de Toxicologie du Quebec, Le Centre Hospitalier de l'Universite Laval, 2705 boul. Laurier, Quebec, Que., Canada G1V 4G2. (Prepared 6 times per year at 1-15 ug Cd/l.)
2. H. Marchandise, Community Bureau of Reference-BCR, Directorate General XII, Commission of the European Communities, 200, rue de la Loi, B-1049, Brussels, Belgium. (Prepared as BI CBM-1 at 5.37 ug Cd/l, and BI CBM-2 at 12.38 ug Cd/l.)
3. Kaulson Laboratories Inc., 691 Bloomfield Ave., Caldwell, NJ 07006; tel: (201) 226-9494, FAX (201) 226-3244. (Prepared as #0141 [As, Cd, Hg, Pb] at 2 levels.)

Cadmium in Urine (CDU)

1. Centre de Toxicologie du Quebec, Le Centre Hospitalier de l'Universite Laval, 2705 boul. Laurier, Quebec, Que., Canada G1V 4G2. (Prepared 6 times per year.)
2. National Institute of Standards and Technology (NIST), Dept. of Commerce, Gaithersburg, MD; tel: (301) 975-6776. (Prepared as SRM 2670 freeze-dried urine [metals]; set includes normal and elevated levels of metals; cadmium is certified for elevated level of 88.0 ug/l in reconstituted urine.)
3. Kaulson Laboratories Inc., 691 Bloomfield Ave., Caldwell, NJ 07006; tel: (201) 226-9494, FAX (201) 226-3244. (Prepared as #0140 [As, Cd, Hg, Pb] at 2 levels.)

3.3.1.2 QA/QC procedures for establishing control of B(2)MU

A written, detailed QA/QC plan for B(2)MU analysis should be developed.

The QA/QC plan should contain a protocol similar to those protocols developed for the CDB/CDU analyses. Differences in analyses may warrant some differences in the QA/QC protocol, but procedures to ensure analytical integrity should be developed and followed.

Examples of performance summaries that can be provided include measurements of accuracy (i.e., the means of measured values versus target values for the control samples) and precision (i.e., based on duplicate analyses). It is recommended that the accuracy and precision measurements be compared to those reported as achievable by the Pharmacia Delphia kit (Pharmacia 1990) to determine if and when unsatisfactory analyses have arisen. If the

measurement error of 1 or more of the control samples is more than 15%, the run exceeds control limits. Similarly, this decision is warranted when the average CV for duplicate samples is greater than 5%.

3.3.2 Procedures for Record Keeping

To satisfy reporting requirements for commercial analyses of CDB, CDU and/or B(2)MU performed for the medical monitoring program mandated under the cadmium rule, participating laboratories should maintain the following documentation for each analyte:

1. For each analytic instrument on which analyte determinations are made, records relating to the most recent calibration and QC sample analyses;
2. For these instruments, a tabulated record for each analyte of those determinations found to be within and outside of control limits over the past 2 years;
3. Results for the previous 2 years of the QC sample analyses conducted under the internal QA/QC program (this information should be: Provided for each analyte for which determinations are made and for each analytic instrument used for this purpose, sufficient to demonstrate that internal QA/QC programs are being executed properly, and consistent with data sent to responsible physicians).
4. Duplicate copies of monitoring results for each analyte sent to clients during the previous 5 years, as well as associated information; supporting material such as chain-of-custody forms also should be retained; and,
5. Proficiency test results and related materials received while participating in the CTQ interlaboratory program over the past 2 years; results also should be tabulated to provide a serial record of relative error (derived per Section 3.3.3 below).

3.3.3 Reporting Procedures

Participating laboratories should maintain these documents: QA/QC program plans; QA/QC status reports; CTQ proficiency program reports; and, analytical data reports. The information that should be included in these reports is summarized in Table 2; a copy of each report should be sent to the responsible physician.

TABLE 2 - REPORTING PROCEDURES FOR LABORATORIES PARTICIPATING IN THE CADMIUM MEDICAL MONITORING PROGRAM

| Report | Frequency Time Frame) | Contents |
|----------------------|--------------------------|---|
| 1 QA/QC Program Plan | Once (initially) | A detailed description of the QA/QC protocol to be established by the laboratory to maintain control of analyte determinations. |
| 2 QA/QC | Every 2 months | Results of the QC samples |

| | | |
|--------------------------|---------------------------------|--|
| Status Report | | incorporated into regular runs for each instrument (over the period since the last report). |
| 3 Proficiency Report | Attached to every data report | Results from the last full year of proficiency samples submitted to the CTQ program. Results of the 100 most recent QC samples incorporated into regular runs for each instrument. |
| 4 Analytical Data Report | For all reports of data results | Date the sample was received. Date the sample was analyzed. Appropriate chain-of-custody information. Types of analyses performed. Results of the requested analyses. Copy of the most current proficiency report. |

As noted in Section 3.3.1, a QA/QC program plan should be developed that documents internal QA/QC procedures (defined under Section 3.3.1) to be implemented by the participating laboratory for each analyte; this plan should provide a list identifying each instrument used in making analyte determinations.

A QA/QC status report should be written bimonthly for each analyte. In this report, the results of the QC program during the reporting period should be reported for each analyte in the following manner: The number (N) of QC samples analyzed during the period; a table of the target levels defined for each sample and the corresponding measured values; the mean of F/T value (as defined below) for the set of QC samples run during the period; and, use of the mean + or - 2 unbiased standard deviation (as defined below) for the set of QC samples run during the period as a measure of precision.

As noted in Section 2, an F/T value for a QC sample is the ratio of the measured concentration of analyte to the established (i.e., reference) concentration of analyte for that QC sample. The equation below describes the derivation of the mean for F/T values, the mean, (with N being the total number of samples analyzed):

$$\bar{X} = \frac{\sum (F/T)}{N}$$

The standard deviation, unbiased standard deviation, for these measurements is derived using the following equation (note that 2 unbiased standard deviation is twice this value):

$$\hat{\sigma} = \left[\frac{\sum (F/T - \bar{X})^2}{N-1} \right]^{\frac{1}{2}}$$

The nonmandatory QA/QC protocol (see Attachment 1) indicates that QC samples should be divided into several discrete pools, and a separate estimate of precision for each pool then should be derived. Several precision estimates should be provided for concentrations which differ in average value. These precision measures may be used to document improvements in performance with regard to the combined pool.

Participating laboratories should use the CTQ proficiency program for each analyte. Results of the this program will be sent by CTQ directly to physicians designated by the participating laboratories. Proficiency results from the CTQ program are used to establish the accuracy of results from each participating laboratory, and should be provided to responsible physicians for use in trend analysis. A proficiency report consisting of these proficiency results should accompany data reports as an attachment.

For each analyte, the proficiency report should include the results from the 6 previous proficiency rounds in the following format:

1. Number (N) of samples analyzed;
2. Mean of the target levels, $(1/N) \sum T(i)$, with T(i) being a consensus mean for the sample;
3. Mean of the measurements, $(1/N) \sum M(i)$, with M(i) being a sample measurement;
4. A measure of error defined by:

$$(1/N) \sum (T(i) - M(i))^2$$

Analytical data reports should be submitted to responsible physicians directly. For each sample, report the following information: The date the sample was received; the date the sample was analyzed; appropriate chain-of-custody information; the type(s) of analyses performed; and, the results of the analyses. This information should be reported on a form similar to the form provided or an appropriate form. The most recent proficiency program report should accompany the analytical data reports (as an attachment).

Confidence intervals for the analytical results should be reported as $X \pm 2$ unbiased standard deviation, with X being the measured value and 2 unbiased standard deviation the standard deviation calculated as described above.

For CDU or B(2)MU results, which are combined with CRTU measurements for proper reporting, the 95% confidence limits are derived from the limits for CDU or B(2)MU, (p), and the limits for CRTU, (q), as follows:

$$\frac{X}{Y} \pm \text{or} - \left(\frac{1}{Y} \right)^{1/2} (\sqrt{p^2 + X^2} + \sqrt{q^2 + Y^2})$$

For these calculations, $X \pm p$ is the measurement and confidence limits for CDU or B(2)MU, and $Y \pm q$ is the measurement and confidence limit for CRTU.

Participating laboratories should notify responsible physicians as soon as they receive information indicating a change in their accreditation status with the CTQ or the CAP. These physicians should not be expected to wait until formal notice of a status change has been received from the CTQ or the CAP.

3.4 Instructions to Physicians

Physicians responsible for the medical monitoring of cadmium-exposed workers must collect the biological samples from workers; they then should select laboratories to perform the required analyses, and should interpret the analytic results.

3.4.1 Sample Collection and Holding Procedures

Blood Samples. The following procedures are recommended for the collection, shipment and storage of blood samples for CDB analysis to reduce analytical variability; these recommendations were obtained primarily through personal communications with J.P. Weber of the CTQ (1991), and from reports by the Centers for Disease Control (CDC, 1986) and Stoeppler and Brandt (1980).

To the extent possible, blood samples should be collected from workers at the same time of day. Workers should shower or thoroughly wash their hands and arms before blood samples are drawn. The following materials are needed for blood sample collection: Alcohol wipes; sterile gauze sponges; band-aids; 20 gauge, 1.5 - in. stainless steel needles (sterile); preprinted labels; tourniquets; vacutainer holders; 3 - ml "metal free" vacutainer tubes (i.e., dark-blue caps), with EDTA as an anti-coagulant; and, styrofoam vacutainer shipping containers.

Whole blood samples are taken by venipuncture. Each blue-capped tube should be labeled or coded for the worker and company before the sample is drawn. (Blue-capped tubes are recommended instead of red-capped tubes because the latter may consist of red coloring pigment containing cadmium, which could contaminate the samples.) Immediately after sampling, the vacutainer tubes must be thoroughly mixed by inverting the tubes at least 10 times manually or mechanically using a Vortex device (for 15 sec). Samples should be refrigerated immediately or stored on ice until they can be packed for shipment to the participating laboratory for analysis.

The CDC recommends that blood samples be shipped with a "cool pak" to keep the samples cold during shipment. However, the CTQ routinely ships and receives blood samples for cadmium analysis that have not been kept cool during shipment. The CTQ has found no deterioration of cadmium in biological fluids that were shipped via parcel post without a cooling agent, even though these deliveries often take 2 weeks to reach their destination.

Urine Samples. The following are recommended procedures for the collection, shipment and storage of urine for CDU and B(2)MU analyses, and were obtained primarily through personal communications with J.P. Weber of the CTQ (1991), and from reports by the CDC (1986) and Stoeppler and Brandt (1980).

Single "spot" samples are recommended. As B2M can degrade in the bladder, workers should first empty their bladder and then drink a large glass of water at the start of the visit. Urine samples then should be collected within 1 hour. Separate samples should be collected for CDU and B(2)MU using the following materials: Sterile urine collection cups (250 ml); small sealable plastic bags; preprinted labels; 15-ml polypropylene or polyethylene screw-cap tubes; lab gloves ("metal free"); and, preservatives (as indicated).

The sealed collection cup should be kept in the plastic bag until collection time. The workers should wash their hands with soap and water before receiving the collection cup. The collection cup should not be opened until just before voiding and the cup should be sealed immediately after filling. It is important that the inside of the container and cap are not touched by, or come into contact with, the body, clothing or other surfaces.

For CDU analyzes, the cup is swirled gently to resuspend any solids, and the 15-ml tube is filled with 10-12 ml urine. The CDC recommends the addition of 100 ul concentrated HNO₃ as a preservative before sealing the tube and then freezing the sample. The CTQ recommends minimal handling and does not acidify their interlaboratory urine reference materials prior to shipment, nor do they freeze the sample for shipment. At the CTQ, if the urine sample has much sediment, the sample is acidified in the lab to free any cadmium in the precipitate.

For B2M, the urine sample should be collected directly into a polyethylene bottle previously washed with dilute nitric acid. The pH of the urine should be measured and adjusted to 8.0 with 0.1 N NaOH immediately following collection. Samples should be frozen and stored at -20 deg. C until testing is performed. The B2M in the samples should be stable for 2 days when stored at 2-8 deg. C, and for at least 2 months at -20 deg. C. Repeated freezing and thawing should be avoided to prevent denaturing the B2M (Pharmacia 1990).

3.4.2 Recommendations for Evaluating Laboratories

Using standard error data and the results of proficiency testing obtained from CTQ, responsible physicians can make an informed choice of which laboratory to select to analyze biological samples. In general, laboratories with small standard errors and little disparity between target and measured values tend to make precise and accurate sample determinations. Estimates of precision provided to the physicians with each set of monitoring results can be compared to previously-reported proficiency and precision estimates. The latest precision estimates should be at least as small as the standard error reported previously by the laboratory. Moreover, there should be no indication that precision is deteriorating (i.e., increasing values for the precision estimates). If precision is deteriorating, physicians may decide to use another laboratory for these analyses. QA/QC information provided by the participating laboratories to physicians can, therefore, assist physicians in evaluating laboratory performance.

3.4.3 Use and Interpretation of Results

When the responsible physician has received the CDB, CDU and/or B(2)MU results, these results must be compared to the action levels discussed in the final rule for cadmium. The

comparison of the sample results to action levels is straightforward. The measured value reported from the laboratory can be compared directly to the action levels; if the reported value exceeds an action level, the required actions must be initiated.

4.0 BACKGROUND

Cadmium is a naturally-occurring environmental contaminant to which humans are continually exposed in food, water, and air. The average daily intake of cadmium by the U.S. population is estimated to be 10-20 ug/day. Most of this intake is via ingestion, for which absorption is estimated at 4-7% (Kowal et al. 1979). An additional nonoccupational source of cadmium is smoking tobacco; smoking a pack of cigarettes a day adds an additional 2-4 ug cadmium to the daily intake, assuming absorption via inhalation of 25-35% (Nordberg and Nordberg 1988; Friberg and Elinder 1988; Travis and Haddock 1980).

Exposure to cadmium fumes and dusts in an occupational setting where air concentrations are 20-50 ug/m³ results in an additional daily intake of several hundred micrograms (Friberg and Elinder 1988, p. 563). In such a setting, occupational exposure to cadmium occurs primarily via inhalation, although additional exposure may occur through the ingestion of material via contaminated hands if workers eat or smoke without first washing. Some of the particles that are inhaled initially may be ingested when the material is deposited in the upper respiratory tract, where it may be cleared by mucociliary transport and subsequently swallowed.

Cadmium introduced into the body through inhalation or ingestion is transported by the albumin fraction of the blood plasma to the liver, where it accumulates and is stored principally as a bound form complexed with the protein metallothionein. Metallothionein-bound cadmium is the main form of cadmium subsequently transported to the kidney; it is these 2 organs, the liver and kidney, in which the majority of the cadmium body burden accumulates. As much as one half of the total body burden of cadmium may be found in the kidneys (Nordberg and Nordberg 1988).

Once cadmium has entered the body, elimination is slow; about 0.02% of the body burden is excreted per day via urinary/fecal elimination. The whole-body half-life of cadmium is 10-35 years, decreasing slightly with increasing age (Travis and Haddock 1980).

The continual accumulation of cadmium is the basis for its chronic noncarcinogenic toxicity. This accumulation makes the kidney the target organ in which cadmium toxicity usually is first observed (Piscator 1964). Renal damage may occur when cadmium levels in the kidney cortex approach 200 ug/g wet tissue-weight (Travis and Haddock 1980).

The kinetics and internal distribution of cadmium in the body are complex, and depend on whether occupational exposure to cadmium is ongoing or has terminated. In general, cadmium in blood is related principally to recent cadmium exposure, while cadmium in urine reflects cumulative exposure (i.e., total body burden)(Lauwerys et al. 1976; Friberg and Elinder 1988).

4.1 Health Effects

Studies of workers in a variety of industries indicate that chronic exposure to cadmium may be linked to several adverse health effects including kidney dysfunction, reduced pulmonary function, chronic lung disease and cancer (Federal Register 1990). The primary sites for cadmium-associated cancer appear to be the lung and the prostate.

Cancer. Evidence for an association between cancer and cadmium exposure comes from both epidemiological studies and animal experiments. Pott (1965) found a statistically significant elevation in the incidence of prostate cancer among a cohort of cadmium workers. Other epidemiology studies also report an elevated incidence of prostate cancer; however, the increases observed in these other studies were not statistically significant (Meridian Research, Inc. 1989).

One study (Thun et al. 1985) contains sufficiently quantitative estimates of cadmium exposure to allow evaluation of dose-response relationships between cadmium exposure and lung cancer. A statistically significant excess of lung cancer attributed to cadmium exposure was found in this study, even after accounting for confounding variables such as coexposure to arsenic and smoking habits (Meridian Research, Inc. 1989).

Evidence for quantifying a link between lung cancer and cadmium exposure comes from a single study (Takenaka et al. 1983). In this study, dose-response relationships developed from animal data were extrapolated to humans using a variety of models. OSHA chose the multistage risk model for estimating the risk of cancer for humans using these animal data. Animal injection studies also suggest an association between cadmium exposure and cancer, particularly observations of an increased incidence of tumors at sites remote from the point of injection. The International Agency for Research on Cancer (IARC) (Supplement 7, 1987) indicates that this, and related, evidence is sufficient to classify cadmium as an animal carcinogen. However, the results of these injection studies cannot be used to quantify risks attendant to human occupational exposures due to differences in routes of exposure (Meridian Research, Inc. 1989).

Based on the above-cited studies, the U.S. Environmental Protection Agency (EPA) classifies cadmium as "B1," a probable human carcinogen (USEPA 1985). IARC in 1987 recommended that cadmium be listed as a probable human carcinogen.

Kidney Dysfunction. The most prevalent nonmalignant effect observed among workers chronically exposed to cadmium is kidney dysfunction. Initially, such dysfunction is manifested by proteinuria (Meridian Research, Inc. 1989; Roth Associates, Inc. 1989). Proteinuria associated with cadmium exposure is most commonly characterized by excretion of low-molecular weight proteins (15,000-40,000 MW), accompanied by loss of electrolytes, uric acid, calcium, amino acids, and phosphate. Proteins commonly excreted include B-2-microglobulin (B2M), retinol binding protein (RBP), immunoglobulin light chains, and lysozyme. Excretion of low molecular weight proteins is characteristic of damage to the proximal tubules of the kidney (Iwao et al. 1980).

Exposure to cadmium also may lead to urinary excretion of high- molecular weight proteins such as albumin, immunoglobulin G, and glycoproteins (Meridian Research, Inc. 1989; Roth Associates, Inc. 1989). Excretion of high-molecular weight proteins is indicative of damage to

the glomeruli of the kidney. Bernard et al. (1979) suggest that cadmium-associated damage to the glomeruli and damage to the proximal tubules of the kidney develop independently of each other, but may occur in the same individual.

Several studies indicate that the onset of low-molecular weight proteinuria is a sign of irreversible kidney damage (Friberg et al. 1974; Roels et al. 1982; Piscator 1984; Elinder et al. 1985; Smith et al. 1986). For many workers, once sufficiently elevated levels of B2M are observed in association with cadmium exposure, such levels do not appear to return to normal even when cadmium exposure is eliminated by removal of the worker from the cadmium-contaminated work environment (Friberg, exhibit 29, 1990).

Some studies indicate that cadmium-induced proteinuria may be progressive; levels of B(2)MU increase even after cadmium exposure has ceased (Elinder et al. 1985). Other researchers have reached similar conclusions (Frieburg testimony, OSHA docket exhibit 29, Elinder testimony, OSHA docket exhibit 55, and OSHA docket exhibits 8-86B). Such observations are not universal, however (Smith et al. 1986; Tsuchiya 1976). Studies in which proteinuria has not been observed, however, may have initiated the reassessment too early (Meridian Research, Inc. 1989; Roth Associates, Inc. 1989; Roels 1989).

A quantitative assessment of the risks of developing kidney dysfunction as a result of cadmium exposure was performed using the data from Ellis et al. (1984) and Falck et al. (1983). Meridian Research, Inc. (1989) and Roth Associates, Inc. (1989) employed several mathematical models to evaluate the data from the 2 studies, and the results indicate that cumulative cadmium exposure levels between 5 and 100 ug-years/m(3) correspond with a one-in-a-thousand probability of developing kidney dysfunction.

When cadmium exposure continues past the onset of early kidney damage (manifested as proteinuria), chronic nephrotoxicity may occur (Meridian Research, Inc. 1989; Roth Associates, Inc. 1989). Uremia, which is the loss of the glomerulus' ability to adequately filter blood, may result. This condition leads to severe disturbance of electrolyte concentrations, which may result in various clinical complications including atherosclerosis, hypertension, pericarditis, anemia, hemorrhagic tendencies, deficient cellular immunity, bone changes, and other problems. Progression of the disease may require dialysis or a kidney transplant.

Studies in which animals are chronically exposed to cadmium confirm the renal effects observed in humans (Friberg et al. 1986). Animal studies also confirm cadmium-related problems with calcium metabolism and associated skeletal effects, which also have been observed among humans. Other effects commonly reported in chronic animal studies include anemia, changes in liver morphology, immunosuppression and hypertension. Some of these effects may be associated with cofactors; hypertension, for example, appears to be associated with diet, as well as with cadmium exposure. Animals injected with cadmium also have shown testicular necrosis.

4.2 Objectives for Medical Monitoring

In keeping with the observation that renal disease tends to be the earliest clinical manifestation of cadmium toxicity, the final cadmium standard mandates that eligible workers must be medically monitored to prevent this condition (as well as cadmium-induced cancer). The objectives of medical-monitoring, therefore, are to: Identify workers at significant risk of adverse health effects from excess, chronic exposure to cadmium; prevent future cases of cadmium-induced disease; detect and minimize existing cadmium-induced disease; and, identify workers most in need of medical intervention.

The overall goal of the medical monitoring program is to protect workers who may be exposed continuously to cadmium over a 45-year occupational lifespan. Consistent with this goal, the medical monitoring program should assure that:

1. Current exposure levels remain sufficiently low to prevent the accumulation of cadmium body burdens sufficient to cause disease in the future by monitoring CDB as an indicator of recent cadmium exposure;
2. Cumulative body burdens, especially among workers with undefined historical exposures, remain below levels potentially capable of leading to damage and disease by assessing CDU as an indicator of cumulative exposure to cadmium; and,
3. Health effects are not occurring among exposed workers by determining B(2)MU as an early indicator of the onset of cadmium-induced kidney disease.

4.3 Indicators of Cadmium Exposure and Disease

Cadmium is present in whole blood bound to albumin, in erythrocytes, and as a metallothionein-cadmium complex. The metallothionein-cadmium complex that represents the primary transport mechanism for cadmium delivery to the kidney. CDB concentrations in the general, nonexposed population average 1 ug Cd/l whole blood, with smokers exhibiting higher levels (see Section 5.1.6). Data presented in Section 5.1.6 shows that 95% of the general population not occupationally exposed to cadmium have CDB levels less than 5 ug Cd/l.

If total body burdens of cadmium remain low, CDB concentrations indicate recent exposure (i.e., daily intake). This conclusion is based on data showing that cigarette smokers exhibit CDB concentrations of 2-7 ug/l depending on the number of cigarettes smoked per day (Nordberg and Nordberg 1988), while CDB levels for those who quit smoking return to general population values (approximately 1 ug/l) within several weeks (Lauwerys et al. 1976). Based on these observations, Lauwerys et al. (1976) concluded that CDB has a biological half-life of a few weeks to less than 3 months. As indicated in Section 3.1.6, the upper 95th percentile for CDB levels observed among those who are not occupationally exposed to cadmium is 5 ug/l, which suggests that the absolute upper limit to the range reported for smokers by Nordberg and Nordberg may have been affected by an extreme value (i.e., beyond 2 σ above the mean).

Among occupationally-exposed workers, the occupational history of exposure to cadmium must be evaluated to interpret CDB levels. New workers, or workers with low exposures to cadmium, exhibit CDB levels that are representative of recent exposures, similar to the general population.

However, for workers with a history of chronic exposure to cadmium, who have accumulated significant stores of cadmium in the kidneys/liver, part of the CDB concentrations appear to indicate body burden. If such workers are removed from cadmium exposure, their CDB levels remain elevated, possibly for years, reflecting prior long-term accumulation of cadmium in body tissues. This condition tends to occur, however, only beyond some threshold exposure value, and possibly indicates the capacity of body tissues to accumulate cadmium which cannot be excreted readily (Friberg and Elinder 1988; Nordberg and Nordberg 1988).

CDU is widely used as an indicator of cadmium body burdens (Nordberg and Nordberg 1988). CDU is the major route of elimination and, when CDU is measured, it is commonly expressed either as ug Cd/l urine (unadjusted), ug Cd/l urine (adjusted for specific gravity), or ug Cd/g CRTU (see Section 5.2.1). The metabolic model for CDU is less complicated than CDB, since CDU is dependent in large part on the body (i.e., kidney) burden of cadmium. However, a small proportion of CDU still be attributed to recent cadmium exposure, particularly if exposure to high airborne concentrations of cadmium occurred. Note that CDU is subject to larger interindividual and day-to-day variations than CDB, so repeated measurements are recommended for CDU evaluations.

CDU is bound principally to metallothionein, regardless of whether the cadmium originates from metallothionein in plasma or from the cadmium pool accumulated in the renal tubules. Therefore, measurement of metallothionein in urine may provide information similar to CDU, while avoiding the contamination problems that may occur during collection and handling urine for cadmium analysis (Nordberg and Nordberg 1988). However, a commercial method for the determination of metallothionein at the sensitivity levels required under the final cadmium rule is not currently available; therefore, analysis of CDU is recommended.

Among the general population not occupationally exposed to cadmium, CDU levels average less than 1 ug/l (see Section 5.2.7). Normalized for creatinine (CRTU), the average CDU concentration of the general population is less than 1 ug/g CRTU. As cadmium accumulates over the lifespan, CDU increases with age. Also, cigarette smokers may eventually accumulate twice the cadmium body burden of nonsmokers, CDU is slightly higher in smokers than in nonsmokers, even several years after smoking cessation (Nordberg and Nordberg 1988). Despite variations due to age and smoking habits, 95% of those not occupationally exposed to cadmium exhibit levels of CDU less than 3 ug/g CRTU (based on the data presented in Section 5.2.7).

About 0.02% of the cadmium body burden is excreted daily in urine. When the critical cadmium concentration (about 200 ppm) in the kidney is reached, or if there is sufficient cadmium-induced kidney dysfunction, dramatic increases in CDU are observed (Nordberg and Nordberg 1988). Above 200 ppm, therefore, CDU concentrations cease to be an indicator of cadmium body burden, and are instead an index of kidney failure.

Proteinuria is an index of kidney dysfunction, and is defined by OSHA to be a material impairment. Several small proteins may be monitored as markers for proteinuria. Below levels indicative of proteinuria, these small proteins may be early indicators of increased risk of

cadmium-induced renal tubular disease. Analytes useful for monitoring cadmium-induced renal tubular damage include:

1. B-2-Microglobulin (B2M), currently the most widely used assay for detecting kidney dysfunction, is the best characterized analyte available (Iwao et al. 1980; Chia et al. 1989);
2. Retinol Binding Protein (RBP) is more stable than B2M in acidic urine (i.e., B2M breakdown occurs if urinary pH is less than 5.5; such breakdown may result in false [i.e., low] B2M values [Bernard and Lauwerys, 1990]);
3. N-Acetyl-B-Glucosaminidase (NAG) is the analyte of an assay that is simple, inexpensive, reliable, and correlates with cadmium levels under 10 ug/g CRTU, but the assay is less sensitive than RBP or B2M (Kawada et al. 1989);
4. Metallothionein (MT) correlates with cadmium and B2M levels, and may be a better predictor of cadmium exposure than CDU and B2M (Kawada et al. 1989);
5. Tamm-Horsfall Glycoprotein (THG) increases slightly with elevated cadmium levels, but this elevation is small compared to increases in urinary albumin, RBP, or B2M (Bernard and Lauwerys 1990);
6. Albumin (ALB), determined by the biuret method, is not sufficiently sensitive to serve as an early indicator of the onset of renal disease (Piscator 1962);
7. Albumin (ALB), determined by the Amido Black method, is sensitive and reproducible, but involves a time-consuming procedure (Piscator 1962);
8. Glycosaminoglycan (GAG) increases among cadmium workers, but the significance of this effect is unknown because no relationship has been found between elevated GAG and other indices of tubular damage (Bernard and Lauwerys 1990);
9. Trehalase seems to increase earlier than B2M during cadmium exposure, but the procedure for analysis is complicated and unreliable (Iwata et al. 1988); and,
10. Kallikrein is observed at lower concentrations among cadmium- exposed workers than among normal controls (Roels et al. 1990).

Of the above analytes, B2M appears to be the most widely used and best characterized analyte to evaluate the presence/absence, as well as the extent of, cadmium-induced renal tubular damage (Kawada, Koyama, and Suzuki 1989; Shaikh and Smith 1984; Nogawa 1984). However, it is important that samples be collected and handled so as to minimize B2M degradation under acidic urine conditions.

The threshold value of B(2)MU commonly used to indicate the presence of kidney damage 300 ug/g CRTU (Kjellstrom et al. 1977a; Buchet et al. 1980; and Kowal and Zirkes 1983). This value represents the upper 95th or 97.5th percentile level of urinary excretion observed among those without tubular dysfunction (Elinder, exbt L-140-45, OSHA docket H057A). In agreement with

these conclusions, the data presented in Section 5.3.7 of this protocol generally indicate that the level of 300 ug/g CRTU appears to define the boundary for kidney dysfunction. It is not clear, however, that this level represents the upper 95th percentile of values observed among those who fail to demonstrate proteinuria effects.

Although elevated B(2)MU levels appear to be a fairly specific indicator of disease associated with cadmium exposure, other conditions that may lead to elevated B(2)MU levels include high fevers from influenza, extensive physical exercise, renal disease unrelated to cadmium exposure, lymphomas, and AIDS (Iwao et al. 1980; Schardun and van Epps 1987). Elevated B2M levels observed in association with high fevers from influenza or from extensive physical exercise are transient, and will return to normal levels once the fever has abated or metabolic rates return to baseline values following exercise. The other conditions linked to elevated B2M levels can be diagnosed as part of a properly-designed medical examination. Consequently, monitoring B2M, when accompanied by regular medical examinations and CDB and CDU determinations (as indicators of present and past cadmium exposure), may serve as a specific, early indicator of cadmium-induced kidney damage.

4.4 Criteria for Medical Monitoring of Cadmium Workers

Medical monitoring mandated by the final cadmium rule includes a combination of regular medical examinations and periodic monitoring of 3 analytes: CDB, CDU and B(2)MU. As indicated above, CDB is monitored as an indicator of current cadmium exposure, while CDU serves as an indicator of the cadmium body burden; B(2)MU is assessed as an early marker of irreversible kidney damage and disease.

The final cadmium rule defines a series of action levels that have been developed for each of the 3 analytes to be monitored. These action levels serve to guide the responsible physician through a decision-making process. For each action level that is exceeded, a specific response is mandated. The sequence of action levels, and the attendant actions, are described in detail in the final cadmium rule.

Other criteria used in the medical decision-making process relate to tests performed during the medical examination (including a determination of the ability of a worker to wear a respirator). These criteria, however, are not affected by the results of the analyte determinations addressed in the above paragraphs and, consequently, will not be considered further in these guidelines.

4.5 Defining to Quality and Proficiency of the Analyte Determinations

As noted above in Sections 2 and 3, the quality of a measurement should be defined along with its value to properly interpret the results. Generally, it is necessary to know the accuracy and the precision of a measurement before it can be properly evaluated. The precision of the data from a specific laboratory indicates the extent to which the repeated measurements of the same sample vary within that laboratory. The accuracy of the data provides an indication of the extent to which these results deviate from average results determined from many laboratories performing the same measurement (i.e., in the absence of an independent determination of the true value of a

measurement). Note that terms are defined operationally relative to the manner in which they will be used in this protocol. Formal definitions for the terms in italics used in this section can be found in the list of definitions (Section 2).

Another data quality criterion required to properly evaluate measurement results is the limit of detection of that measurement. For measurements to be useful, the range of the measurement which is of interest for biological monitoring purposes must lie entirely above the limit of detection defined for that measurement.

The overall quality of a laboratory's results is termed the performance of that laboratory. The degree to which a laboratory satisfies a minimum performance level is referred to as the proficiency of the laboratory. A successful medical monitoring program, therefore, should include procedures developed for monitoring and recording laboratory performance; these procedures can be used to identify the most proficient laboratories.

5.0 Overview of Medical Monitoring Tests for CDB, CDU, B(2)MU and CRTU

To evaluate whether available methods for assessing CDB, CDU, B(2)MU and CRTU are adequate for determining the parameters defined by the proposed action levels, it is necessary to review procedures available for sample collection, preparation and analysis. A variety of techniques for these purposes have been used historically for the determination of cadmium in biological matrices (including CDB and CDU), and for the determination of specific proteins in biological matrices (including B(2)MU). However, only the most recent techniques are capable of satisfying the required accuracy, precision and sensitivity (i.e., limit of detection) for monitoring at the levels mandated in the final cadmium rule, while still facilitating automated analysis and rapid processing.

5.1 Measuring Cadmium in Blood (CDB)

Analysis of biological samples for cadmium requires strict analytical discipline regarding collection and handling of samples. In addition to occupational settings, where cadmium contamination would be apparent, cadmium is a ubiquitous environmental contaminant, and much care should be exercised to ensure that samples are not contaminated during collection, preparation or analysis. Many common chemical reagents are contaminated with cadmium at concentrations that will interfere with cadmium analysis; because of the widespread use of cadmium compounds as colored pigments in plastics and coatings, the analyst should continually monitor each manufacturer's chemical reagents and collection containers to prevent contamination of samples.

Guarding against cadmium contamination of biological samples is particularly important when analyzing blood samples because cadmium concentrations in blood samples from nonexposed populations are generally less than 2 ug/l (2 ng/ml), while occupationally-exposed workers can be at medical risk to cadmium toxicity if blood concentrations exceed 5 ug/l (ACGIH 1991 and 1992). This narrow margin between exposed and unexposed samples requires that exceptional

care be used in performing analytic determinations for biological monitoring for occupational cadmium exposure.

Methods for quantifying cadmium in blood have improved over the last 40 years primarily because of improvements in analytical instrumentation. Also, due to improvements in analytical techniques, there is less need to perform extensive multi-step sample preparations prior to analysis. Complex sample preparation was previously required to enhance method sensitivity (for cadmium), and to reduce interference by other metals or components of the sample.

5.1.1 Analytical Techniques Used to Monitor Cadmium in Biological Matrices

TABLE 3 - COMPARISON OF ANALYTICAL PROCEDURES/INSTRUMENTATION FOR DETERMINATION OF CADMIUM IN BIOLOGICAL SAMPLES

| Analytical procedure | Limit of detection [ng/(g or ml)] | Specified biological matrix | Reference | Comments |
|---|-----------------------------------|-----------------------------|-----------------------------------|---|
| Flame Atomic Absorption Spectroscopy (FAAS). | > or = 1.0 | Any Matrix | Perkin-Elmer (1982)... | Not sensitive enough for biomonitoring without extensive sample digestion metal chelation and organic solvent extraction. |
| Graphite Furnace Atomic Absorption Spectroscopy (GFAAS). | 0.04 | Urine ... | Pruszkowska et al (1983) | Methods of choice for routine cadmium analysis. |
| Inductively-Coupled Argon Plasma Atomic Emission Spectroscopy (ICAP AES). | > or = 0.20 | Blood ... | Stoeppler and Brandt (1980)..... | |
| Neutron Activation Gamma Spectroscopy (NA). | 2.0 | Any matrix | NIOSH (1984A).... | Requires extensive sample preparation and concentration of metal with chelating resin. Advantage is simultaneous analyses for as many as 10 metals from 1 sample. |
| Isotope Dilution Mass Spectroscopy (IDMS). | 1.5 | In vivo (liver).. | Ellis et al. (1983)..... | Only available in vivo method for direct determination of cadmium body tissue burdens; expensive; absolute determination of cadmium in reference materials. |
| Differential Pulse Anodic | < 1.0 | Any matrix | Michiels and DeBievre (1986)..... | Suitable for absolute determination of cadmium in reference materials; expensive. |
| | < 1.0 | Any matrix | Stoeppler and Brandt | Suitable for absolute determination of cadmium |

| | | | |
|--------------------------------|--|-------------|--|
| Stripping Voltammetry (DPASV). | | (1980)..... | in reference materials; efficient method to check accuracy of analytical method. |
|--------------------------------|--|-------------|--|

A number of analytical techniques have been used for determining cadmium concentrations in biological materials. A summary of the characteristics of the most widely employed techniques is presented in Table 3. The technique most suitable for medical monitoring for cadmium is atomic absorption spectroscopy (AAS).

To obtain a measurement using AAS, a light source (i.e., hollow cathode or electrode-free discharge lamp) containing the element of interest as the cathode, is energized and the lamp emits a spectrum that is unique for that element. This light source is focused through a sample cell, and a selected wavelength is monitored by a monochromator and photodetector cell. Any ground state atoms in the sample that match those of the lamp element and are in the path of the emitted light may absorb some of the light and decrease the amount of light that reaches the photodetector cell. The amount of light absorbed at each characteristic wavelength is proportional to the number of ground state atoms of the corresponding element that are in the pathway of the light between the source and detector.

To determine the amount of a specific metallic element in a sample using AAS, the sample is dissolved in a solvent and aspirated into a high-temperature flame as an aerosol. At high temperatures, the solvent is rapidly evaporated or decomposed and the solute is initially solidified; the majority of the sample elements then are transformed into an atomic vapor. Next, a light beam is focused above the flame and the amount of metal in the sample can be determined by measuring the degree of absorbance of the atoms of the target element released by the flame at a characteristic wavelength.

A more refined atomic absorption technique, flameless AAS, substitutes an electrothermal, graphite furnace for the flame. An aliquot (10-100 ul) of the sample is pipetted into the cold furnace, which is then heated rapidly to generate an atomic vapor of the element.

AAS is a sensitive and specific method for the elemental analysis of metals; its main drawback is nonspecific background absorption and scattering of the light beam by particles of the sample as it decomposes at high temperatures; nonspecific absorbance reduces the sensitivity of the analytical method. The problem of nonspecific absorbance and scattering can be reduced by extensive sample pretreatment, such as ashing and/or acid digestion of the sample to reduce its organic content.

Current AAS instruments employ background correction devices to adjust electronically for background absorption and scattering. A common method to correct for background effects is to use a deuterium arc lamp as a second light source. A continuum light source, such as the deuterium lamp, emits a broad spectrum of wavelengths instead of specific wavelengths characteristic of a particular element, as with the hollow cathode tube. With this system, light from the primary source and the continuum source are passed alternately through the sample cell.

The target element effectively absorbs light only from the primary source (which is much brighter than the continuum source at the characteristic wavelengths), while the background matrix absorbs and scatters light from both sources equally. Therefore, when the ratio of the two beams is measured electronically, the effect of nonspecific background absorption and scattering is eliminated. A less common, but more sophisticated, background correction system is based on the Zeeman effect, which uses a magnetically-activated light polarizer to compensate electronically for nonspecific absorption and scattering.

Atomic emission spectroscopy with inductively-coupled argon plasma (AES-ICAP) is widely used to analyze for metals. With this instrument, the sample is aspirated into an extremely hot argon plasma flame, which excites the metal atoms; emission spectra specific for the sample element then are generated. The quanta of emitted light passing through a monochromator are amplified by photomultiplier tubes and measured by a photodetector to determine the amount of metal in the sample. An advantage of AES-ICAP over AAS is that multi-elemental analyses of a sample can be performed by simultaneously measuring specific elemental emission energies. However, AES-ICAP lacks the sensitivity of AAS, exhibiting a limit of detection which is higher than the limit of detection for graphite-furnace AAS (Table 3).

Neutron activation (NA) analysis and isotope dilution mass spectrometry (IDMS) are 2 additional, but highly specialized, methods that have been used for cadmium determinations. These methods are expensive because they require elaborate and sophisticated instrumentation.

NA analysis has the distinct advantage over other analytical methods of being able to determine cadmium body burdens in specific organs (e.g., liver, kidney) in vivo (Ellis et al. 1983). Neutron bombardment of the target transforms cadmium-113 to cadmium-114, which promptly decays (< 10(-14) sec) to its ground state, emitting gamma rays that are measured using large gamma detectors; appropriate shielding and instrumentation are required when using this method.

IDMS analysis, a definitive but laborious method, is based on the change in the ratio of 2 isotopes of cadmium (cadmium 111 and 112) that occurs when a known amount of the element (with an artificially altered ratio of the same isotopes [i.e., a cadmium 111 "spike"]) is added to a weighed aliquot of the sample (Michiels and De Bievre 1986).

5.1.2 Methods Developed for CDB Determinations

A variety of methods have been used for preparing and analyzing CDB samples; most of these methods rely on one of the analytical techniques described above. Among the earliest reports, Princi (1947) and Smith et al. (1955) employed a colorimetric procedure to analyze for CDB and CDU. Samples were dried and digested through several cycles with concentrated mineral acids (HNO₃ and H₂SO₄) and hydrogen peroxide (H₂O₂). The digest was neutralized, and the cadmium was complexed with diphenylthiocarbazon and extracted with chloroform. The dithizone-cadmium complex then was quantified using a spectrometer.

Colorimetric procedures for cadmium analyses were replaced by methods based on atomic absorption spectroscopy (AAS) in the early 1960s, but many of the complex sample preparation

procedures were retained. Kjellstrom (1979) reports that in Japanese, American and Swedish laboratories during the early 1970s, blood samples were wet ashed with mineral acids or ashed at high temperature and wetted with nitric acid. The cadmium in the digest was complexed with metal chelators including diethyl dithiocarbamate (DDTC), ammonium pyrrolidine dithiocarbamate (APDC) or diphenylthiocarbazone (dithizone) in ammonia-citrate buffer and extracted with methyl isobutyl ketone (MIBK). The resulting solution then was analyzed by flame AAS or graphite-furnace AAS for cadmium determinations using deuterium-lamp background correction.

In the late 1970s, researchers began developing simpler preparation procedures. Roels et al. (1978) and Roberts and Clark (1986) developed simplified digestion procedures. Using the Roberts and Clark method, a 0.5 ml aliquot of blood is collected and transferred to a digestion tube containing 1 ml concentrated HNO₃. The blood is then digested at 110 deg. C for 4 hours. The sample is reduced in volume by continued heating, and 0.5 ml 30% H₂O₂ is added as the sample dries. The residue is dissolved in 5 ml dilute (1%) HNO₃, and 20 ul of sample is then analyzed by graphite-furnace AAS with deuterium-background correction.

The current trend in the preparation of blood samples is to dilute the sample and add matrix modifiers to reduce background interference, rather than digesting the sample to reduce organic content. The method of Stoeppler and Brandt (1980), and the abbreviated procedure published in the American Public Health Association's (APHA) Methods for Biological Monitoring (1988), are straightforward and are nearly identical. For the APHA method, a small aliquot (50-300 ul) of whole blood that has been stabilized with ethylenediaminetetraacetate (EDTA) is added to 1.0 ml 1M HNO₃, vigorously shaken and centrifuged. Aliquots (10-25 ul) of the supernatant then are then analyzed by graphite-furnace AAS with appropriate background correction.

Using the method of Stoeppler and Brandt (1980), aliquots (50-200 ul) of whole blood that have been stabilized with EDTA are pipetted into clean polystyrene tubes and mixed with 150-600 ul of 1M HNO₃. After vigorous shaking, the solution is centrifuged and a 10-25 ul aliquot of the supernatant then is analyzed by graphite-furnace AAS with appropriate background correction.

Claeys-Thoreau (1982) and DeBenzo et al. (1990) diluted blood samples at a ratio of 1:10 with a matrix modifier (0.2% Triton X-100, a wetting agent) for direct determinations of CDB. DeBenzo et al. also demonstrated that aqueous standards of cadmium, instead of spiked, whole-blood samples, could be used to establish calibration curves if standards and samples are treated with additional small volumes of matrix modifiers (i.e., 1% HNO₃, 0.2% ammonium hydrogenphosphate and 1 mg/ml magnesium salts.)

These direct dilution procedures for CDB analysis are simple and rapid. Laboratories can process more than 100 samples a day using a dedicated graphite-furnace AAS, an auto-sampler, and either a Zeeman- or a deuterium-background correction system. Several authors emphasize using optimum settings for graphite-furnace temperatures during the drying, charring, and atomization processes associated with the flameless AAS method, and the need to run frequent QC samples when performing automated analysis.

5.1.3 Sample Collection and Handling

Sample collection procedures are addressed primarily to identify ways to minimize the degree of variability that may be introduced by sample collection during medical monitoring. It is unclear at this point the extent to which collection procedures contribute to variability among CDB samples. Sources of variation that may result from sampling procedures include time-of-day effects and introduction of external contamination during the collection process. To minimize these sources, strict adherence to a sample collection protocol is recommended. Such a protocol must include provisions for thorough cleaning of the site from which blood will be extracted; also, every effort should be made to collect samples near the same time of day. It is also important to recognize that under the recent OSHA blood-borne pathogens standard (29 CFR 1910.1030), blood samples and certain body fluids must be handled and treated as if they are infectious.

5.1.4 Best Achievable Performance

The best achievable performance using a particular method for CDB determinations is assumed to be equivalent to the performance reported by research laboratories in which the method was developed.

For their method, Roberts and Clark (1986) demonstrated a limit of detection of 0.4 ug Cd/l in whole blood, with a linear response curve from 0.4 to 16.0 ug Cd/l. They report a coefficient of variation (CV) of 6.7% at 8.0 ug/l.

The APHA (1988) reports a range of 1.0-25 ug/l, with a CV of 7.3% (concentration not stated). Insufficient documentation was available to critique this method.

Stoeppler and Brandt (1980) achieved a detection limit of 0.2 ug Cd/l whole blood, with a linear range of 0.4-12.0 ug Cd/l, and a CV of 15-30%, for samples at < 1.0 ug/l. Improved precision (CV of 3.8%) was reported for CDB concentrations at 9.3 ug/l.

5.1.5 General Method Performance

For any particular method, the performance expected from commercial laboratories may be somewhat lower than that reported by the research laboratory in which the method was developed. With participation in appropriate proficiency programs and use of a proper in-house QA/QC program incorporating provisions for regular corrective actions, the performance of commercial laboratories is expected to approach that reported by research laboratories. Also, the results reported for existing proficiency programs serve as a gauge of the likely level of performance that currently can be expected from commercial laboratories offering these analyses.

Weber (1988) reports on the results of the proficiency program run by the Centre de Toxicologie du Quebec (CTQ). As indicated previously, participants in that program receive 18 blood samples per year having cadmium concentrations ranging from 0.2-20 ug/l. Currently, 76 laboratories are participating in this program. The program is established for several analytes in

addition to cadmium, and not all of these laboratories participate in the cadmium proficiency-testing program.

Under the CTQ program, cadmium results from individual laboratories are compared against the consensus mean derived for each sample. Results indicate that after receiving 60 samples (i.e., after participation for approximately three years), 60% of the laboratories in the program are able to report results that fall within + or - ug/l or 15% of the mean, whichever is greater. (For this procedure, the 15% criterion was applied to concentrations exceeding 7 ug/l.) On any single sample of the last 20 samples, the percentage of laboratories falling within the specified range is between 55 and 80%.

The CTQ also evaluates the performance of participating laboratories against a less severe standard: + or - ug/l or 15% of the mean, whichever is greater (Weber 1988); 90% of participating laboratories are able to satisfy this standard after approximately 3 years in the program. (The 15% criterion is used for concentrations in excess of 13 ug/l.) On any single sample of the last 15 samples, the percentage of laboratories falling within the specified range is between 80 and 95% (except for a single test for which only 60% of the laboratories achieved the desired performance).

Based on the data presented in Weber (1988), the CV for analysis of CDB is nearly constant at 20% for cadmium concentrations exceeding 5 ug/l, and increases for cadmium concentrations below 5 ug/l. At 2 ug/l, the reported CV rises to approximately 40%. At 1 ug/l, the reported CV is approximately 60%.

Participating laboratories also tend to overestimate concentrations for samples exhibiting concentrations less than 2 ug/l (see Figure 11 of Weber 1988). This problem is due in part to the proficiency evaluation criterion that allows reporting a minimum + or - 2.0 ug/l for evaluated CDB samples. There is currently little economic or regulatory incentive for laboratories participating in the CTQ program to achieve greater accuracy for CDB samples containing cadmium at concentrations less than 2.0 ug/l, even if the laboratory has the experience and competency to distinguish among lower concentrations in the samples obtained from the CTQ.

The collective experience of international agencies and investigators demonstrate the need for a vigorous QC program to ensure that CDB values reported by participating laboratories are indeed reasonably accurate. As Friberg (1988) stated:

"Information about the quality of published data has often been lacking. This is of concern as assessment of metals in trace concentrations in biological media are fraught with difficulties from the collection, handling, and storage of samples to the chemical analyses. This has been proven over and over again from the results of interlaboratory testing and quality control exercises. Large variations in results were reported even from 'experienced' laboratories."

The UNEP/WHO global study of cadmium biological monitoring set a limit for CDB accuracy using the maximum allowable deviation method at $Y = X + \text{or} - (0.1 X + 1)$ for a targeted concentration of 10 ug Cd/l (Friberg and Vahter 1983). The performance of participating

laboratories over a concentration range of 1.5-12 ug/l was reported by Lind et al. (1987). Of the 3 QC runs conducted during 1982 and 1983, 1 or 2 of the 6 laboratories failed each run. For the years 1983 and 1985, between zero and 2 laboratories failed each of the consecutive QC runs.

In another study (Vahter and Friberg 1988), QC samples consisting of both external (unknown) and internal (stated) concentrations were distributed to laboratories participating in the epidemiology research. In this study, the maximum acceptable deviation between the regression analysis of reported results and reference values was set at $Y = X + \text{or} - (0.05 X + 0.2)$ for a concentration range of 0.3-5.0 ug Cd/l. It is reported that only 2 of 5 laboratories had acceptable data after the first QC set, and only 1 of 5 laboratories had acceptable data after the second QC set. By the fourth QC set, however, all 5 laboratories were judged proficient.

The need for high quality CDB monitoring is apparent when the toxicological and biological characteristics of this metal are considered; an increase in CDB from 2 to 4 ug/l could cause a doubling of the cadmium accumulation in the kidney, a critical target tissue for selective cadmium accumulation (Nordberg and Nordberg 1988).

Historically, the CDC's internal QC program for CDB cadmium monitoring program has found achievable accuracy to be + or - 10% of the true value at CDB concentrations $>$ or = 5.0 ug/l (Paschal 1990). Data on the performance of laboratories participating in this program currently are not available.

5.1.6 Observed CDB Concentrations

As stated in Section 4.3, CDB concentrations are representative of ongoing levels of exposure to cadmium. Among those who have been exposed chronically to cadmium for extended periods, however, CDB may contain a component attributable to the general cadmium body burden.

5.1.6.1 CDB concentrations among unexposed samples

Numerous studies have been conducted examining CDB concentrations in the general population, and in control groups used for comparison with cadmium-exposed workers. A number of reports have been published that present erroneously high values of CDB (Nordberg and Nordberg 1988). This problem was due to contamination of samples during sampling and analysis, and to errors in analysis. Early AAS methods were not sufficiently sensitive to accurately estimate CDB concentrations.

Table 4 presents results of recent studies reporting CDB levels for the general U.S. population not exposed occupationally to cadmium. Other surveys of tissue cadmium using U.S. samples and conducted as part of a cooperative effort among Japan, Sweden and the U.S., did not collect CDB data because standard analytical methodologies were unavailable, and because of analytic problems (Kjellstrom 1979; SWRI 1978).

TABLE 4. -- BLOOD CADMIUM CONCENTRATIONS OF U.S. POPULATION NOT OCCUPATIONALLY EXPOSED TO CADMIUM(a)

| | | | | | | |
|--|--|--|--|--|--|--|
| | | | | | | |
|--|--|--|--|--|--|--|

| Study No. | No. in study (n) | Sex | Age | Smoking habits (b) | Arithmetic mean (+/-S.D.) (c) | Absolute range or (95% CI) (d) |
|-----------|------------------|-----|---------|--------------------|-------------------------------|--------------------------------|
| 1 | 80 | M | 4 to 69 | NS,S | 1.13 | 0.35-3.3 |
| | 88 | F | 4 to 69 | NS, S | 1.03 | 0.21-3.3 |
| | 115 | M/F | 4 to 69 | NS, | 0.95 | 0.21-3.3 |
| | 31 | M/F | 4 to 69 | S | 1.54 | 0.4-3.3 |
| 2 | 10 | M | Adults. | (?) | 2.0+/-2.1 | (0.5-5.0) |
| 3 | 24 | M | Adults. | NS | | |
| | 20 | M | Adults. | S | | |
| | 64 | F | Adults. | NS | | |
| 4 | 39 | F | Adults. | S | | |
| | 32 | M | Adults. | S,NS | | |
| 5 | 35 | M | Adults. | (?) | 2.1+/-2.1 | (0.5-7.3) |

TABLE 4. -- BLOOD CADMIUM CONCENTRATIONS OF U.S. POPULATION NOT OCCUPATIONALLY EXPOSED TO CADMIUM(a)

[Continued]

| Study No. | Geometric mean (+/- GSD) (c) | Lower 95th percentile of distribution (f) | Upper 95th percentile of distribution (f) | Reference |
|-----------|------------------------------|---|---|-----------------------------|
| 1 | 0.98+/-1.71 | 0.4 | 2.4 | Kowal et al. (1979). |
| | 0.91+/-1.63 | 0.4 | 2.0 | |
| | 0.85+/-1.59 | 0.4 | 1.8 | |
| | 1.37+/-1.65 | 0.6 | 3.2 | |
| 2 | | (g)(0) | (g)(5.8) | Ellis et al. (1983) |
| 3 | 0.6+/-1.87 | 0.2 | 1.8 | Frieberg and Vahter (1983). |
| | 1.2+/-2.13 | 0.3 | 4.4 | |
| | 0.5+/-1.85 | 0.2 | 1.4 | |
| | 0.8+/-2.22 | 0.2 | 3.1 | |
| 4 | 1.2+/-2.0 | 0.4 | 3.9 | Thun et al. (1989). |
| 5 | | (g)(0) | (g)(5.6) | Mueller et al. (1989) |

Footnote(a) Concentrations reported in ug Cd/l blood unless otherwise stated.

Footnote(b) NS - never smoked; S - current cigarette smoker.

Footnote(c) S.D. - Arithmetic Standard Deviation.

Footnote(d) C.I. - Confidence interval.

Footnote(e) GSD - Geometric Standard Deviation.

Footnote(f) Based on an assumed lognormal distribution.

Footnote(g) Based on an assumed normal distribution.

Arithmetic and/or geometric means and standard deviations are provided in Table 4 for measurements among the populations defined in each study listed. The range of reported measurements and/or the 95% upper and lower confidence intervals for the means are presented when this information was reported in a study. For studies reporting either an arithmetic or geometric standard deviation along with a mean, the lower and upper 95th percentile for the distribution also were derived and reported in the table.

The data provided in table 4 from Kowal et al. (1979) are from studies conducted between 1974 and 1976 evaluating CDB levels for the general population in Chicago, and are considered to be representative of the U.S. population. These studies indicate that the average CDB concentration among those not occupationally exposed to cadmium is approximately 1 ug/l.

In several other studies presented in Table 4, measurements are reported separately for males and females, and for smokers and nonsmokers. The data in this table indicate that similar CDB levels are observed among males and females in the general population, but that smokers tend to exhibit higher CDB levels than nonsmokers. Based on the Kowal et al. (1979) study, smokers not occupationally exposed to cadmium exhibit an average CDB level of 1.4 ug/l.

In general, nonsmokers tend to exhibit levels ranging to 2 ug/l, while levels observed among smokers range to 5 ug/l. Based on the data presented in Table 4, 95% of those not occupationally exposed to cadmium exhibit CDB levels less than 5 ug/l.

5.1.6.2 CDB concentrations among exposed workers

Table 5 is a summary of results from studies reporting CDB levels among workers exposed to cadmium in the work place. As in Table 4, arithmetic and/or geometric means and standard deviations are provided if reported in the listed studies. The absolute range, or the 95% confidence interval around the mean, of the data in each study are provided when reported. In addition, the lower and upper 95th percentile of the distribution are presented for each study in which a mean and corresponding standard deviation were reported. Table 5 also provides estimates of the duration, and level, of exposure to cadmium in the work place if these data were reported in the listed studies. The data presented in Table 5 suggest that CDB levels are dose related. Sukuri et al. (1983) show that higher CDB levels are observed among workers experiencing higher work place exposure. This trend appears to be true of every the studies listed in the table.

CDB levels reported in table 5 are higher among those showing signs of cadmium-related kidney damage than those showing no such damage. Lauwerys et al. (1976) report CDB levels among

workers with kidney lesions that generally are above the levels reported for workers without kidney lesions. Ellis et al. (1983) report a similar observation comparing workers with and without renal dysfunction, although they found more overlap between the 2 groups than Lauwerys et al.

TABLE 5. - BLOOD CADMIUM IN WORKERS EXPOSED TO CADMIUM IN THE WORKPLACE

| Study number | Work environment (worker population monitored) | Number in study | Employment in years (mean) | Mean concentration of cadmium in air (ug/m(3)) |
|--------------|---|-----------------|----------------------------|--|
| 1 | Ni-Cd battery plant and Cd production plant: (Workers without kidney lesions)..... | 96 | 3-40 | < than = to 90 |
| | | 25 | | |
| 2 | Ni-Cd battery plant: (Smokers) | 7 | (5) | 10.1 |
| | | 8 | (9) | 7.0 |
| 3 | Cadmium alloy plant: (High exposure group)..... | 7 | (10.6) | [1,000-5 yrs; 40-5 yrs] |
| | | 9 | (7.3) | |
| 4 | Retrospective study of workers with renal problems: (Before removal)..... | 19 | 15-41 | |
| | | | (27.2) | |
| | | | (g)(4.2) | |
| 5 | Cadmium production plant: | | | |

| | | | | |
|---------|--|----|----------|-------|
| | (Workers without renal dysfunction). | 33 | 1-34 | |
| | (Workers with renal dysfunction). | 18 | 10-34 | |
| 6 | Cd-Cu alloy plant..... | 75 | Up to 39 | |
| 7 | Cadmium recovery operation - Current (19) and former (26) workers. | 45 | (19.0) | |
| 8 | Cadmium recovery operation | 40 | | |

TABLE 5. - BLOOD CADMIUM IN WORKERS EXPOSED TO CADMIUM IN THE WORKPLACE

[Continued]

| Study number | Work environment (worker population monitored) | Concentrations of Cadmium in Blood(a) | | |
|--------------|--|---------------------------------------|---------------------------------|-------------------------|
| | | Arithmetic mean (+/- S.D.)(b) | Absolute range or (95% C.I.)(c) | Geometric mean (GSD)(d) |
| 1 | Ni-Cd battery plant and Cd production plant: | | | |
| | (Workers without kidney lesions)..... | 21.4 +/- 1.9 | | |
| | (Workers with kidney lesions)..... | 38.8 +/- 3.8 | | |
| 2 | Ni-Cd battery plant: | | | |
| | (Smokers) | 22.7 | 7.3 - 67.2 | |
| | (Nonsmokers)... | 7.0 | 4.9 - 10.5 | |

| | | | | |
|---|--|--------------|------------|-------------|
| 3 | Cadmium alloy plant: | | | |
| | (High exposure group)..... | 20.8 +/- 7.1 | | |
| | (Low exposure group)..... | 7.1 +/- 1.1 | | |
| 4 | Retrospective study of workers with renal problems: | | | |
| | (Before removal)..... | 39.9 +/- 3.7 | 11 - 179 | |
| | (After removal)..... | 14.1 +/- 5.6 | 5.7 - 27.4 | |
| 5 | Cadmium production plant: | | | |
| | (Workers without renal dysfunction). | 15 +/- 5.7 | 7 - 31 | |
| | (Workers with renal dysfunction). | 24 +/- 8.5 | 10 - 34 | |
| 6 | Cd-Cu alloy plant..... | | | 8.8 +/- 1.1 |
| 7 | Cadmium recovery operation - Current (19) and former (26) workers. | | | 7.9 +/- 2.0 |
| 8 | Cadmium recovery operation | 10.2 +/- 5.3 | 2.2 - 18.8 | |

TABLE 5. - BLOOD CADMIUM IN WORKERS EXPOSED TO CADMIUM IN THE WORKPLACE

[Continued]

| Study number | Work environment (worker population monitored) | Concentrations of Cadmium in Blood(a) | | |
|--------------|--|---------------------------------------|--------------------------|-----------|
| | | Lower 95th percentile of | Upper 95th percentile of | Reference |
| | | | | |

| | | range(c) () (f) | range(c) () (f) | |
|---------|---|---------------------|---------------------|---------------------------------------|
| 1 | Ni-Cd battery plant and Cd production plant: (Workers without kidney lesions)..... (Workers with kidney lesions)..... | (18) (32) | (25) (45) | Lauwerys et al. 1976. |
| 2 | Ni-Cd battery plant: (Smokers) (Nonsmokers)... | | | Adamsson et al. (1979). |
| 3 | Cadmium alloy plant: (High exposure group)..... (Low exposure group)..... | (7.3) (5.1) | (34) (9.1) | Sukuri et al. 1982. |
| 4 | Retrospective study of workers with renal problems: (Before removal)..... (After removal)..... | (34) (4.4) | (46) (24) | Roels et al. 1982. |
| 5 | Cadmium production plant: (Workers without renal dysfunction). (Workers with renal dysfunction). | (5.4) (9.3) | (25) (39) | Ellis et al. 1983. |
| 6 | Cd-Cu alloy plant..... | 7.5 | 10 | Mason et al. 1988. |
| 7 | Cadmium recovery | | | Thun et al. |

| | | | | |
|---------|--|-------|------|----------------------------|
| | operation - Current (19) and former (26) workers. | 2.5 | 25 | 1989. |
| 8 | Cadmium recovery operation | (1.3) | (19) | Mueller et al. 1989. |

Footnote(a) Concentrations reported in ug Cd/I blood unless otherwise stated.

Footnote(b) S.D. - Standard Deviation.

Footnote(c) C.I. - Confidence Interval.

Footnote(d) GSD - Geometric Standard Deviation.

Footnote(e) Based on assumed lognormal distribution.

Footnote(f) Based on assumed normal distribution.

Footnote(g) Years following removal.

The data in table 5 also indicate that CDB levels are higher among those experiencing current occupational exposure than those who have been removed from such exposure. Roels et al. (1982) indicate that CDB levels observed among workers experiencing ongoing exposure in the work place are almost entirely above levels observed among workers removed from such exposure. This finding suggests that CDB levels decrease once cadmium exposure has ceased.

A comparison of the data presented in tables 4 and 5 indicates that CDB levels observed among cadmium-exposed workers is significantly higher than levels observed among the unexposed groups. With the exception of 2 studies presented in table 5 (1 of which includes former workers in the sample group tested), the lower 95th percentile for CDB levels among exposed workers are greater than 5 ug/l, which is the value of the upper 95th percentile for CDB levels observed among those who are not occupationally exposed. Therefore, a CDB level of 5 ug/l represents a threshold above which significant work place exposure to cadmium may be occurring.

5.1.7 Conclusions and Recommendations for CDB

Based on the above evaluation, the following recommendations are made for a CDB proficiency program.

5.1.7.1 Recommended method

The method of Stoeppler and Brandt (1980) should be adopted for analyzing CDB. This method was selected over other methods for its straightforward sample-preparation procedures, and because limitations of the method were described adequately. It also is the method used by a plurality of laboratories currently participating in the CTQ proficiency program. In a recent CTQ interlaboratory comparison report (CTQ 1991), analysis of the methods used by laboratories to measure CDB indicates that 46% (11 of 24) of the participating laboratories used the Stoeppler and Brandt methodology (HNO(3) deproteinization of blood followed by analysis of the supernatant by GF-AAS). Other CDB methods employed by participating laboratories identified in the CTQ report include dilution of blood (29%), acid digestion (12%) and miscellaneous methods (12%).

Laboratories may adopt alternate methods, but it is the responsibility of the laboratory to demonstrate that the alternate methods meet the data quality objectives defined for the Stoeppler and Brandt method (see Section 5.1.7.2 below).

5.1.7.2 Data quality objectives

Based on the above evaluation, the following data quality objectives (DQOs) should facilitate interpretation of analytical results.

Limit of Detection. 0.5 ug/l should be achievable using the Stoeppler and Brandt method. Stoeppler and Brandt (1980) report a limit of detection equivalent to $< \text{ or } = 0.2 \text{ ug/l}$ in whole blood using 25 ul aliquots of deproteinized, diluted blood samples.

Accuracy. Initially, some of the laboratories performing CDB measurements may be expected to satisfy criteria similar to the less severe criteria specified by the CTQ program, i.e., measurements within 2 ug/l or 15% (whichever is greater) of the target value. About 60% of the laboratories enrolled in the CTQ program could meet this criterion on the first proficiency test (Weber 1988).

Currently, approximately 12 laboratories in the CTQ program are achieving an accuracy for CDB analysis within the more severe constraints of $+ \text{ or } - 1 \text{ ug/l}$ or 15% (whichever is greater). Later, as laboratories gain experience, they should achieve the level of accuracy exhibited by these 12 laboratories. The experience in the CTQ program has shown that, even without incentives, laboratories benefit from the feedback of the program; after they have analyzed 40-50 control samples from the program, performance improves to the point where about 60% of the laboratories can meet the stricter criterion of $+ \text{ or } - 1 \text{ ug/l}$ or 15% (Weber 1988). Thus, this stricter target accuracy is a reasonable DQO.

Precision. Although Stoeppler and Brandt (1980) suggest that a coefficient of variation (CV) near 1.3% (for a 10 ug/l concentration) is achievable for within-run reproducibility, it is recognized that other factors affecting within- and between-run comparability will increase the achievable CV. Stoeppler and Brandt (1980) observed CVs that were as high as 30% for low concentrations (0.4 ug/l), and CVs of less than 5% for higher concentrations.

For internal QC samples (see Section 3.3.1), laboratories should attain an overall precision near 25%. For CDB samples with concentrations less than 2 ug/l, a target precision of 40% is reasonable, while precisions of 20% should be achievable for concentrations greater than 2 ug/l. Although these values are more strict than values observed in the CTQ interlaboratory program reported by Webber (1988), they are within the achievable limits reported by Stoeppler and Brandt (1980).

5.1.7.3 Quality assurance/quality control

Commercial laboratories providing measurement of CDB should adopt an internal QA/QC program that incorporates the following components: Strict adherence to the selected method, including all calibration requirements; regular incorporation of QC samples during actual runs; a

protocol for corrective actions, and documentation of these actions; and, participation in an interlaboratory proficiency program. Note that the nonmandatory QA/QC program presented in Attachment 1 is based on the Stoeppler and Brandt method for CDB analysis. Should an alternate method be adopted, the laboratory should develop a QA/QC program satisfying the provisions of Section 3.3.1.

5.2 Measuring Cadmium in Urine (CDU)

As in the case of CDB measurement, proper determination of CDU requires strict analytical discipline regarding collection and handling of samples. Because cadmium is both ubiquitous in the environment and employed widely in coloring agents for industrial products that may be used during sample collection, preparation and analysis, care should be exercised to ensure that samples are not contaminated during the sampling procedure.

Methods for CDU determination share many of the same features as those employed for the determination of CDB. Thus, changes and improvements to methods for measuring CDU over the past 40 years parallel those used to monitor CDB. The direction of development has largely been toward the simplification of sample preparation techniques made possible because of improvements in analytic techniques.

5.2.1 Units of CDU Measurement

Procedures adopted for reporting CDU concentrations are not uniform. In fact, the situation for reporting CDU is more complicated than for CDB, where concentrations are normalized against a unit volume of whole blood.

Concentrations of solutes in urine vary with several biological factors (including the time since last voiding and the volume of liquid consumed over the last few hours); as a result, solute concentrations should be normalized against another characteristic of urine that represents changes in solute concentrations. The 2 most common techniques are either to standardize solute concentrations against the concentration of creatinine, or to standardize solute concentrations against the specific gravity of the urine. Thus, CDU concentrations have been reported in the literature as "uncorrected" concentrations of cadmium per volume of urine (i.e., ug Cd/l urine), "corrected" concentrations of cadmium per volume of urine at a standard specific gravity (i.e., ug Cd/l urine at a specific gravity of 1.020), or "corrected" mass concentration per unit mass of creatinine (i.e., ug Cd/g creatinine). (CDU concentrations [whether uncorrected or corrected for specific gravity, or normalized to creatinine] occasionally are reported in nanomoles [i.e., nmoles] of cadmium per unit mass or volume. In this protocol, these values are converted to ug of cadmium per unit mass or volume using $89 \text{ nmoles of cadmium} = 10 \text{ ug.}$)

While it is agreed generally that urine values of analytes should be normalized for reporting purposes, some debate exists over what correction method should be used. The medical community has long favored normalization based on creatinine concentration, a common urinary constituent. Creatinine is a normal product of tissue catabolism, is excreted at a uniform rate, and the total amount excreted per day is constant on a day-to-day basis (NIOSH 1984b). While this

correction method is accepted widely in Europe, and within some occupational health circles, Kowals (1983) argues that the use of specific gravity (i.e., total solids per unit volume) is more straightforward and practical (than creatinine) in adjusting CDU values for populations that vary by age or gender.

Kowals (1983) found that urinary creatinine (CRTU) is lower in females than males, and also varies with age. Creatinine excretion is highest in younger males (20-30 years old), decreases at middle age (50-60 years), and may rise slightly in later years. Thus, cadmium concentrations may be underestimated for some workers with high CRTU levels.

Within a single void urine collection, urine concentration of any analyte will be affected by recent consumption of large volumes of liquids, and by heavy physical labor in hot environments. The absolute amount of analyte excreted may be identical, but concentrations will vary widely so that urine must be corrected for specific gravity (i.e., to normalize concentrations to the quantity of total solute) using a fixed value (e.g., 1.020 or 1.024). However, since heavy-metal exposure may increase urinary protein excretion, there is a tendency to underestimate cadmium concentrations in samples with high specific gravities when specific-gravity corrections are applied.

Despite some shortcomings, reporting solute concentrations as a function of creatinine concentration is accepted generally; OSHA therefore recommends that CDU levels be reported as the mass of cadmium per unit mass of creatinine (ug/g CTRU).

Reporting CDU as ug/g CRTU requires an additional analytical process beyond the analysis of cadmium: Samples must be analyzed independently for creatinine so that results may be reported as the ratio of cadmium to creatinine concentrations found in the urine sample. Consequently, the overall quality of the analysis depends on the combined performance by a laboratory on these 2 determinations. The analysis used for CDU determinations is addressed below in terms of ug Cd/l, with analysis of creatinine addressed separately. Techniques for assessing creatinine are discussed in Section 5.4.

Techniques for deriving cadmium as a ratio of CRTU, and the confidence limits for independent measurements of cadmium and CRTU, are provided in Section 3.3.3.

5.2.2 Analytical Techniques Used to Monitor CDU

Analytical techniques used for CDU determinations are similar to those employed for CDB determinations; these techniques are summarized in Table 3. As with CDB monitoring, the technique most suitable for CDU determinations is atomic absorption spectroscopy (AAS). AAS methods used for CDU determinations typically employ a graphite furnace, with background correction made using either the deuterium-lamp or Zeeman techniques; Section 5.1.1 provides a detailed description of AAS methods.

5.2.3 Methods Developed for CDU Determinations

Princi (1947), Smith et al. (1955), Smith and Kench (1957), and Tsuchiya (1967) used calorimetric procedures similar to those described in the CDB section above to estimate CDU concentrations. In these methods, urine (50 ml) is reduced to dryness by heating in a sand bath and digested (wet ashed) with mineral acids. Cadmium then is complexed with dithiazone, extracted with chloroform and quantified by spectrophotometry. These early studies typically report reagent blank values equivalent to 0.3 ug Cd/l, and CDU concentrations among nonexposed control groups at maximum levels of 10 ug Cd/l -- erroneously high values when compared to more recent surveys of cadmium concentrations in the general population.

By the mid-1970s, most analytical procedures for CDU analysis used either wet ashing (mineral acid) or high temperatures (>400 deg. C) to digest the organic matrix of urine, followed by cadmium chelation with APDC or DDTC solutions and extraction with MIBK. The resulting aliquots were analyzed by flame or graphite-furnace AAS (Kjellstrom 1979).

Improvements in control over temperature parameters with electrothermal heating devices used in conjunction with flameless AAS techniques, and optimization of temperature programs for controlling the drying, charring, and atomization processes in sample analyses, led to improved analytical detection of diluted urine samples without the need for sample digestion or ashing. Roels et al. (1978) successfully used a simple sample preparation, dilution of 1.0 ml aliquots of urine with 0.1 N HNO₃, to achieve accurate low-level determinations of CDU.

In the method described by Pruszkowska et al. (1983), which has become the preferred method for CDU analysis, urine samples were diluted at a ratio of 1:5 with water; diammonium hydrogenphosphate in dilute HNO₃ was used as a matrix modifier. The matrix modifier allows for a higher charring temperature without loss of cadmium through volatilization during preatomization. This procedure also employs a stabilized temperature platform in a graphite furnace, while nonspecific background absorption is corrected using the Zeeman technique. This method allows for an absolute detection limit of approximately 0.04 ug Cd/l urine.

5.2.4 Sample Collection and Handling

Sample collection procedures for CDU may contribute to variability observed among CDU measurements. Sources of variation attendant to sampling include time-of-day, the interval since ingestion of liquids, and the introduction of external contamination during the collection process. Therefore, to minimize contributions from these variables, strict adherence to a sample-collection protocol is recommended. This protocol should include provisions for normalizing the conditions under which urine is collected. Every effort also should be made to collect samples during the same time of day.

Collection of urine samples from an industrial work force for biological monitoring purposes usually is performed using "spot" (i.e., single-void) urine with the pH of the sample determined immediately. Logistic and sample-integrity problems arise when efforts are made to collect urine over long periods (e.g., 24 hrs). Unless single-void urines are used, there are numerous opportunities for measurement error because of poor control over sample collection, storage and environmental contamination.

To minimize the interval during which sample urine resides in the bladder, the following adaption to the "spot" collection procedure is recommended: The bladder should first be emptied, and then a large glass of water should be consumed; the sample may be collected within an hour after the water is consumed.

5.2.5 Best Achievable Performance

Performance using a particular method for CDU determinations is assumed to be equivalent to the performance reported by the research laboratories in which the method was developed. Pruszkowska et al. (1983) report a detection limit of 0.04 ug/l CDU, with a CV of < 4% between 0-5 ug/l. The CDC reports a minimum CDU detection limit of 0.07 ug/l using a modified method based on Pruszkowska et al. (1983). No CV is stated in this protocol; the protocol contains only rejection criteria for internal QC parameters used during accuracy determinations with known standards (Attachment 8 of exhibit 106 of OSHA docket H057A). Stoeppler and Brandt (1980) report a CDU detection limit of 0.2 ug/l for their methodology.

5.2.6 General Method Performance

For any particular method, the expected initial performance from commercial laboratories may be somewhat lower than that reported by the research laboratory in which the method was developed. With participation in appropriate proficiency programs, and use of a proper in-house QA/QC program incorporating provisions for regular corrective actions, the performance of commercial laboratories may be expected to improve and approach that reported by a research laboratories. The results reported for existing proficiency programs serve to specify the initial level of performance that likely can be expected from commercial laboratories offering analysis using a particular method.

Weber (1988) reports on the results of the CTQ proficiency program, which includes CDU results for laboratories participating in the program. Results indicate that after receiving 60 samples (i.e., after participating in the program for approximately 3 years), approximately 80% of the participating laboratories report CDU results ranging between + or - 2 ug/l or 15% of the consensus mean, whichever is greater. On any single sample of the last 15 samples, the proportion of laboratories falling within the specified range is between 75 and 95%, except for a single test for which only 60% of the laboratories reported acceptable results. For each of the last 15 samples, approximately 60% of the laboratories reported results within + or - 1 ug or 15% of the mean, whichever is greater. The range of concentrations included in this set of samples was not reported.

Another report from the CTQ (1991) summarizes preliminary CDU results from their 1991 interlaboratory program. According to the report, for 3 CDU samples with values of 9.0, 16.8, 31.5 ug/l, acceptable results (target of + or - 2 ug/l or 15% of the consensus mean, whichever is greater) were achieved by only 44-52% of the 34 laboratories participating in the CDU program. The overall CVs for these 3 CDU samples among the 34 participating laboratories were 31%, 25%, and 49%, respectively. The reason for this poor performance has not been determined.

A more recent report from the CTQ (Weber, private communication) indicates that 36% of the laboratories in the program have been able to achieve the target of + or - 1 ug/l or 15% for more than 75% of the samples analyzed over the last 5 years, while 45% of participating laboratories achieved a target of + or - 2 ug/l or 15% for more than 75% of the samples analyzed over the same period.

Note that results reported in the interlaboratory programs are in terms of ug Cd/l of urine, unadjusted for creatinine. The performance indicated, therefore, is a measure of the performance of the cadmium portion of the analyses, and does not include variation that may be introduced during the analysis of CRTU.

5.2.7 Observed CDU Concentrations

Prior to the onset of renal dysfunction, CDU concentrations provide a general indication of the exposure history (i.e., body burden)(see Section 4.3). Once renal dysfunction occurs, CDU levels appear to increase and are no longer indicative solely of cadmium body burden (Friberg and Elinder 1988).

5.2.7.1 Range of CDU Concentrations Observed Among Unexposed Samples

Surveys of CDU concentrations in the general population were first reported from cooperative studies among industrial countries (i.e., Japan, U.S. and Sweden) conducted in the mid-1970s. In summarizing these data, Kjellstrom (1979) reported that CDU concentrations among Dallas, Texas men (age range: < 9-59 years; smokers and nonsmokers) varied from 0.11-1.12 ug/l (uncorrected for creatinine or specific gravity). These CDU concentrations are intermediate between population values found in Sweden (range: 0.11-0.80 ug/l) and Japan (range: 0.14-2.32 ug/l).

Kowal and Zirkes (1983) reported CDU concentrations for almost 1,000 samples collected during 1978-79 from the general U.S. adult population (i.e., nine states; both genders; ages 20-74 years). They report that CDU concentrations are lognormally distributed; low levels predominated, but a small proportion of the population exhibited high levels. These investigators transformed the CDU concentrations values, and reported the same data 3 different ways: ug/l urine (unadjusted), ug/l (specific gravity adjusted to 1.020), and ug/g CRTU. These data are summarized in Tables 6 and 7.

Based on further statistical examination of these data, including the lifestyle characteristics of this group, Kowal (1988) suggested increased cadmium absorption (i.e., body burden) was correlated with low dietary intakes of calcium and iron, as well as cigarette smoking.

CDU levels presented in Table 6 are adjusted for age and gender. Results suggest that CDU levels may be slightly different among men and women (i.e., higher among men when values are unadjusted, but lower among men when the values are adjusted, for specific gravity or CRTU). Mean differences among men and women are small compared to the standard deviations, and therefore may not be significant. Levels of CDU also appear to increase with age. The data in

Table 6 suggest as well that reporting CDU levels adjusted for specific gravity or as a function of CRTU results in reduced variability.

TABLE 6 - URINE CADMIUM CONCENTRATIONS IN THE U.S. ADULT POPULATION:
NORMAL AND CONCENTRATION-ADJUSTED VALUES BY AGE AND SEX(1)

| | Geometric means (and geometric standard deviations) | | |
|---------------------|---|--------------------------------|--------------------------|
| | Unadjusted (ug/l) | SG-adjusted(2) (ug/l at 1.020) | Creatine-adjusted (ug/g) |
| SEX: | | | |
| Male (n=484) | 0.55 (2.9) | 0.73 (2.6) | 0.55 (2.7) |
| Female (n=498) | 0.49 (3.0) | 0.86 (2.7) | 0.78 (2.7) |
| Age: | | | |
| 20-29 (n=222) | 0.32 (3.0) | 0.43 (2.7) | 0.32 (2.7) |
| 30-39 (n=141) | 0.46 (3.2) | 0.70 (2.8) | 0.54 (2.7) |
| 40-49 (n=142) | 0.50 (3.0) | 0.81 (2.6) | 0.70 (2.7) |
| 50-59 (n=117) | 0.61 (2.9) | 0.99 (2.4) | 0.90 (2.3) |
| 60-69 (n=272) | 0.76 (2.6) | 1.16 (2.3) | 1.03 (2.3) |

Footnote(1) From Kowal and Zirkes, 1983.

Footnote(2) SC-adjusted is adjusted for specific gravity.

TABLE 7 - URINE CADMIUM CONCENTRATIONS IN THE U.S. ADULT POPULATION:
CUMULATIVE FREQUENCY DISTRIBUTION OF URINARY CADMIUM (N=982)(1)

| Range of Concentrations | Unadjusted (ug/l) percent | SG-adjusted (ug/l at 1.020) percent | Creatine-adjusted (ug/g) percent |
|-------------------------|---------------------------|-------------------------------------|----------------------------------|
| <0.5 | 43.9 | 28.0 | 35.8 |
| 0.6 - 1.0 | 71.7 | 56.4 | 65.6 |
| 1.1 - 1.5 | 84.4 | 74.9 | 81.4 |
| 1.6 - 2.0 | 91.3 | 84.7 | 88.9 |
| 2.1 - 3.0 | 97.3 | 94.4 | 95.8 |
| 3.1 - 4.0 | 98.8 | 97.4 | 97.2 |
| 4.1 - 5.0 | 99.4 | 98.2 | 97.9 |
| 5.1 - 10.0 | 99.6 | 99.4 | 99.3 |
| 10.0 - 20.0 | 99.8 | 99.6 | 99.6 |

Footnote(1) Source: Kowal and Zirkes (1983)

The data in the Table 6 indicate the geometric mean of CDU levels observed among the general population is 0.52 ug Cd/l urine (unadjusted), with a geometric standard deviation of 3.0. Normalized for creatinine, the geometric mean for the population is 0.66 ug/g CRTU, with a geometric standard deviation of 2.7. Table 7 provides the distributions of CDU concentrations for the general population studied by Kowal and Zirkes. The data in this table indicate that 95%

of the CDU levels observed among those not occupationally exposed to cadmium are below 3 ug/g CRTU.

5.2.7.2 Range of CDU concentrations observed among exposed workers

Table 8 is a summary of results from available studies of CDU concentrations observed among cadmium-exposed workers. In this table, arithmetic and/or geometric means and standard deviations are provided if reported in these studies. The absolute range for the data in each study, or the 95% confidence interval around the mean of each study, also are provided when reported. The lower and upper 95th percentile of the distribution are presented for each study in which a mean and corresponding standard deviation were reported. Table 8 also provides estimates of the years of exposure, and the levels of exposure, to cadmium in the work place if reported in these studies. Concentrations reported in this table are in ug/g CRTU, unless otherwise stated.

TABLE 8. - URINE CADMIUM CONCENTRATIONS IN WORKERS EXPOSED TO CADMIUM IN THE WORKPLACE

| Study number | Work environment (worker population monitored) | Number in study (n) | Employment in years (mean) | Mean concentration of cadmium in air (ug/m(3)) |
|--------------|---|---------------------|----------------------------|--|
| 1 | Ni-Cd battery plant and Cd production plant: (Workers without kidney lesions)..... (Workers with kidney lesions)..... | 96 25 | 3-40 | < than = to 90 |
| 2 | Ni-Cd battery plant..... (Smokers) (Nonsmokers)... | 7 8 | (5) (9) | 10.1 7.0 |
| 3 | Cadmium salts production facility. | 148 | (15.4) | |
| 4 | Retrospective study of workers with renal problems: | 19 | 15-41 | |

| | | | | |
|---------|--------------------------------------|-------|----------|-----------------|
| | (Before removal)..... | | (27.2) | |
| | (After removal)..... | | (4.2)(g) | |
| 5 | Cadmium production plant: | | | |
| | (Workers without renal dysfunction). | 33 | 1-34 | |
| | (Workers with renal dysfunction). | 18 | 10-34 | |
| 6 | Cd-Cu alloy plant..... | 75 | Up to 39 | Note h |
| 7 | Cadmium recovery operation. | 45 | (19) | 87 |
| 8 | Pigment manufacturing plant. | 29 | (12.8) | 0.18-3.0 |
| 9 | Pigment manufacturing plant. | 26 | (12.1) | < than = to 3.0 |

TABLE 8. - URINE CADMIUM CONCENTRATIONS IN WORKERS EXPOSED TO CADMIUM IN THE WORKPLACE

[Continued]

| Study number | Work environment (worker population monitored) | Concentrations of Cadmium in Urine(a) | | |
|--------------|--|---------------------------------------|---------------------------------|-------------------------|
| | | Arithmetic mean (+/- S.D.)(b) | Absolute range or (95% C.I.)(c) | Geometric mean (GSD)(d) |
| 1 | Ni-Cd battery plant and Cd production plant: (Workers without | | | |

| | | | | |
|---------|--|---------------|------------|---------------|
| | kidney lesions)..... | 16.3 +/- 16.7 | | |
| | (Workers with kidney lesions)..... | 48.2 +/- 42.6 | | |
| 2 | Ni-Cd battery plant..... | | | |
| | (Smokers) | 5.5 | 1.0 - 14.7 | |
| | (Nonsmokers)... | 3.6 | 0 .5 - 9.3 | |
| 3 | Cadmium salts production facility. | 15.8 | 2 - 150 | |
| 4 | Retrospective study of wokers with renal problems: | | | |
| | (Before removal)..... | 39.4 +/- 28.1 | 10.8 - 117 | |
| | (After removal)..... | 16.4 +/- 9.0 | 80 - 42.3 | |
| 5 | Cadmium production plant: | | | |
| | (Workers without renal dysfunction). | 9.4 +/- 6.9 | 2 - 27 | |
| | (Workers with renal dysfunction). | 22.8 +/- 12.7 | 8 - 55 | |
| 6 | Cd-Cu alloy plant..... | 6.9 +/- 9.4 | | |
| 7 | Cadmium recovery operation. | 9.3 +/- 6.9 | | |
| 8 | Pigment manufacturing plant. | | 0.2 - 9.5 | 1.1 |
| 9 | Pigment manufacturing plant. | | | 1.25 +/- 2.45 |

TABLE 8. - URINE CADMIUM CONCENTRATIONS IN WORKERS EXPOSED TO CADMIUM IN THE WORKPLACE

[Continued]

| Study number | Work environment (worker population monitored) | Concentrations of Cadmium in Urine(a) | | |
|--------------|---|---|---|-------------------------|
| | | Lower 95th percentile of range(c) () (f) | Upper 95th percentile of range(c) () (f) | Reference |
| 1 | Ni-Cd battery plant and Cd production plant: (Workers without kidney lesions)..... (Workers with kidney lesions)..... | (0) (0) | (44) (120) | Lauwerys et al. 1976. |
| 2 | Ni-Cd battery plant..... (Smokers) (Nonsmokers).... | | | Adamsson et al. (1979). |
| 3 | Cadmium salts production facility. | | | Butchet et al. 1980. |
| 4 | Retrospective study of workers with renal problems: (Before removal)..... (After removal)..... | (0) (1.0) | (88) (32) | Roels et al. 1982. |
| 5 | Cadmium production plant: (Workers without renal dysfunction). (Workers with renal dysfunction). | (0) (1) | (21) (45) | Ellis et al. 1983. |

| | | | | | |
|---|-------|------------------------------------|-------|-------|----------------------------|
| 6 | | Cd-Cu alloy plant..... | (0) | (23) | Mason et al. 1988. |
| 7 | | Cadmium recovery operation. | (0) | (21) | Thun et al. 1989. |
| 8 | | Pigment manufacturing plant. | | | Mueller et al. 1989. |
| 9 | | Pigment manufacturing plant. | 0.3 | 6 | Kawada et al. 1990. |

Footnote(a) Concentrations reported in ug/g Cr.

Footnote(b) S.D. - Standard Deviation.

Footnote(c) C.I. - Confidence Interval.

Footnote(d) GSD - Geometric Standard Deviation.

Footnote(e) Based on assumed lognormal distribution.

Footnote(f) Based on assumed normal distribution.

Footnote(g) Years following removal.

Footnote(h) Equivalent to 50 for 20-22 yrs.

Data in Table 8 from Lauwerys et al. (1976) and Ellis et al. (1983) indicate that CDU concentrations are higher among those exhibiting kidney lesions or dysfunction than among those lacking these symptoms. Data from the study by Roels et al. (1982) indicate that CDU levels decrease among workers removed from occupational exposure to cadmium in comparison to workers experiencing ongoing exposure. In both cases, however, the distinction between the 2 groups is not as clear as with CDB; there is more overlap in CDU levels observed among each of the paired populations than is true for corresponding CDB levels. As with CDB levels, the data in Table 8 suggest increased CDU concentrations among workers who experienced increased overall exposure.

Although a few occupationally-exposed workers in the studies presented in Table 8 exhibit CDU levels below 3 ug/g CRTU, most of those workers exposed to cadmium levels in excess of the PEL defined in the final cadmium rule exhibit CDU levels above 3 ug/g CRTU; this level represents the upper 95th percentile of the CDU distribution observed among those who are not occupationally exposed to cadmium (Table 7).

The mean CDU levels reported in Table 8 among occupationally-exposed groups studied (except 2) exceed 3 ug/g CRTU. Correspondingly, the level of exposure reported in these studies (with 1 exception) are significantly higher than what workers will experience under the final cadmium rule. The 2 exceptions are from the studies by Mueller et al. (1989) and Kawada et al. (1990); these studies indicate that workers exposed to cadmium during pigment manufacture do not exhibit CDU levels as high as those levels observed among workers exposed to cadmium in other occupations. Exposure levels, however, were lower in the pigment manufacturing plants studied. Significantly, workers removed from occupational cadmium exposure for an average of 4 years

still exhibited CDU levels in excess of 3 ug/g CRTU (Roels et al. 1982). In the single-exception study with a reported level of cadmium exposure lower than levels proposed in the final rule (i.e., the study of a pigment manufacturing plant by Kawada et al. 1990), most of the workers exhibited CDU levels less than 3 ug/g CRTU (i.e., the mean value was only 1.3 ug/g CRTU). CDU levels among workers with such limited cadmium exposure are expected to be significantly lower than levels of other studies reported in Table 8.

Based on the above data, a CDU level of 3 ug/g CRTU appears to represent a threshold above which significant work place exposure to cadmium occurs over the work span of those being monitored. Note that this threshold is not as distinct as the corresponding threshold described for CDB. In general, the variability associated with CDU measurements among exposed workers appears to be higher than the variability associated with CDB measurements among similar workers.

5.2.8 Conclusions and Recommendations for CDU

The above evaluation supports the following recommendations for a CDU proficiency program. These recommendations address only sampling and analysis procedures for CDU determinations specifically, which are to be reported as an unadjusted ug Cd/l urine. Normalizing this result to creatinine requires a second analysis for CRTU so that the ratio of the 2 measurements can be obtained. Creatinine analysis is addressed in Section 5.4. Formal procedures for combining the 2 measurements to derive a value and a confidence limit for CDU in ug/g CRTU are provided in Section 3.3.3.

5.2.8.1 Recommended Method

The method of Pruszkowska et al. (1983) should be adopted for CDU analysis. This method is recommended because it is simple, straightforward and reliable (i.e., small variations in experimental conditions do not affect the analytical results).

A synopsis of the methods used by laboratories to determine CDU under the interlaboratory program administered by the CTQ (1991) indicates that more than 78% (24 of 31) of the participating laboratories use a dilution method to prepare urine samples for CDU analysis. Laboratories may adopt alternate methods, but it is the responsibility of the laboratory to demonstrate that the alternate methods provide results of comparable quality to the Pruszkowska method.

5.2.8.2 Data Quality Objectives

The following data quality objectives should facilitate interpretation of analytical results, and are achievable based on the above evaluation.

Limit of Detection. A level of 0.5 ug/l (i.e., corresponding to a detection limit of 0.5 ug/g CRTU, assuming 1 g CRT/l urine) should be achievable. Pruszkowska et al. (1983) achieved a limit of detection of 0.04 ug/l for CDU based on the slope the curve for their working standards (0.35 pg Cd/0.0044, A signal=1% absorbance using GF-AAS).

The CDC reports a minimum detection limit for CDU of 0.07 ug/l using a modified Pruszkowska method. This limit of detection was defined as 3 times the standard deviation calculated from 10 repeated measurements of a "low level" CDU test sample (Attachment 8 of exhibit 106 of OSHA docket H057A).

Stoeppler and Brandt (1980) report a limit of detection for CDU of 0.2 ug/l using an aqueous dilution (1:2) of the urine samples.

Accuracy. A recent report from the CTQ (Weber, private communication) indicates that 36% of the laboratories in the program achieve the target of + or - 1 ug/l or 15% for more than 75% of the samples analyzed over the last 5 years, while 45% of participating laboratories achieve a target of + or - 2 ug/l or 15% for more than 75% of the samples analyzed over the same period. With time and a strong incentive for improvement, it is expected that the proportion of laboratories successfully achieving the stricter level of accuracy should increase. It should be noted, however, these indices of performance do not include variations resulting from the ancillary measurement of CRTU (which is recommended for the proper recording of results). The low cadmium levels expected to be measured indicate that the analysis of creatinine will contribute relatively little to the overall variability observed among creatinine-normalized CDU levels (see Section 5.4). The initial target value for reporting CDU under this program, therefore, is set at + or - 1 ug/g CRTU or 15% (whichever is greater).

Precision. For internal QC samples (which are recommended as part of an internal QA/QC program, Section 3.3.1), laboratories should attain an overall precision of 25%. For CDB samples with concentrations less than 2 ug/l, a target precision of 40% is acceptable, while precisions of 20% should be achievable for CDU concentrations greater than 2 ug/l. Although these values are more stringent than those observed in the CTQ interlaboratory program reported by Webber (1988), they are well within limits expected to be achievable for the method as reported by Stoeppler and Brandt (1980).

5.2.8.3 Quality Assurance/Quality Control

Commercial laboratories providing CDU determinations should adopt an internal QA/QC program that incorporates the following components: Strict adherence to the selected method, including calibration requirements; regular incorporation of QC samples during actual runs; a protocol for corrective actions, and documentation of such actions; and, participation in an interlaboratory proficiency program. Note that the nonmandatory program presented in Attachment 1 as an example of an acceptable QA/QC program, is based on using the Pruszkowska method for CDU analysis. Should an alternate method be adopted by a laboratory, the laboratory should develop a QA/QC program equivalent to the nonmandatory program, and which satisfies the provisions of Section 3.3.1.

5.3 Monitoring B-2-Microglobulin in Urine (B(2)MU)

As indicated in Section 4.3, B(2)MU appears to be the best of several small proteins that may be monitored as early indicators of cadmium- induced renal damage. Several analytic techniques are available for measuring B2M.

5.3.1 Units of B(2)MU Measurement

Procedures adopted for reporting B(2)MU levels are not uniform. In these guidelines, OSHA recommends that B(2)MU levels be reported as ug/g CRTU, similar to reporting CDU concentrations. Reporting B(2)MU normalized to the concentration of CRTU requires an additional analytical process beyond the analysis of B2M: Independent analysis for creatinine so that results may be reported as a ratio of the B2M and creatinine concentrations found in the urine sample. Consequently, the overall quality of the analysis depends on the combined performance on these 2 analyses. The analysis used for B(2)MU determinations is described in terms of ug B2M/l urine, with analysis of creatinine addressed separately. Techniques used to measure creatinine are provided in Section 5.4. Note that Section 3.3.3 provides techniques for deriving the value of B2M as function of CRTU, and the confidence limits for independent measurements of B2M and CRTU.

5.3.2 Analytical Techniques Used to Monitor B(2)MU

One of the earliest tests used to measure B(2)MU was the radial immunodiffusion technique. This technique is a simple and specific method for identification and quantitation of a number of proteins found in human serum and other body fluids when the protein is not readily differentiated by standard electrophoretic procedures. A quantitative relationship exists between the concentration of a protein deposited in a well that is cut into a thin agarose layer containing the corresponding monospecific antiserum, and the distance that the resultant complex diffuses. The wells are filled with an unknown serum and the standard (or control), and incubated in a moist environment at room temperature. After the optimal point of diffusion has been reached, the diameters of the resulting precipitation rings are measured. The diameter of a ring is related to the concentration of the constituent substance. For B(2)MU determinations required in the medical monitoring program, this method requires a process that may be insufficient to concentrate the protein to levels that are required for detection.

Radioimmunoassay (RIA) techniques are used widely in immunologic assays to measure the concentration of antigen or antibody in body-fluid samples. RIA procedures are based on competitive-binding techniques. If antigen concentration is being measured, the principle underlying the procedure is that radioactive-labeled antigen competes with the sample's unlabeled antigen for binding sites on a known amount of immobile antibody. When these 3 components are present in the system, an equilibrium exists. This equilibrium is followed by a separation of the free and bound forms of the antigen. Either free or bound radioactive-labeled antigen can be assessed to determine the amount of antigen in the sample. The analysis is performed by measuring the level of radiation emitted either by the bound complex following removal of the solution containing the free antigen, or by the isolated solution containing the residual-free antigen. The main advantage of the RIA method is the extreme sensitivity of

detection for emitted radiation and the corresponding ability to detect trace amounts of antigen. Additionally, large numbers of tests can be performed rapidly.

The enzyme-linked immunosorbent assay (ELISA) techniques are similar to RIA techniques except that nonradioactive labels are employed. This technique is safe, specific and rapid, and is nearly as sensitive as RIA techniques. An enzyme-labeled antigen is used in the immunologic assay; the labeled antigen detects the presence and quantity of unlabeled antigen in the sample. In a representative ELISA test, a plastic plate is coated with antibody (e.g., antibody to B2M). The antibody reacts with antigen (B2M) in the urine and forms an antigen-antibody complex on the plate. A second anti-B2M antibody (i.e., labeled with an enzyme) is added to the mixture and forms an antibody-antigen-antibody complex. Enzyme activity is measured spectrophotometrically after the addition of a specific chromogenic substrate which is activated by the bound enzyme. The results of a typical test are calculated by comparing the spectrophotometric reading of a serum sample to that of a control or reference serum. In general, these procedures are faster and require less laboratory work than other methods.

In a fluorescent ELISA technique (such as the one employed in the Pharmacia Delphia test for B2M), the labeled enzyme is bound to a strong fluorescent dye. In the Pharmacia Delphia test, an antigen bound to a fluorescent dye competes with unlabeled antigen in the sample for a predetermined amount of specific, immobile antibody. Once equilibrium is reached, the immobile phase is removed from the labeled antigen in the sample solution and washed; an enhancement solution then is added that liberates the fluorescent dye from the bound antigen-antibody complex. The enhancement solution also contains a chelate that complexes with the fluorescent dye in solution; this complex increases the fluorescent properties of the dye so that it is easier to detect.

To determine the quantity of B2M in a sample using the Pharmacia Delphia test, the intensity of the fluorescence of the enhancement solution is measured. This intensity is proportional to the concentration of labeled antigen that bound to the immobile antibody phase during the initial competition with unlabeled antigen from the sample. Consequently, the intensity of the fluorescence is an inverse function of the concentration of antigen (B2M) in the original sample. The relationship between the fluorescence level and the B2M concentration in the sample is determined using a series of graded standards, and extrapolating these standards to find the concentration of the unknown sample.

5.3.3 Methods Developed for B(2)MU Determinations

B(2)MU usually is measured by radioimmunoassay (RIA) or enzyme-linked immunosorbent assay (ELISA); however, other methods (including gel electrophoresis, radial immunodiffusion, and nephelometric assays) also have been described (Schardun and van Epps 1987). RIA and ELISA methods are preferred because they are sensitive at concentrations as low as micrograms per liter, require no concentration processes, are highly reliable and use only a small sample volume.

Based on a survey of the literature, the ELISA technique is recommended for monitoring B(2)MU. While RIAs provide greater sensitivity (typically about 1 ug/l, Evrin et al. 1971), they depend on the use of radioisotopes; use of radioisotopes requires adherence to rules and regulations established by the Atomic Energy Commission, and necessitates an expensive radioactivity counter for testing. Radioisotopes also have a relatively short half-life, which corresponds to a reduced shelf life, thereby increasing the cost and complexity of testing. In contrast, ELISA testing can be performed on routine laboratory spectrophotometers, do not necessitate adherence to additional rules and regulations governing the handling of radioactive substances, and the test kits have long shelf lives. Further, the range of sensitivity commonly achieved by the recommended ELISA test (i.e., the Pharmacia Delphia test) is approximately 100 ug/l (Pharmacia 1990), which is sufficient for monitoring B(2)MU levels resulting from cadmium exposure. Based on the studies listed in Table 9 (Section 5.3.7), the average range of B2M concentrations among the general, nonexposed population falls between 60 and 300 ug/g CRTU. The upper 95th percentile of distributions, derived from studies in Table 9 which reported standard deviations, range between 180 and 1,140 ug/g CRTU. Also, the Pharmacia Delphia test currently is the most widely used test for assessing B(2)MU.

5.3.4 Sample Collection and Handling

As with CDB or CDU, sample collection procedures are addressed primarily to identify ways to minimize the degree of variability introduced by sample collection during medical monitoring. It is unclear the extent to which sample collection contributes to B(2)MU variability. Sources of variation include time-of-day effects, the interval since consuming liquids and the quantity of liquids consumed, and the introduction of external contamination during the collection process. A special problem unique to B2M sampling is the sensitivity of this protein to degradation under acid conditions commonly found in the bladder. To minimize this problem, strict adherence to a sampling protocol is recommended. The protocol should include provisions for normalizing the conditions under which the urine is collected. Clearly, it is important to minimize the interval urine spends in the bladder. It also is recommended that every effort be made to collect samples during the same time of day.

Collection of urine samples for biological monitoring usually is performed using "spot" (i.e., single-void) urine. Logistics and sample integrity become problems when efforts are made to collect urine over extended periods (e.g., 24 hrs). Unless single-void urines are used, numerous opportunities exist for measurement error because of poor control over sample collection, storage and environmental contamination.

To minimize the interval that sample urine resides in the bladder, the following adaption to the "spot" collection procedure is recommended: The bladder should be emptied and then a large glass of water should be consumed; the sample then should be collected within an hour after the water is consumed.

5.3.5 Best Achievable Performance

The best achievable performance is assumed to be equivalent to the performance reported by the manufacturers of the Pharmacia Delphia test kits (Pharmacia 1990). According to the insert that comes with these kits, QC results should be within + or - 2 SDs of the mean for each control sample tested; a CV of less than or equal to 5.2% should be maintained. The total CV reported for test kits is less than or equal to 7.2%.

5.3.6 General Method Performance

Unlike analyses for CDB and CDU, the Pharmacia Delphia test is standardized in a commercial kit that controls for many sources of variation. In the absence of data to the contrary, it is assumed that the achievable performance reported by the manufacturer of this test kit will serve as an achievable performance objective. The CTQ proficiency testing program for B(2)MU analysis is expected to use the performance parameters defined by the test kit manufacturer as the basis of the B(2)MU proficiency testing program.

Note that results reported for the test kit are expressed in terms of ug B2M/l of urine, and have not been adjusted for creatinine. The indicated performance, therefore, is a measure of the performance of the B2M portion of the analyses only, and does not include variation that may have been introduced during the analysis of creatinine.

5.3.7 Observed B(2)MU Concentrations

As indicated in Section 4.3, the concentration of B(2)MU may serve as an early indicator of the onset of kidney damage associated with cadmium exposure.

5.3.7.1 Range of B(2)MU Concentrations Among Unexposed Samples

Most of the studies listed in Table 9 report B(2)MU levels for those who were not occupationally exposed to cadmium. Studies noted in the second column of this table (which contain the footnote "d") reported B(2)MU concentrations among cadmium-exposed workers who, nonetheless, showed no signs of proteinuria. These latter studies are included in this table because, as indicated in Section 4.3, monitoring B(2)MU is intended to provide advanced warning of the onset of kidney dysfunction associated with cadmium exposure, rather than to distinguish relative exposure. This table, therefore, indicates the range of B(2)MU levels observed among those who had no symptoms of renal dysfunction (including cadmium-exposed workers with none of these symptoms).

Table 9 - B-2-Microglobulin Concentrations Observed in Urine Among Those not Occupationally Exposed to Cadmium

| Study No. | No. in study | Geometric mean | Geometric standard deviation | Lower 95th percentile of distribution(a) | Upper 95th percentile of distribution(a) | Reference |
|-----------|--------------|----------------|------------------------------|--|--|-----------|
| 1.... | 133 m(b) | 115 ug/g(c) | 4.03... | 12..... | 1,140 | ishizaki |

| | | | | | | |
|-------|----------|-------------------------|---------------|----------------------|-----------------------|--|
| 2.... | 161 f(b) | 146 ug/g(c) | 3.11... | 23..... | 940 ug/g(c)... | et al. 1989. ishizaki et al. 1989. |
| 3.... | 10..... | 84 ug/g.... | | | | Ellis et al. 1983. |
| 4.... | 203.... | 76 ug/l.... | | | | Stewart and Hughes 1981. |
| 5.... | 9..... | 103 ug/g... | | | | Chia et al. 1989. |
| 6.... | 47(d).. | 86 ug/L.... | 1.9.... | 30 ug/l.. | 250 ug/L. | Kjell- strom et al. 1977. |
| 7.... | 1,000(e) | 68.1 ug/gr Cr(f).... | 3.1 m & f. | < 10 u/gr Cr(h).. | 320 ug/gr Cr (h).. | Kowal 1983. |
| 8.... | 87..... | 71 ug/g(i). | | 7(h)..... | 200(h)... | Buchet et al. 1980. |
| 9.... | 10..... | 0.073 mg/24h | | | | Evrin et al. 1971. |
| 10... | 59..... | 156 ug/g... | 1.1(j). | 130..... | 180..... | Mason et al. 1988. |
| 11... | 8..... | 118 ug/g... | | | | Iwao et al. 1980. |
| 12... | 34..... | 79 ug/g.... | | | | Wibowo et al. 1982. |
| 13... | 41 m... | | | | 400 ug/gr Cr(k) | Falck et al. 1983. |
| 14... | 35(n).. | 67..... | | | | Roels et al. 1991. |
| 15... | 31(d).. | 63..... | | | | Roels et al. 1991. |
| 16... | 36(d).. | 77(i)..... | | | | Miksche et al. 1981. |
| 17... | 18(n).. | 130..... | | | | Kawada et al. 1989. |
| 18... | 32(p).. | 122..... | | | | Kawada et al. 1989. |
| 19... | 18(d).. | 295..... | 1.4.... | 170..... | 510..... | Thun et al. 1989. |

Footnote(a) Based on an assumed lognormal distribution
Footnote(b) m = males, f = females
Footnote(c) Aged general population from non-polluted area; 47.9% population aged 50-69; 52.1% > than or = to 70 years of age; values reported in study
Footnote(d) Exposed workers without proteinuria
Footnote(e) 492 females, 484 males
Footnote(f) Creatinine-adjusted; males = 68.1 ug/g Cr, females = 64.3 ug/g Cr
Footnote(h) Reported in the study
Footnote(i) Arithmetic mean
Footnote(j) Geometric standard error
Footnote(k) Upper 95% tolerance limits: for Falck this is based on the 24 hour urine sample
Footnote(n) Controls
Footnote(p) Exposed synthetic resin and pigment workers without proteinuria; Cadmium in urine levels up to 10 ug/g Cr

To the extent possible, the studies listed in Table 9 provide geometric means and geometric standard deviations for measurements among the groups defined in each study. For studies reporting a geometric standard deviation along with a mean, the lower and upper 95th percentile for these distributions were derived and reported in the table.

The data provided from 15 of the 19 studies listed in Table 9 indicate that the geometric mean concentration of B2M observed among those who were not occupationally exposed to cadmium is 70-170 ug/g CRTU. Data from the 4 remaining studies indicate that exposed workers who exhibit no signs of proteinuria show mean B(2)MU levels of 60-300 ug/g CRTU. B(2)MU values in the study by Thun et al. (1989), however, appear high in comparison to the other 3 studies.

If this study is removed, B(2)MU levels for those who are not occupationally exposed to cadmium are similar to B(2)MU levels found among cadmium-exposed workers who exhibit no signs of kidney dysfunction. Although the mean is high in the study by Thun et al., the range of measurements reported in this study is within the ranges reported for the other studies.

Determining a reasonable upper limit from the range of B2M concentrations observed among those who do not exhibit signs of proteinuria is problematic. Elevated B(2)MU levels are among the signs used to define the onset of kidney dysfunction. Without access to the raw data from the studies listed in Table 9, it is necessary to rely on reported standard deviations to estimate an upper limit for normal B(2)MU concentrations (i.e., the upper 95th percentile for the distributions measured). For the 8 studies reporting a geometric standard deviation, the upper 95th percentiles for the distributions are 180-1140 ug/g CRTU. These values are in general agreement with the upper 95th percentile for the distribution (i.e., 631 ug/g CRTU) reported by Buchet et al. (1980). These upper limits also appear to be in general agreement with B(2)MU values (i.e., 100-690 ug/g CRTU) reported as the normal upper limit by Iwao et al. (1980), Kawada et al. (1989), Wibowo et al. (1982), and Schardun and van Epps (1987). These values must be compared to levels reported among those exhibiting kidney dysfunction to define a threshold level for kidney dysfunction related to cadmium exposure.

5.3.7.2 Range of B(2)MU Concentrations Among Exposed Workers

Table 10 presents results from studies reporting B(2)MU determinations among those occupationally exposed to cadmium in the work place; in some of these studies, kidney dysfunction was observed among exposed workers, while other studies did not make an effort to distinguish among exposed workers based on kidney dysfunction. As with Table 9, this table provides geometric means and geometric standard deviations for the groups defined in each study if available. For studies reporting a geometric standard deviation along with a mean, the lower and upper 95th percentiles for the distributions are derived and reported in the table.

Table 10. - B(2)-Microglobulin Concentrations Observed in Urine Among Occupationally-Exposed Workers

| Study number | N | Concentration of B(2)-microglobulin in urine | | | | Reference |
|--------------|-------|--|-----------------|--------------------|--------------------|-------------------------|
| | | Geometric mean (ug/g) (a) | Geom. Std. Dev. | L 95% of range (b) | U 95% of range (b) | |
| 1..... | 1,424 | 160 | 6.19 | 8.1 | 3,300 | Ishizaki et al. 1989. |
| 2..... | 1,754 | 260 | 6.50 | 12 | 5,600 | Ishizaki et al. 1989. |
| 3..... | 33 | 210 | | | | Ellis et al. 1983. |
| 4..... | 65 | 210 | | | | Chia et al. 1989. |
| 5..... | (c)44 | 5,700 | 6.49 | (d)300 | (d)98,000 | Kjellstrom et al. 1977. |
| 6..... | 148 | (e)180 | | (f)110 | (f)280 | Buchet et al. 1980. |
| 7..... | 37 | 160 | 3.90 | 17 | 1,500 | Kenzaburo et al. 1979. |
| 8..... | (c)45 | 3,300 | 8.70 | (d)310 | (d)89,000 | Mason et al. 1988. |
| 9..... | (c)10 | 6,100 | 5.99 | (f)650 | (f)57,000 | Falck et al. 1983. |
| 10..... | (c)11 | 3,900 | 2.96 | (d)710 | (d)15,000 | Elinder et al. 1985. |
| 11..... | (c)12 | 300 | | | | Roels et al. 1991. |

| | | | | | | |
|--------|-------|----------|-------|--------|-----------|---------------------------|
| 12.... | (g)8 | 7,400 | | | | Roels et al. 1991. |
| 13.... | (c)23 | (h)1,800 | | | | Roels et al. 1989. |
| 14.... | 10 | 690 | | | | Iwao et al. 1980. |
| 15.... | 34 | 71 | | | | Wibowo et al. 1982. |
| 16.... | (c)15 | 4,700 | 6.49 | (d)590 | (d)93,000 | Thun et al. 1989. |

Footnote(a) Unless otherwise stated.

Footnote(b) Based on an assumed lognormal distribution.

Footnote(c) Among workers diagnosed as having renal dysfunction; for Elinder this means B(2) levels greater than 300 micrograms per gram creatinine (ug/gr Cr); for Roels, 1991, range = 31-35, 170 ugB(2)/gr Cr and geometric mean = 63 among healthy workers; for Mason B(2)>300 ug/gr Cr.

Footnote(d) Based on a detailed review of the data by OSHA.

Footnote(e) Arithmetic mean.

Footnote(f) Reported in the study.

Footnote(g) Retired workers.

Footnote(h) 1,800 ugB(2)/gr Cr for first survey; second survey = 1,600; third survey = 2,600; fourth survey = 2,600; fifth survey = 2,600.

The data provided in Table 10 indicate that the mean B(2)MU concentration observed among workers experiencing occupational exposure to cadmium (but with undefined levels of proteinuria) is 160-7400 ug/g CRTU. One of these studies reports geometric means lower than this range (i.e., as low as 71 ug/g CRTU); an explanation for this wide spread in average concentrations is not available.

Seven of the studies listed in Table 10 report a range of B(2)MU levels among those diagnosed as having renal dysfunction. As indicated in this table, renal dysfunction (proteinuria) is defined in several of these studies by B(2)MU levels in excess of 300 ug/g CRTU (see footnote "c" of Table 10); therefore, the range of B(2)MU levels observed in these studies is a function of the operational definition used to identify those with renal dysfunction. Nevertheless, a B(2)MU level of 300 ug/g CRTU appears to be a meaningful threshold for identifying those having early signs of kidney damage. While levels much higher than 300 ug/g CRTU have been observed among those with renal dysfunction, the vast majority of those not occupationally exposed to cadmium exhibit much lower B(2)MU concentrations (see Table 9). Similarly, the vast majority of workers not exhibiting renal dysfunction are found to have levels below 300 ug/g CRTU (Table 9).

The 300 ug/g CRTU level for B(2)MU proposed in the above paragraph has support among researchers as the threshold level that distinguishes between cadmium-exposed workers with and without kidney dysfunction. For example, in the guide for physicians who must evaluate

cadmium-exposed workers written for the Cadmium Council by Dr. Lauwerys, levels of B2M greater than 200-300 ug/g CRTU are considered to require additional medical evaluation for kidney dysfunction (exhibit 8-447, OSHA docket H057A). The most widely used test for measuring B2M (i.e., the Pharmacia Delphia test) defines B(2)MU levels above 300 ug/l as abnormal (exhibit L-140-1, OSHA docket H057A).

Dr. Elinder, chairman of the Department of Nephrology at the Karolinska Institute, testified at the hearings on the proposed cadmium rule. According to Dr. Elinder (exhibit L-140-45, OSHA docket H057A), the normal concentration of B(2)MU has been well documented (Evrin and Wibell 1972; Kjellstrom et al. 1977a; Elinder et al. 1978, 1983; Buchet et al. 1980; Jawaid et al. 1983; Kowal and Zirkes, 1983). Elinder stated that the upper 95 or 97.5 percentiles for B(2)MU among those without tubular dysfunction is below 300 ug/g CRTU (Kjellstrom et al. 1977a; Buchet et al. 1980; Kowal and Zirkes, 1983). Elinder defined levels of B2M above 300 ug/g CRTU as "slight" proteinuria.

5.3.8 Conclusions and Recommendations for B(2)MU

Based on the above evaluation, the following recommendations are made for a B(2)MU proficiency testing program. Note that the following discussion addresses only sampling and analysis for B(2)MU determinations (i.e., to be reported as an unadjusted ug B(2)M/l urine). Normalizing this result to creatinine requires a second analysis for CRTU (see Section 5.4) so that the ratio of the 2 measurements can be obtained.

5.3.8.1 Recommended Method

The Pharmacia Delphia method (Pharmacia 1990) should be adopted as the standard method for B(2)MU determinations. Laboratories may adopt alternate methods, but it is the responsibility of the laboratory to demonstrate that alternate methods provide results of comparable quality to the Pharmacia Delphia method.

5.3.8.2 Data Quality Objectives

The following data quality objectives should facilitate interpretation of analytical results, and should be achievable based on the above evaluation.

Limit of Detection. A limit of 100 ug/l urine should be achievable, although the insert to the test kit (Pharmacia 1990) cites a detection limit of 150 ug/l; private conversations with representatives of Pharmacia, however, indicate that the lower limit of 100 ug/l should be achievable provided an additional standard of 100 ug/l B2M is run with the other standards to derive the calibration curve (Section 3.3.1.1). The lower detection limit is desirable due to the proximity of this detection limit to B(2)MU values defined for the cadmium medical monitoring program.

Accuracy. Because results from an interlaboratory proficiency testing program are not available currently, it is difficult to define an achievable level of accuracy. Given the general performance

parameters defined by the insert to the test kits, however, an accuracy of + or - 15% of the target value appears achievable.

Due to the low levels of B(2)MU to be measured generally, it is anticipated that the analysis of creatinine will contribute relatively little to the overall variability observed among creatinine-normalized B(2)MU levels (see Section 5.4). The initial level of accuracy for reporting B(2)MU levels under this program should be set at + or - 15%.

Precision. Based on precision data reported by Pharmacia (1990), a precision value (i.e., CV) of 5% should be achievable over the defined range of the analyte. For internal QC samples (i.e., recommended as part of an internal QA/QC program, Section 3.3.1), laboratories should attain precision near 5% over the range of concentrations measured.

5.3.8.3 Quality Assurance/Quality Control

Commercial laboratories providing measurement of B(2)MU should adopt an internal QA/QC program that incorporates the following components: Strict adherence to the Pharmacia Delphia method, including calibration requirements; regular use of QC samples during routine runs; a protocol for corrective actions, and documentation of these actions; and, participation in an interlaboratory proficiency program. Procedures that may be used to address internal QC requirements are presented in Attachment 1. Due to differences between analyses for B(2)MU and CDB/CDU, specific values presented in Attachment 1 may have to be modified. Other components of the program (including characterization runs), however, can be adapted to a program for B(2)MU.

5.4 Monitoring Creatinine in Urine (CRTU)

Because CDU and B(2)MU should be reported relative to concentrations of CRTU, these concentrations should be determined in addition CDU and B(2)MU determinations.

5.4.1 Units of CRTU Measurement

CDU should be reported as ug Cd/g CRTU, while B(2)MU should be reported as ug B2M/g CRTU. To derive the ratio of cadmium or B2M to creatinine, CRTU should be reported in units of g crtn/l of urine. Depending on the analytical method, it may be necessary to convert results of creatinine determinations accordingly.

5.4.2 Analytical Techniques Used to Monitor CRTU

Of the techniques available for CRTU determinations, an absorbance spectrophotometric technique and a high-performance liquid chromatography (HPLC) technique are identified as acceptable in this protocol.

5.4.3 Methods Developed for CRTU Determinations

CRTU analysis performed in support of either CDU or B(2)MU determinations should be performed using either of the following 2 methods:

1. The Du Pont method (i.e., Jaffe method), in which creatinine in a sample reacts with picrate under alkaline conditions, and the resulting red chromophore is monitored (at 510 nm) for a fixed interval to determine the rate of the reaction; this reaction rate is proportional to the concentration of creatinine present in the sample (a copy of this method is provided in Attachment 2 of this protocol); or,

2. The OSHA SLC Technical Center (OSLTC) method, in which creatinine in an aliquot of sample is separated using an HPLC column equipped with a UV detector; the resulting peak is quantified using an electrical integrator (a copy of this method is provided in Attachment 3 of this protocol).

5.4.4 Sample Collection and Handling

CRTU samples should be segregated from samples collected for CDU or B(2)MU analysis. Sample-collection techniques have been described under Section 5.2.4. Samples should be preserved either to stabilize CDU (with HNO₃) or B(2)MU (with NaOH). Neither of these procedures should adversely affect CRTU analysis (see Attachment 3).

5.4.5 General Method Performance

Data from the OSLTC indicate that a CV of 5% should be achievable using the OSLTC method (Septon, L private communication). The achievable accuracy of this method has not been determined.

Results reported in surveys conducted by the CAP (CAP 1991a, 1991b and 1992) indicate that a CV of 5% is achievable. The accuracy achievable for CRTU determinations has not been reported.

Laboratories performing creatinine analysis under this protocol should be CAP accredited and should be active participants in the CAP surveys.

5.4.6 Observed CRTU Concentrations

Published data suggest the range of CRTU concentrations is 1.0-1.6 g in 24-hour urine samples (Harrison 1987). These values are equivalent to about 1 g/l urine.

5.4.7 Conclusions and Recommendations for CRTU

5.4.7.1 Recommended Method

Use either the Jaffe method (Attachment 2) or the OSLTC method (Attachment 3). Alternate methods may be acceptable provided adequate performance is demonstrated in the CAP program.

5.4.7.2 Data Quality Objectives

Limit of Detection. This value has not been formally defined; however, a value of 0.1 g/l urine should be readily achievable.

Accuracy. This value has not been defined formally; accuracy should be sufficient to retain accreditation from the CAP.

Precision. A CV of 5% should be achievable using the recommended methods.

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Attachment 1 - Nonmandatory Protocol for an Internal Quality Assurance/Quality Control Program

The following is an example of the type of internal quality

assurance/quality control program that assures adequate control to satisfy OSHA requirements under this protocol. However, other approaches may also be acceptable.

As indicated in Section 3.3.1 of the protocol, the QA/QC program for CDB and CDU should address, at a minimum, the following:

- calibration;
- establishment of control limits;
- internal QC analyses and maintaining control; and
- corrective action protocols.

This illustrative program includes both initial characterization runs to establish the performance of the method and ongoing analysis of quality control samples intermixed with compliance samples to maintain control.

Calibration

Before any analytical runs are conducted, the analytic instrument must be calibrated. This is to be done at the beginning of each day on which quality control samples and/or compliance samples are run. Once calibration is established, quality control samples or compliance samples may be run. Regardless of the type of samples run, every fifth sample must be a standard to assure that the calibration is holding.

Calibration is defined as holding if every standard is within plus or minus (+ or -) 15% of its theoretical value. If a standard is more than plus or minus 15% of its theoretical value, then the run is out of control due to calibration error and the entire set of samples must either be reanalyzed after recalibrating or results should be recalculated based on a statistical curve derived from the measurement of all standards.

It is essential that the highest standard run is higher than the highest sample run. To assure that this is the case, it may be necessary to run a high standard at the end of the run, which is selected based on the results obtained over the course of the run.

All standards should be kept fresh, and as they get old, they should be compared with new standards and replaced if they exceed the new standards by + or - 15%.

Initial Characterization Runs and Establishing Control

A participating laboratory should establish four pools of quality control samples for each of the analytes for which determinations will be made. The concentrations of quality control samples within each pool are to be centered around each of the four target levels for the particular analyte identified in Section 4.4 of the protocol.

Within each pool, at least 4 quality control samples need to be established with varying concentrations ranging between plus or minus 50% of the target value of that pool. Thus for the medium-high cadmium in blood pool, the theoretical values of the quality control samples may range from 5 to 15 ug/l, (the target value is 10 ug/l). At least 4 unique theoretical values must be represented in this pool.

The range of theoretical values of plus or minus 50% of the target value of a pool means that there will be overlap of the pools. For example, the range of values for the medium-low pool for

cadmium in blood is 3.5 to 10.5 ug/l while the range of values for the medium-high pool is 5 to 15 ug/l. Therefore, it is possible for a quality control sample from the medium-low pool to have a higher concentration of cadmium than a quality control sample from the medium-high pool.

Quality control samples may be obtained as commercially available reference materials, internally prepared, or both. Internally prepared samples should be well characterized and traced or compared to a reference material for which a consensus value for concentration is available. Levels of analyte in the quality control samples must be concealed from the analyst prior to the reporting of analytical results. Potential sources of materials that may be used to construct quality control samples are listed in Section 3.3.1 of the protocol.

Before any compliance samples are analyzed, control limits must be established. Control limits should be calculated for every pool of each analyte for which determinations will be made and control charts should be kept for each pool of each analyte. A separate set of control charts and control limits should be established for each analytical instrument in a laboratory that will be used for analysis of compliance samples.

At the beginning of this QA/QC program, control limits should be based on the results of the analysis of 20 quality control samples from each pool of each analyte. For any given pool, the 20 quality control samples should be run on 20 different days. Although no more than one sample should be run from any single pool on a particular day, a laboratory may run quality control samples from different pools on the same day. This constitutes a set of initial characterization runs.

For each quality control sample analyzed, the value F/T (defined in the glossary) should be calculated. To calculate the control limits for a pool of an analyte, it is first necessary to calculate the mean, of the F/T values for each quality control sample in a pool and then to calculate its standard deviation σ (sigma). Thus, for the control limit for a pool, the mean is calculated as:

$$\frac{\left(\sum \frac{F}{T}\right)}{N}$$

and $\hat{\sigma}$ is calculated as

$$\left[\frac{\sum \left(\frac{F}{T} - \bar{X}\right)^2}{(N-1)} \right]^{\frac{1}{2}}$$

Where N is the number of quality control samples run for a pool.

The control limit for a particular pool is then given by the mean plus or minus 2 standard deviations (unbiased).

The control limits may be no greater than 40% of the mean F/T value. If three standard deviations are greater than 40% of the mean F/T value, then analysis of compliance samples may not begin(1). Instead, an investigation into the causes of the large standard deviation should begin, and the inadequacies must be remedied. Then, control limits must be reestablished which will mean repeating the running 20 quality control samples from each pool over 20 days.

Footnote(1) Note that the value, "40%" may change over time as experience is gained with the program.

Internal Quality Control Analyses and Maintaining Control

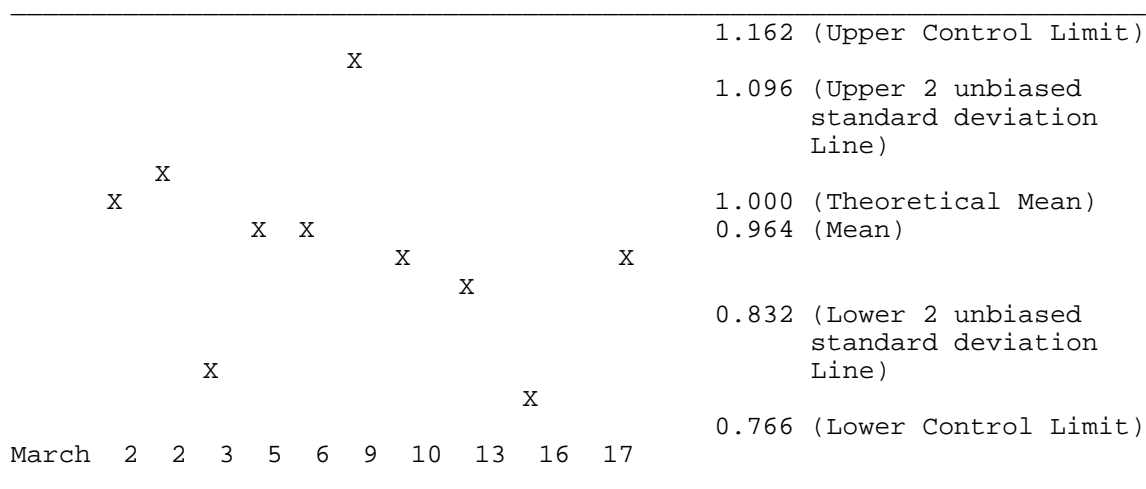
Once control limits have been established for each pool of an analyte, analysis of compliance samples may begin. During any run of compliance samples, quality control samples are to be interspersed at a rate of no less than 5% of the compliance sample workload. When quality control samples are run, however, they should be run in sets consisting of one quality control sample from each pool. Therefore, it may be necessary, at times, to intersperse quality control samples at a rate greater than 5%.

There should be at least one set of quality control samples run with any analysis of compliance samples. At a minimum, for example, 4 quality control samples should be run even if only 1 compliance sample is run. Generally, the number of quality control samples that should be run

are a multiple of four with the minimum equal to the smallest multiple of four that is greater than 5% of the total number of samples to be run. For example, if 300 compliance samples of an analyte are run, then at least 16 quality control samples should be run (16 is the smallest multiple of four that is greater than 15, which is 5% of 300).

Control charts for each pool of an analyte (and for each instrument in the laboratory to be used for analysis of compliance samples) should be established by plotting F/T versus date as the quality control sample results are reported. On the graph there should be lines representing the control limits for the pool, the mean F/T limits for the pool, and the theoretical F/T of 1.000. Lines representing plus or minus (+ or -) 2 unbiased standard deviation should also be represented on the charts. A theoretical example of a control chart is presented in Figure 1.

FIGURE 1 - THEORETICAL EXAMPLE OF A CONTROL CHART FOR A POOL OF AN ANALYTE



All quality control samples should be plotted on the chart, and the charts should be checked for visual trends. If a quality control sample falls above or below the control limits for its pool, then corrective steps must be taken (see the section on corrective actions below). Once a laboratory's program has been established, control limits should be updated every 2 months.

The updated control limits should be calculated from the results of the last 100 quality control samples run for each pool. If 100 quality control samples from a pool have not been run at the time of the update, then the limits should be based on as many as have been run provided at least 20 quality control samples from each pool have been run over 20 different days.

The trends that should be looked for on the control charts are:

1. 10 consecutive quality control samples falling above or below the mean;
2. 3 consecutive quality control samples falling more than 2 unbiased standard deviation from the mean (above or below the 2 unbiased standard deviation lines of the chart); or

3. the mean calculated to update the control limits falls more than 10% above or below the theoretical mean of 1.000.

If any of these trends is observed, then all analysis must be stopped, and an investigation into the causes of the errors must begin. Before the analysis of compliance samples may resume, the inadequacies must be remedied and the control limits must be reestablished for that pool of an analyte. Reestablishment of control limits will entail running 20 sets of quality control samples over 20 days.

Note that alternative procedures for defining internal quality control limits may also be acceptable. Limits may be based, for example, on proficiency testing, such as + or - 1 ug or 15% of the mean (whichever is greater). These should be clearly defined.

Corrective actions

Corrective action is the term used to describe the identification and remediation of errors occurring within an analysis. Corrective action is necessary whenever the result of the analysis of any quality control sample falls outside of the established control limits. The steps involved may include simple things like checking calculations of basic instrument maintenance, or it may involve more complicated actions like major instrument repair. Whatever the source of error, it must be identified and corrected (and a Corrective Action Report (CAR) must be completed. CARs should be kept on file by the laboratory.

Attachment 2

Creatinine in Urine (Jaffe Procedure)

Intended Use: The CREA pack is used in the Du Pont ACA(R) discrete clinical analyzer to quantitatively measure creatinine in serum and urine.

Summary: The CREA method employs a modification of the kinetic Jaffe reaction reported by Larsen. This method has been reported to be less susceptible than conventional methods to interference from noncreatinine, Jaffe-positive compounds(1).

Footnote(1) Note: Numbered subscripts refer to the bibliography and lettered subscripts refer to footnotes.

A split sample comparison between the CREA method and a conventional Jaffe procedure on Autoanalyzer(R) showed a good correlation. (See Specific Performance Characteristics).

Autoanalyzer,(R) is a registered trademark of Technicon Corp., Tarrytown, NY.

Principles of Procedure: In the presence of a strong base such as NaOH, picrate reacts with creatinine to form a red chromophore. The rate of increasing absorbance at 510 nm due to the formation of this chromophore during a 17.07-second measurement period is directly proportional to the creatinine concentration in the sample.

NaOH

Creatinine + Picrate ----> Red chromophore
(absorbs at 510 nm)

Reagents:

| Compartment(a) | Form | Ingredient | Quantity(b) |
|-------------------|------------|-----------------------------|-------------|
| No. 2, 3, & 4 ... | Liquid ... | Picrate | 0.11 mmol. |
| No. 6 | Liquid ... | NaOH (for pH adjustment(c)) | |

Footnote(a) Compartments are numbered 1-7, with compartment #7 located closest to pack fill position #2.

Footnote(b) Nominal value at manufacture.

Footnote(c) See Precautions.

Precautions: Compartment #6 Contains 75uL of 10 N NaOH; Avoid Contact; Skin Irritant; Rinse Contacted Area With Water. Comply With OSHA's Bloodborne Pathogens Standard While Handling Biological Samples (29 CFR 1910.1039).

Used Packs Contain Human Body Fluids; Handle With Appropriate Care.

FOR IN VITRO DIAGNOSTIC USE.

Mixing and Diluting: Mixing and diluting are automatically performed by the ACA(R) discrete clinical analyzer. The sample cup must contain sufficient quantity to accommodate the sample volume plus the "dead volume"; precise cup filling is not required.

SAMPLE CUP VOLUMES (uL)

| Analyzer | Standard | | Microsystem | |
|---------------|----------|-------|-------------|-------|
| | Dead | Total | Dead | Total |
| II, III | 120 | 3000 | 10 | 500 |
| IV, SX | 120 | 3000 | 30 | 500 |
| V | 90 | 3000 | 10 | 500 |

Storage of Unprocessed Packs: Store at 2-8 deg. C. Do not freeze. Do not expose to temperatures above 35 deg. C or to direct sunlight.

Expiration: Refer to EXPIRATION DATE on the tray label.

Specimen Collection: Serum or urine can be collected and stored by normal procedures.(2)

Known Interfering Substances:(3)

- Serum Protein Influence -- Serum protein levels exert a direct influence on the CREA assay. The following should be taken into account when this method is used for urine samples and when it is calibrated: Aqueous creatinine standards or urine specimens will give CREA results depressed by approximately 0.7 mg/dL [62 umol/L](d) and will be less precise than samples containing more than 3 g/dL [30 g/L] protein.

Footnote(d) Systeme International d'unités (S.I. Units) are in brackets.

All urine specimens should be diluted with an albumin solution to give a final protein concentration of at least 3 g/dL [30 g/L]. Du Pont Enzyme Diluent (Cat. #790035-901) may be used for this purpose.

- High concentration of endogenous bilirubin (>20 mg/dL [>342 umol/L]) will give depressed CREA results (average depression 0.8 mg/dL [71 umol/L]).(4)

- Grossly hemolyzed (hemoglobin >100 mg/dL [>62 umol/L]) or visibly lipemic specimens may cause falsely elevated CREA results.(5),(6)

- The following cephalosporin antibiotics do not interfere with the CREA method when present at the concentrations indicated. Systematic inaccuracies (bias) due to these substances are less than or equal to 0.1 mg/dL [8.84 umol/L] at CREA concentrations of approximately 1 mg/dL [88 umol/L].

| Antibiotic | Peak Serum Level (7), (8), (9) | | Drug concentration | |
|--------------------|-----------------------------------|------------|--------------------|----------|
| | mg/dL | [mmol/L] | mg/dL | [mmol/L] |
| Cephaloridine | 1.4 | 0.3 | 25 | 6.0 |
| Cephalexin | 0.6 - 2.0 | 0.2 - 0.6 | 25 | 7.2 |
| Cephmandole | 1.3 - 2.5 | 0.3 - 0.5 | 25 | 4.9 |
| Cephapirin | 2.0 | 0.4 | 25 | 5.6 |
| Cephadrine | 1.5 - 2.0 | 0.4 - 0.6 | 25 | 7.1 |
| Cefazolin | 2.5 - 5.0 | 0.55 - 1.1 | 50 | 11.0 |

- The following cephalosporin antibiotics have been shown to affect CREA results when present at the indicated concentrations. System inaccuracies (bias) due to these substances are greater than 0.1 mg/dL [8.84 umol/L] at CREA concentrations of:

| Antibiotic | Peak Serum Level (8), (10) | | Drug concentration | | |
|------------|-------------------------------|----------|--------------------|----------|--------|
| | mg/dL | [mmol/L] | mg/dL | [mmol/L] | Effect |

| | | | | | |
|----------------|-------|-----------|-----|------|--------------------------|
| Cephalothin .. | 1 - 6 | 0.2 - 1.5 | 100 | 25.2 | Below 20 - 25 percent |
| Cephoxitin ... | 2.0 | 0.5 | 5.0 | 1.2 | Above 35 - 40 percent |

- The single wavelength measurement used in this method eliminates interference from chromophores whose 510 nm absorbance is constant throughout the measurement period.

- Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot to lot.

Procedure:

TEST MATERIALS

| Item | II, III Du Pont cat. No. | IV, SX Du Pont cat. No. | V DuPont cat No. |
|--|--------------------------|-------------------------|------------------|
| ACA(R) CREA Analytical Test Pack | 701976901 | 701976901 | 701976901 |
| Sample System Kit | 710642901 | 710642901 | 713697901 |
| or | | | |
| Micro Sample System Kit | 702694901 | 710356901 | NA |
| and | | | |
| Micro Sample System Holders .. | 702785000 | NA | NA |
| DYLUX(R) Photosensitive..... | | | |
| Printer Paper | 700036000 | NA | NA |
| Thermal Printer Paper | NA | 710639901 | 713645901 |
| Du Pont Purified Water | 704209901 | 710615901 | 710815901 |
| Cell Wash Solution | 701864901 | 710664901 | 710864901 |

Test Steps: The operator need only load the sample kit and appropriate test pack(s) into a properly prepared ACA(R) discrete clinical analyzer. It automatically advances the pack(s) through the test steps and prints a result(s). See the Instrument Manual of the ACA(R) analyzer for details of mechanical travel of the test pack(s).

Preset Creatinine (CREA) Test Conditions

- Sample Volume: 200 uL.
- Diluent: Purified Water.
- Temperature: 37.0 + or - 0.1 deg. C.
- Reaction Period: 29 seconds.
- Type of Measurement: Rate.

- Measurement Period: 17.07 seconds.

- Wavelength: 510 nm.

- Units: mg/dL [umol/L].

Calibration: The general calibration procedure is described in the Calibration/Verification chapter of the Manuals.

The following information should be considered when calibrating the CREA method.

- Assay Range: 0-20 mg/mL [0-1768 umol/L](e).

Footnote(e) For the results in S.I. units [umol/L] the conversion factor is 88.4.

- Reference Material: Protein containing primary standards(f) or secondary calibrators such as Du Pont Elevated Chemistry Control (Cat. #790035903) and Normal Chemistry Control (Cat. #790035905)(g).

Footnote(f) Refer to the Creatinine Standard Preparation and Calibration Procedure available on request from a Du Pont Representative.

Footnote(g) If the Du Pont Chemistry Controls are being used, prepare them according to the instructions on the product insert sheets.

- Suggested Calibration Levels: 1,5,20, mg/mL [88, 442, 1768 umol/L].

- Calibration Scheme: 3 levels, 3 packs per level.

- Frequency: Each new pack lot. Every 3 months for any one pack lot.

PRESET CREATININE (CREA) TEST CONDITIONS

| Item | ACA(R) II analyzer | ACA(R) III, IV, SX, V analyzer |
|--------------------------|-----------------------|--------------------------------|
| Count by | One(1) [Five (5)] | NA |
| Decimal Point | 0.0 mg/dL | 000.0 mg/dL |
| Location | [000. umol/L] | [000 umol/L] |
| Assigned Starting | 999.8 | - 1.000 E1 |
| Point or Offset C(0) ... | [9823.] | [- 8.840 E2] |
| Scale Factor or | 0.2000 | 2.004 E-1(h) |
| Assigned | mg/dL/count(h) | |
| Linear Term C(1)(h)..... | [0.3536 umol/L/count. | [1.772E1] |

Footnote(h) The preset scale factor (linear term) was derived from the molar absorptivity of the indicator and is based on an absorbance to activity relationship (sensitivity) of 0.596 (mA/min)/(U/L). Due to small differences in filters and electronic components between instruments, the actual scale factor (linear term) may differ slightly from that given above.

Quality Control: Two types of quality control procedures are recommended:

- General Instrument Check. Refer to the Filter Balance Procedure and the Absorbance Test Method described in the ACA Analyzer Instrument Manual. Refer also to the ABS Test Methodology literature.

- Creatinine Method Check. At least once daily run a CREA test on a solution of known creatinine activity such as an assayed control or calibration standard other than that used to calibrate the CREA method. For further details review the Quality Assurance Section of the Chemistry Manual. The result obtained should fall within acceptable limits defined by the day-to-day variability of the system as measured in the user's laboratory. (See SPECIFIC PERFORMANCE CHARACTERISTICS for guidance.) If the result falls outside the laboratory's acceptable limits, follow the procedure outlined in the Chemistry Troubleshooting Section of the Chemistry Manual.

A possible system malfunction is indicated when analysis of a sample with five consecutive test packs gives the following results:

| Level | SD |
|---------------------------------------|-----------------------------|
| 1 mg/dL [88 umol/L] | >0.15 mg/dL [>13 umol/L] |
| 20 mg/dL [1768 umol/L] | >0.68 mg/dL [>60 umol/L] |

Refer to the procedure outlined in the Trouble Shooting Section of the Manual.

Results: The ACA(R) analyzer automatically calculates and prints the CREA result in mg/dL [umol/L].

Limitation of Procedure: Results >20 mg/dL [1768 umol/L]:

- Dilute with suitable protein base diluent. Reassay. Correct for diluting before reporting.

The reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing a letter code or word immediately following the numerical value should not be reported. Refer to the Manual for the definition of error codes.

Reference Interval

Serum:(11)(i)

Males 0.8-1.3 md/dL [71-115 umol/L]

Females 0.6-1.0 md/dL [53-88 umol/L]

Urine:(12)

Males 0.6-2.5 g/24 hr [53-221 mmol/24 hr]

Females 0.6-1.5 g/24 hr [53-133 mmol/24 hr]

Footnote(i) Reference interval data obtained from 200 apparently healthy individuals (71 males, 129 females) between the ages of 19 and 72.

Each laboratory should establish its own reference intervals for CREA as performed on the analyzer.

Specific Performance Characteristics(j)

Footnote(j) All specific performance characteristics tests were run after normal recommended equipment quality control checks were performed (see Instrument Manual).

REPRODUCIBILITY(k)

| Material | Mean | Standard Deviation (% CV) | |
|-------------------|--------|---------------------------|-------------|
| | | Within-Run | Between-Day |
| Lyophilized | 1.3 | 0.05 (3.7) | 0.05 (3.7) |
| Control | [115] | [4.4] | [4.4] |
| Lyophilized | 20.6 | 0.12 (0.6) | 0.37 (1.8) |
| Control | [1821] | [10.6] | [32.7] |

Footnote(k) Specimens at each level were analyzed in duplicate for twenty days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

CORRELATION (Regression statistics)(l)

| Comparative Method | Slope | Intercept | Correlation Coefficient | n |
|-----------------------|-------|-----------|-------------------------|-----|
| Autoanalyzer(R) | 1.03 | 0.03[2.7] | 0.997 | 260 |

Footnote(l) Model equation for regression statistics is:

Result of

ACA(R) Analyzer = Slope (Comparative method result) + intercept

Assay Range:(m) 0.0-20.0 mg/dl [0-1768 umol]

Footnote(m) See REPRODUCIBILITY for method performance within the assay range.

Analytical Specificity:

See KNOWN INTERFERING SUBSTANCES section for details.

Bibliography:

- (1) Larsen, K, Clin Chem Acta 41, 209 (1972).
- (2) Tietz, NW, Fundamentals of Clinical Chemistry, W. B. Saunders Co., Philadelphia, PA, 1976, pp 47-52, 1211.
- (3) Supplementary information pertaining to the effects of various drugs and patient conditions on in vivo or in vitro diagnostic levels can be found in "Drug Interferences with Clinical Laboratory Tests," Clin. Chem 21 (5) (1975), and "Effects of Disease on Clinical Laboratory Tests," Clin Chem, 26 (4) 1D-476D (1980).
- (4) Watkins, R. Fieldkamp, SC, Thibert, RJ, and Zak, B, Clin Chem, 21, 1002 (1975).
- (5) Kawas, EE, Richards, AH, and Bigger, R, An Evaluation of a Kinetic Creatinine Test for the Du Pont ACA, Du Pont Company, Wilmington, DE (February 1973). (Reprints available from Du Pont Company, Diagnostic Systems)
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- (7) Physicians' Desk Reference, Medical Economics Company, 33 Edition, 1979.
- (8) Henry, JB, Clinical Diagnosis and Management by Laboratory Methods, W.B. Saunders Co., Philadelphia, PA 1979, Vol. III.
- (9) Krupp, MA, Tierney, LM Jr., Jawetz, E, Roe, RI, Camargo, CA, Physicians Handbook, Lange Medical Publications, Los Altos, CA, 1982 pp 635-636.
- (10) Sarah, AJ, Koch, TR, Drusano, GL, Celoxitin Falsely Elevates Creatinine Levels, JAMA 247, 205-206 (1982).
- (11) Gadsden, RH, and Phelps, CA, A Normal Range Study of Amylase in Urine and Serum on the Du Pont ACA, Du Pont Company, Wilmington, DE (March 1978). (Reprints available from Du Pont Company, Diagnostic Systems.
- (12) Dicht, JJ, Reference Intervals for Serum Amylase and Urinary Creatinine on the Du Pont ACA(R) Discrete Clinical Analyzer, Du Pont Company, Wilmington, DE (November 1984).

Attachment 3 Analysis of Creatinine for the Normalization of Cadmium and Beta-2-Microglobulin Concentrations in Urine (OSLTC Procedure).

Matrix: Urine

Target Concentration: 1.1 g/L (this amount is representative of creatinine concentrations found in urine).

Procedure: A 1.0 mL aliquot of urine is passed through a C18 SEP-PAK(R) (Waters Associates). Approximately 30 mL of HPLC (high performance liquid chromatography) grade water is then run through the SEP-PAK. The resulting solution is diluted to volume in a 100-mL volumetric flask and analyzed by HPLC using an ultraviolet (UV) detector.

Special Requirements: After collection, samples should be appropriately stabilized for cadmium (Cd) analysis by using 10% high purity (with low Cd background levels) nitric acid (exactly 1.0 mL of 10% nitric acid per 10 mL of urine) or stabilized for Beta-2-Microglobulin (B2M) by taking to pH 7 with dilute NaOH (exactly 1.0 mL of 0.11 N NaOH per 10 mL of urine). If not immediately analyzed, the samples should be frozen and shipped by overnight mail in an insulated container.

Date: January 1992

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Chemists.

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1. General Discussion

1.1. Background

1.1.1. History of procedure

Creatinine has been analyzed by several methods in the past.

The earliest methods were of the wet chemical type. As an example, creatinine reacts with sodium picrate in basic solution to form a red complex, which is then analyzed calorimetrically (Refs. 5.1. and 5.2.).

Since industrial hygiene laboratories will be analyzing for Cd and B2M in urine, they will be normalizing those concentrations to the concentration of creatinine in urine. A literature search revealed several HPLC methods (Refs. 5.3., 5.4., 5.5. and 5.6.) for creatinine in urine and because many industrial hygiene laboratories have HPLC equipment, it was desirable to develop an industrial hygiene HPLC method for creatinine in urine. The method of Hausen, Fuchs, and Wachter was chosen as the starting point for method development. SEP-PAKs were used for sample clarification and cleanup in this method to protect the analytical column. The urine aliquot which has been passed through the SEP-PAK is then analyzed by reverse-phase HPLC using ion-pair techniques.

This method is very similar to that of Ogata and Taguchi (Ref. 5.6.), except they used centrifugation for sample clean-up. It is also of note that they did a comparison of their HPLC results to those of the Jaffe method (a picric acid method commonly used in the health care industry) and found a

linear relationship of close to 1:1. This indicates that either HPLC or colorimetric methods may be used to measure creatinine concentrations in urine.

1.1.2. Physical properties (Ref. 5.7.)

Molecular weight: 113.12

Molecular formula: C(4)-H(7)-N(3)-O

Chemical name: 2-amino-1.5-dihydro-1-methyl-4H-imidazol-4-one

CAS#: 60-27-5

Melting point: 300 deg. C (decomposes)

Appearance: white powder

Solubility: soluble in water; slightly soluble in alcohol; practically insoluble in acetone, ether, and chloroform

Synonyms: 1-methylglycocyanidene, 1-methylhydantoin-2-imide

Structure: see Figure #1

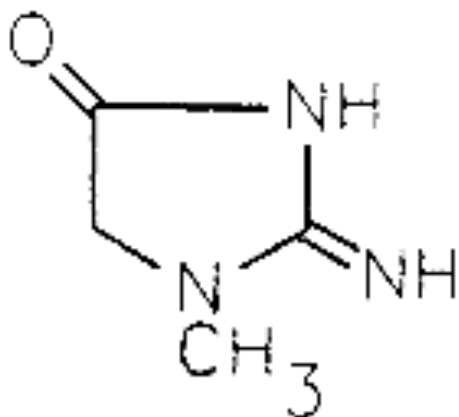


Figure #1

1.2. Advantages

1.2.1. This method offers a simple, straightforward, and specific alternative method to the Jaffe method.

1.2.2. HPLC instrumentation is commonly found in many industrial hygiene laboratories.

2. Sample stabilization procedure

2.1. Apparatus

Metal-free plastic container for urine sample.

2.2. Reagents

2.2.1. Stabilizing Solution -

(1) Nitric acid (10% high purity with low Cd background levels) for stabilizing urine for Cd analysis or

(2) NaOH, 0.11 N, for stabilizing urine for B2M analysis.

2.2.2. HPLC grade water

2.3. Technique

2.3.1. Stabilizing solution is added to the urine sample (see section 2.2.1.). The stabilizing solution should be such that for each 10 mL of urine, add exactly 1.0 mL of stabilizer solution. (Never add water or urine to acid or base. Always add acid or base to water or urine.) Exactly 1.0 mL of 0.11 N NaOH added to 10 mL of urine should result

in a pH of 7. Or add 1.0 mL of 10% nitric acid to 10 mL of urine.

2.3.2. After sample collection seal the plastic bottle securely and wrap it with an appropriate seal. Urine samples should be frozen and then shipped by overnight mail (if shipping is necessary) in an insulated container. (Do not fill plastic bottle too full. This will allow for expansion of contents during the freezing process.)

2.4. The Effect of Preparation and Stabilization Techniques on Creatinine Concentrations

Three urine samples were prepared by making one sample acidic, not treating a second sample, and adjusting a third sample to pH 7. The samples were analyzed in duplicate by two different procedures. For the first procedure a 1.0 mL aliquot of urine was put in a 100 - mL volumetric flask, diluted to volume with HPLC grade water, and then analyzed directly on an HPLC. The other procedure used SEP-PAKs. The SEP-PAK was rinsed with approximately 5 mL of methanol followed by approximately 10 mL of HPLC grade water and both rinses were discarded. Then, 1.0 mL of the urine sample was put through the SEP-PAK, followed by 30 mL of HPLC grade water. The urine and water were transferred to a 100 - mL volumetric flask, diluted to volume with HPLC grade water, and analyzed by HPLC. These three urine samples were analyzed on the day they were obtained and then frozen. The results show that whether the urine is acidic, untreated or adjusted to pH 7, the resulting answer for creatinine is essentially unchanged. The purpose of stabilizing the urine by making it acidic or neutral is for the analysis of Cd or B2M respectively.

COMPARISON OF PREPARATION AND STABILIZATION TECHNIQUES

| Sample | w/o SEP-PAC g/L creatinine) | with SEP-PAK (g/L creatinine) |
|----------------|--------------------------------|----------------------------------|
| Acid..... | 1.10 | 1.10 |
| Acid..... | 1.11 | 1.10 |
| Untreated..... | 1.12 | 1.11 |
| Untreated..... | 1.11 | 1.12 |
| pH7..... | 1.08 | 1.02 |
| pH7..... | 1.11 | 1.08 |

2.5. Storage

After 4 days and 54 days of storage in a freezer, the samples were thawed, brought to room temperature and analyzed using the same procedures as in section 2.4. The results of several days of storage show that the resulting answer for creatinine is essentially unchanged.

STORAGE DATA

| | 4 days | 54 days |
|--|--------|---------|
| | | |

| Sample | W/o SEP-PAC g/L creatinine | With SEP-PAC g/L creatinine | W/o SEP-PAC g/L creatinine | With SEP-PAC g/L creatinine |
|----------------|----------------------------------|-----------------------------------|----------------------------------|-----------------------------------|
| Acid..... | 1.09 | 1.09 | 1.08 | 1.09 |
| Acid..... | 1.10 | 1.10 | 1.09 | 1.10 |
| Acid..... | | | 1.09 | 1.09 |
| Untreated..... | 1.13 | 1.14 | 1.09 | 1.11 |
| Untreated..... | 1.15 | 1.14 | 1.10 | 1.10 |
| Untreated..... | | | 1.09 | 1.10 |
| pH 7..... | 1.14 | 1.13 | 1.12 | 1.12 |
| pH 7..... | 1.14 | 1.13 | 1.12 | 1.12 |
| pH 7..... | | | 1.12 | 1.12 |

2.6. Interferences

None.

2.7. Safety precautions

2.7.1. Make sure samples are properly sealed and frozen before shipment to avoid leakage.

2.7.2. Follow the appropriate shipping procedures.

The following modified special safety precautions are based on those recommended by the Centers for Disease Control (CDC)(Ref. 5.8.) and OSHA's Bloodborne Pathogens standard (29 CFR 1910.1039).

2.7.3. Wear gloves, lab coat, and safety glasses while handling all human urine products. Disposable plastic, glass, and paper (pipet tips, gloves, etc.) that contact urine should be placed in a biohazard autoclave bag.

These bags should be kept in appropriate containers until sealed and autoclaved. Wipe down all work surfaces with 10% sodium hypochlorite solution when work is finished.

2.7.4. Dispose of all biological samples and diluted specimens in a biohazard autoclave bag at the end of the analytical run.

2.7.5. Special care should be taken when handling and dispensing nitric acid. Always remember to add acid to water (or urine). Nitric acid is a corrosive chemical capable of severe eye and skin damage. Wear metal-free gloves, a lab coat, and safety glasses. If the nitric acid comes in contact with any part of the body, quickly wash with copious quantities of water for at least 15 minutes.

2.7.6. Special care should be taken when handling and dispensing NaOH. Always remember to add base to water (or urine). NaOH can cause severe eye and skin damage. Always wear the appropriate gloves, a lab coat, and safety glasses. If the NaOH comes in contact with any part of the body, quickly wash with copious quantities of water for at least 15 minutes.

3. Analytical Procedure

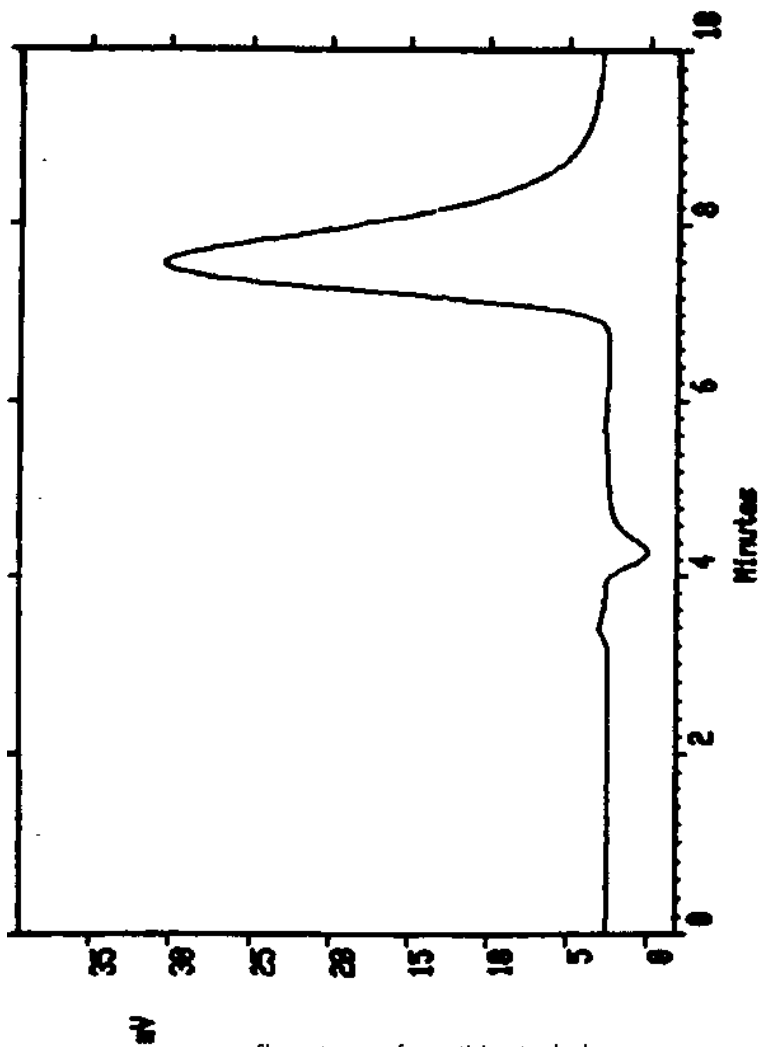
3.1. Apparatus

3.1.1. A high performance liquid chromatograph equipped with pump, sample injector and UV detector.

3.1.2. A C18 HPLC column; 25 cm X 4.6 mm I.D.

3.1.3. An electronic integrator, or some other suitable means

- of determining analyte response.
- 3.1.4. Stripchart recorder.
 - 3.1.5. C18 SEP-PAKs (Waters Associates) or equivalent.
 - 3.1.6. Luer-lock syringe for sample preparation (5 mL or 10 mL).
 - 3.1.7. Volumetric pipettes and flasks for standard and sample preparation.
 - 3.1.8. Vacuum system to aid sample preparation (optional).
- 3.2. Reagents
- 3.2.1. Water, HPLC grade.
 - 3.2.2. Methanol, HPLC grade.
 - 3.2.3. PIC B-7(R) (Waters Associates) in small vials.
 - 3.2.4. Creatinine, anhydrous, Sigma Chemical Corp., purity not listed.
 - 3.2.5. 1-Heptanesulfonic acid, sodium salt monohydrate.
 - 3.2.6. Phosphoric acid.
 - 3.2.7. Mobile phase. It can be prepared by mixing one vial of PIC B-7 into a 1 L solution of 50% methanol and 50% water. The mobile phase can also be made by preparing a solution that is 50% methanol and 50% water with 0.005M heptanesulfonic acid and adjusting the pH of the solution to 3.5 with phosphoric acid.
- 3.3. Standard preparation
- 3.3.1. Stock standards are prepared by weighing 10 to 15 mg of creatinine. This is transferred to a 25-mL volumetric flask and diluted to volume with HPLC grade water.
 - 3.3.2. Dilutions to a working range of 3 to 35 ug/mL are made in either HPLC grade water or HPLC mobile phase (standards give the same detector response in either solution).
- 3.4. Sample preparation
- 3.4.1. The C18 SEP-PAK is connected to a Luer-lock syringe. It is rinsed with 5 mL HPLC grade methanol and then 10 mL HPLC grade methanol and then 10 mL of HPLC grade water. These rinses are discarded.
 - 3.4.2. Exactly 1.0 mL of urine is pipetted into the syringe. The urine is put through the SEP-PAK into a suitable container using a vacuum system.
 - 3.4.3. The walls of the syringe are rinsed in several stages with a total of approximately 30 mL of HPLC grade water. These rinses are put through the SEP-PAK into the same container. The resulting solution is transferred to a 100-mL volumetric flask and then brought to volume with HPLC grade water.
- 3.5. Analysis (conditions and hardware are those used in this evaluation.)
- 3.5.1. Instrument conditions
Column: Zorbax(R) ODS, 5-6 um particle size; 25 cm X 4.6 mm I.D.
Mobile phase: See Section 3.2.7.
Detector: Dual wavelength UV; 229 nm (primary) 254 nm (secondary).
Flow rate: 0.7 mL/minute.
Retention time: 7.2 minutes.
Sensitivity: 0.05 AUFS.
Injection volume: 20 uL
 - 3.5.2. Chromatogram (See Figure #2).



Chromatogram of a creatinine standard
Figure #2 (mV versus minutes)

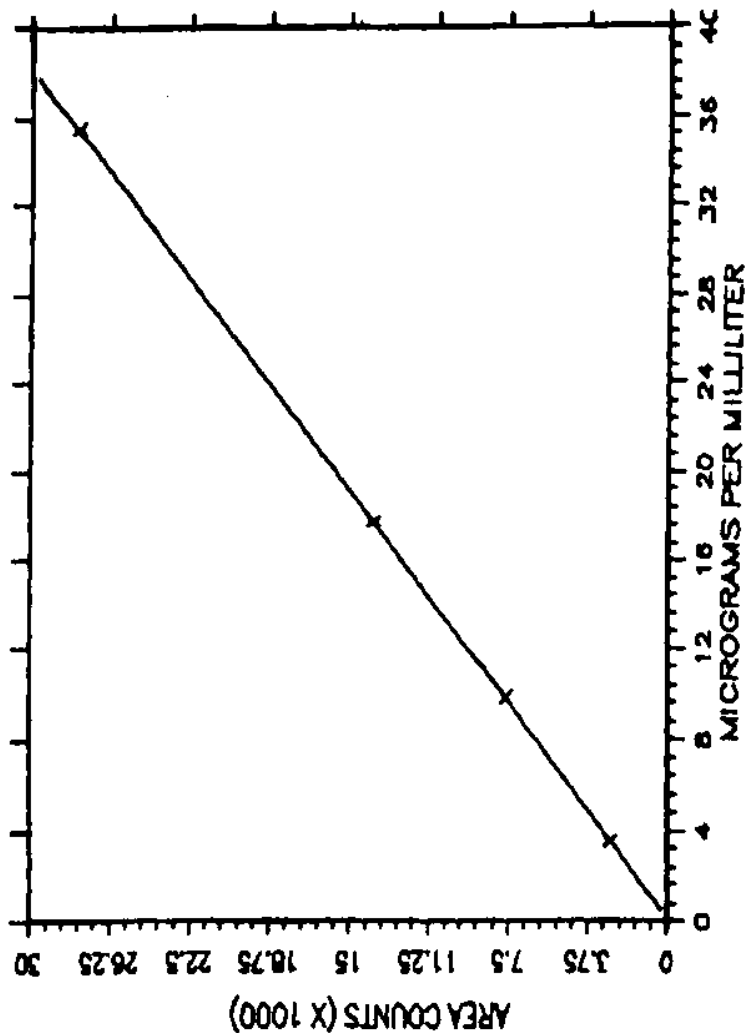
3.6. Interferences

3.6.1. Any compound that has the same retention time as creatinine and absorbs at 229 nm is an interference.

3.6.2. HPLC conditions may be varied to circumvent interferences. In addition, analysis at another UV wavelength (i.e. 254 nm) would allow a comparison of the ratio of response of a standard to that of a sample. Any deviations would indicate an interference.

3.7. Calculations

3.7.1. A calibration curve is constructed by plotting detector response versus standard concentration (See Figure #3).



Calibration curve for creatinine
Figure #3

3.7.2. The concentration of creatinine in a sample is determined by finding the concentration corresponding to its detector response. (See Figure #3).

3.7.3. The ug/mL creatinine from section 3.7.2. is then multiplied by 100 (the dilution factor). This value is equivalent to the micrograms of creatinine in the 1.0 mL stabilized urine aliquot or the milligrams of creatinine per liter of urine. The desired units, g/L is determined by the following relationship:

$$g/L = \frac{ug/mL}{1000} = \frac{mg/L}{1000}$$

3.7.4. The resulting value for creatinine is used to normalize

the urinary concentration of the desired analyte (A) (Cd or B2M) by using the following formula.

$$\frac{\text{ug A/g creatinine}}{\text{creatinine}} = \frac{\text{ug A/g creatinine}}{\text{g/L creatinine}}$$

Where A is the desired analyte. The protocol of reporting such normalized results is ug A/g creatinine.

3.8. Safety precautions. See section 2.7.

4. Conclusions

The determination of creatinine in urine by HLPC is a good alternative to the Jaffe method for industrial hygiene laboratories. Sample clarification with SEP-PAKs did not change the amount of creatinine found in urine samples. However, it does protect the analytical column. The results of the creatinine in urine procedure are unaffected by the pH of the urine sample under the conditions tested by this procedure. Therefore, no special measures are required for creatinine analysis whether the urine sample has been stabilized with 10% nitric acid for the Cd analysis or brought to a pH of 7 with 0.11 NaOH for the B2M analysis.

5. References

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1910.1028 Benzene.

(a) Scope and application.

(1) This section applies to all occupational exposures to benzene. Chemical Abstracts Service Registry No. 71-43-2, except as provided in paragraphs (a)(2) and (a)(3) of this section.

(2) This section does not apply to:

- (i) The storage, transportation, distribution, dispensing, sale or use of gasoline, motor fuels,

or other fuels containing benzene subsequent to its final discharge from bulk wholesale storage facilities, except that operations where gasoline or motor fuels are dispensed for more than 4 hours per day in an indoor location are covered by this section.

(ii) Loading and unloading operations at bulk wholesale storage facilities which use vapor control systems for all loading and unloading operations, except for the provisions of 29 CFR 1910.1200 as incorporated into this section and the emergency provisions of paragraphs (g) and (i)(4) of this section.

(iii) The storage, transportation, distribution or sale of benzene or liquid mixtures containing more than 0.1 percent benzene in intact containers or in transportation pipelines while sealed in such a manner as to contain benzene vapors or liquid, except for the provisions of 29 CFR 1910.1200 as incorporated into this section and the emergency provisions of paragraphs (g) and (i)(4) of this section.

(iv) Containers and pipelines carrying mixtures with less than 0.1 percent benzene and natural gas processing plants processing gas with less than 0.1 percent benzene.

(v) Work operations where the only exposure to benzene is from liquid mixtures containing 0.5 percent or less of benzene by volume, or the vapors released from such liquids until September 12, 1988; work operations where the only exposure to benzene is from liquid mixtures containing 0.3 percent or less of benzene by volume or the vapors released from such liquids from September 12, 1988, to September 12, 1989; and work operations where the only exposure to benzene is from liquid mixtures containing 0.1 percent or less of benzene by volume or the vapors released from such liquids after September 12, 1989; except that tire building machine operators using solvents with more than 0.1 percent benzene are covered by paragraph (i) of this section.

(vi) Oil and gas drilling, production and servicing operations.

(vii) Coke oven batteries.

(3) The cleaning and repair of barges and tankers which have contained benzene are excluded from paragraph (f) methods of compliance, paragraph (e)(1) exposure monitoring-general, and paragraph (e)(6) accuracy of monitoring. Engineering and work practice controls shall be used to keep exposures below 10 ppm unless it is proven to be not feasible.

(b) Definitions.

"Action level" means an airborne concentration of benzene of 0.5 ppm calculated as an 8-hour time-weighted average.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and

Health, U.S. Department of Labor, or designee.

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (1) of this section, or any other person authorized by the Act or regulations issued under the Act.

"Benzene" (C₆H₆) (CAS Registry No. 71-43-2) means liquefied or gaseous benzene. It includes benzene contained in liquid mixtures and the benzene vapors released by these liquids. It does not include trace amounts of unreacted benzene contained in solid materials.

"Bulk wholesale storage facility" means a bulk terminal or bulk plant where fuel is stored prior to its delivery to wholesale customers.

"Container" means any barrel, bottle, can, cylinder, drum, reaction vessel, storage tank, or the like, but does not include piping systems.

"Day" means any part of a calendar day.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may or does result in an unexpected significant release of benzene.

"Employee exposure" means exposure to airborne benzene which would occur if the employee were not using respiratory protective equipment.

"Regulated area" means any area where airborne concentrations of benzene exceed or can reasonably be expected to exceed, the permissible exposure limits, either the 8-hour time weighted average exposure of 1 ppm or the short-term exposure limit of 5 ppm for 15 minutes.

"Vapor control system" means any equipment used for containing the total vapors displaced during the loading of gasoline, motor fuel or other fuel tank trucks and the displacing of these vapors through a vapor processing system or balancing the vapor with the storage tank. This equipment also includes systems containing the vapors displaced from the storage tank during the unloading of the tank truck which balance the vapors back to the tank truck.

(c) Permissible exposure limits (PELs)

(1) Time-weighted average limit (TWA). The employer shall assure that no employee is exposed to an airborne concentration of benzene in excess of one part of benzene per million

parts of air (1 ppm) as an 8-hour time-weighted average.

(2) Short-term exposure limit (STEL). The employer shall assure that no employee is exposed to an airborne concentration of benzene in excess of five (5) ppm as averaged over any 15 minute period.

(d) Regulated areas.

(1) The employer shall establish a regulated area wherever the airborne concentration of benzene exceeds or can reasonably be expected to exceed the permissible exposure limits, either the 8-hour time weighted average exposure of 1 ppm or the short-term exposure limit of 5 ppm for 15 minutes.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be determined from the rest of the workplace in any manner that minimizes the number of employees exposed to benzene within the regulated area.

(e) Exposure monitoring

(1) General.

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of each employee's average exposure to airborne benzene.

(ii) Representative 8-hour TWA employee exposures shall be determined on the basis of one sample or samples representing the full shift exposure for each job classification in each work area.

(iii) Determinations of compliance with the STEL shall be made from 15 minute employee breathing zone samples measured at operations where there is reason to believe exposures are high, such as where tanks are opened, filled, unloaded or gauged; where containers or process equipment are opened and where benzene is used for cleaning or as a solvent in an uncontrolled situation. The employer may use objective data, such as measurements from brief period measuring devices, to determine where STEL monitoring is needed.

(iv) Except for initial monitoring as required under paragraph (e)(2) of this section, where the employer can document that one shift will consistently have higher employee exposures for an operation, the employer shall only be required to determine representative employee exposure for that operation during the shift on which the highest exposure is expected.

(2) Initial monitoring.

(i) Each employer who has a place of employment covered under paragraph (a)(1) of this section shall monitor each of these workplaces and work operations to determine accurately the airborne concentrations of benzene to which employees may be exposed.

(ii) The initial monitoring required under paragraph (e)(2)(i) of this section shall be completed by 60 days after the effective date of this standard or within 30 days of the introduction of benzene into the workplace. Where the employer has monitored within one year prior to the effective date of this standard and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (e)(2)(i) of this section.

(3) Periodic monitoring and monitoring frequency.

(i) If the monitoring required by paragraph (e)(2)(i) of this section reveals employee exposure at or above the action level but at or below the TWA, the employer shall repeat such monitoring for each such employee at least every year.

(ii) If the monitoring required by paragraph (e)(2)(i) of this section reveals employee exposure above the TWA, the employer shall repeat such monitoring for each such employee at least every six (6) months.

(iii) The employer may alter the monitoring schedule from every six months to annually for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee exposure has decreased to the TWA or below, but is at or above the action level.

(iv) Monitoring for the STEL shall be repeated as necessary to evaluate exposures of employees subject to short term exposures.

(4) Termination of monitoring.

(i) If the initial monitoring required by paragraph (e)(2)(i) of this section reveals employee exposure to be below the action level the employer may discontinue the monitoring for that employee, except as otherwise required by paragraph (e)(5) of this section.

(ii) If the periodic monitoring required by paragraph (e)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level the employer may discontinue the monitoring for that employee, except as otherwise required by paragraph (e)(5).

(5) Additional monitoring.

(i) The employer shall institute the exposure monitoring required under paragraphs (e)(2) and (e)(3) of this section when there has been a change in the production, process, control equipment, personnel or work practices which may result in new or additional exposures to benzene, or when the employer has any reason to suspect a change which may result in new or additional exposures.

(ii) Whenever spills, leaks, ruptures or other breakdowns occur that may lead to employee exposure, the employer shall monitor (using area or personal sampling) after the cleanup of the spill or repair of the leak, rupture or other breakdown to ensure that exposures have returned to the level that existed prior to the incident.

(6) Accuracy of monitoring. Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of benzene.

(7) Employee notification of monitoring results.

(i) The employer shall, within 15 working days after the receipt of the results of any monitoring performed under this standard, notify each employee of these results in writing either individually or by posting of results in an appropriate location that is accessible to affected employees. The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) Whenever the PELs are exceeded, the written notification required by paragraph (e)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce the employee exposure to or below the PEL, or shall refer to a document available to the employee which states the corrective actions to be taken.

(f) Methods of compliance

(1) Engineering controls and work practices.

(i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to benzene at or below the permissible exposure limits, except to the extent that the employer can establish that these controls are not feasible or where the provisions of paragraph (f)(1)(iii) or (g)(1) of this section apply.

(ii) Wherever the feasible engineering controls and work practices which can be instituted

are not sufficient to reduce employee exposure to or below the PELs, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section.

(iii) Where the employer can document that benzene is used in a workplace less than a total of 30 days per year, the employer shall use engineering controls, work practice controls or respiratory protection or any combination of these controls to reduce employee exposure to benzene to or below the PELs, except that employers shall use engineering and work practice controls, if feasible, to reduce exposure to or below 10 ppm as an 8-hour TWA.

(2) Compliance program.

(i) When any exposures are over the PEL, the employer shall establish and implement a written program to reduce employee exposure to or below the PEL primarily by means of engineering and work practice controls, as required by paragraph (f)(1) of this section.

(ii) The written program shall include a schedule for development and implementation of the engineering and work practice controls. These plans shall be reviewed and revised as appropriate based on the most recent exposure monitoring data, to reflect the current status of the program.

(iii) Written compliance programs shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives.

(g) Respiratory protection.

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work practice controls.

(ii) Work operations for which the employer establishes that compliance with either the TWA or STEL through the use of engineering and work-practice controls is not feasible; for example, some maintenance and repair activities, vessel cleaning, or other operations for which engineering and work-practice controls are infeasible because exposures are intermittent and limited in duration;

(iii) Work operations for which feasible engineering and work-practice controls are not yet

sufficient, or are not required under paragraph (f)(1)(iii) of this section, to reduce employee exposure to or below the PELs.

(iv) Emergencies.

(2) Respirator program.

(i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) For air-purifying respirators, the employer must replace the air-purifying element at the expiration of its service life or at the beginning of each shift in which such elements are used, whichever comes first.

(iii) If NIOSH approves an air-purifying element with an end-of-service-life indicator for benzene, such an element may be used until the indicator shows no further useful life.

(3) Respirator selection.

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with any organic vapor gas mask or any self-contained breathing apparatus with a full facepiece to use for escape.

(C) Use an organic vapor cartridge or canister with powered and non-powered air-purifying respirators, and a chin-style canister with full facepiece gas masks.

(D) Ensure that canisters used with non-powered air-purifying respirators have a minimum service life of four hours when tested at 150 ppm benzene at a flow rate of 64 liters per minute (LPM), a temperature of 25 [deg]C, and a relative humidity of 85%; for canisters used with tight-fitting or loose-fitting powered air-purifying respirators, the flow rates for testing must be 115 LPM and 170 LPM, respectively.

(ii) Any employee who cannot use a negative-pressure respirator must be allowed to use a respirator with less breathing resistance, such as a powered air-purifying respirator or supplied-air respirator.

(h) Protective clothing and equipment. Personal protective clothing and equipment shall be worn where appropriate to prevent eye contact and limit dermal exposure to liquid benzene. Protective clothing and equipment shall be provided by the employer at no cost to the employee

and the employer shall assure its use where appropriate. Eye and face protection shall meet the requirements of 29 CFR 1910.133.

(i) Medical surveillance

(1) General.

(i) The employer shall make available a medical surveillance program for employees who are or may be exposed to benzene at or above the action level 30 or more days per year; for employees who are or may be exposed to benzene at or above the PELs 10 or more days per year; for employees who have been exposed to more than 10 ppm of benzene for 30 or more days in a year prior to the effective date of the standard when employed by their current employer; and for employees involved in the tire building operations called tire building machine operators, who use solvents containing greater than 0.1 percent benzene.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician and that all laboratory tests are conducted by an accredited laboratory.

(iii) The employer shall assure that persons other than licensed physicians who administer the pulmonary function testing required by this section shall complete a training course in spirometry sponsored by an appropriate governmental, academic or professional institution.

(iv) The employer shall assure that all examinations and procedures are provided without cost to the employee and at a reasonable time and place.

(2) Initial examination.

(i) Within 60 days of the effective date of this standard, or before the time of initial assignment, the employer shall provide each employee covered by paragraph (i)(1)(i) of this section with a medical examination including the following elements:

(A) A detailed occupational history which includes:

- (1) Past work exposure to benzene or any other hematological toxins,
- (2) A family history of blood dyscrasias including hematological neoplasms;
- (3) A history of blood dyscrasias including genetic hemoglobin abnormalities, bleeding abnormalities, abnormal function of formed blood elements;
- (4) A history of renal or liver dysfunction;
- (5) A history of medicinal drugs routinely taken;

(6) A history of previous exposure to ionizing radiation and

(7) Exposure to marrow toxins outside of the current work situation.

(B) A complete physical examination.

(C) Laboratory tests. A complete blood count including a leukocyte count with differential, a quantitative thrombocyte count, hematocrit, hemoglobin, erythrocyte count and erythrocyte indices (MCV, MCH, MCHC). The results of these tests shall be reviewed by the examining physician.

(D) Additional tests as necessary in the opinion of the examining physician, based on alterations to the components of the blood or other signs which may be related to benzene exposure; and

(E) For all workers required to wear respirators for at least 30 days a year, the physical examination shall pay special attention to the cardiopulmonary system and shall include a pulmonary function test.

(ii) No initial medical examination is required to satisfy the requirements of paragraph (i)(2)(i) of this section if adequate records show that the employee has been examined in accordance with the procedures of paragraph (i)(2)(i) of this section within the twelve months prior to the effective date of this standard.

(3) Periodic examinations.

(i) The employer shall provide each employee covered under paragraph (i)(1)(i) of this section with a medical examination annually following the previous examination. These periodic examinations shall include at least the following elements:

(A) A brief history regarding any new exposure to potential marrow toxins, changes in medicinal drug use, and the appearance of physical signs relating to blood disorders:

(B) A complete blood count including a leukocyte count with differential, quantitative thrombocyte count, hemoglobin, hematocrit, erythrocyte count and erythrocyte indices (MCV, MCH, MCHC); and

(C) Appropriate additional tests as necessary, in the opinion of the examining physician, in consequence of alterations in the components of the blood or other signs which may be related to benzene exposure.

(ii) Where the employee develops signs and symptoms commonly associated with toxic exposure to benzene, the employer shall provide the employee with an additional medical examination which shall include those elements considered appropriate by the examining physician.

(iii) For persons required to use respirators for at least 30 days a year, a pulmonary function test shall be performed every three (3) years. A specific evaluation of the cardiopulmonary system shall be made at the time of the pulmonary function test.

(4) Emergency examinations.

(i) In addition to the surveillance required by (i)(1)(i), if an employee is exposed to benzene in an emergency situation, the employer shall have the employee provide a urine sample at the end of the employee's shift and have a urinary phenol test performed on the sample within 72 hours. The urine specific gravity shall be corrected to 1.024.

(ii) If the result of the urinary phenol test is below 75 mg phenol/L of urine, no further testing is required.

(iii) If the result of the urinary phenol test is equal to or greater than 75 mg phenol/L of urine, the employer shall provide the employee with a complete blood count including an erythrocyte count, leukocyte count with differential and thrombocyte count at monthly intervals for a duration of three (3) months following the emergency exposure.

(iv) If any of the conditions specified in paragraph (i)(5)(i) of this section exists, then the further requirements of paragraph (i)(5) of this section shall be met and the employer shall, in addition, provide the employees with periodic examinations if directed by the physician.

(5) Additional examinations and referrals.

(i) Where the results of the complete blood count required for the initial and periodic examinations indicate any of the following abnormal conditions exist, then the blood count shall be repeated within 2 weeks.

(A) The hemoglobin level or the hematocrit falls below the normal limit [outside the 95% confidence interval (C.I.)] as determined by the laboratory for the particular geographic area and/or these indices show a persistent downward trend from the individual's pre-exposure norms; provided these findings cannot be explained by other medical reasons.

(B) The thrombocyte (platelet) count varies more than 20 percent below the employee's most recent values or falls outside the normal limit (95% C.I.) as determined by the laboratory.

(C) The leukocyte count is below 4,000 per mm³ or there is an abnormal differential

count.

(ii) If the abnormality persists, the examining physician shall refer the employee to a hematologist or an internist for further evaluation unless the physician has good reason to believe such referral is unnecessary. (See Appendix C for examples of conditions where a referral may be unnecessary.)

(iii) The employer shall provide the hematologist or internist with the information required to be provided to the physician under paragraph (i)(6) of this section and the medical record required to be maintained by paragraph (k)(2)(ii) of this section.

(iv) The hematologist's or internist's evaluation shall include a determination as to the need for additional tests, and the employer shall assure that these tests are provided.

(6) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this regulation and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's actual or representative exposure level;

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous employment-related medical examinations of the affected employee which is not otherwise available to the examining physician.

(7) Physician's written opinions.

(i) For each examination under this section, the employer shall obtain and provide the employee with a copy of the examining physician's written opinion within 15 days of the examination. The written opinion shall be limited to the following information:

(A) The occupationally pertinent results of the medical examination and tests;

(B) The physician's opinion concerning whether the employee has any detected medical conditions which would place the employee's health at greater than normal risk of material impairment from exposure to benzene;

(C) The physician's recommended limitations upon the employee's exposure to benzene or upon the employee's use of protective clothing or equipment and respirators.

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from benzene exposure which require further explanation or treatment.

(ii) The written opinion obtained by the employer shall not reveal specific records, findings and diagnoses that have no bearing on the employee's ability to work in a benzene-exposed workplace.

(8) Medical removal plan.

(i) When a physician makes a referral to a hematologist/internist as required under paragraph (i)(5)(ii) of this section, the employee shall be removed from areas where exposures may exceed the action level until such time as the physician makes a determination under paragraph (i)(8)(ii) of this section.

(ii) Following the examination and evaluation by the hematologist/internist, a decision to remove an employee from areas where benzene exposure is above the action level or to allow the employee to return to areas where benzene exposure is above the action level shall be made by the physician in consultation with the hematologist/internist. This decision shall be communicated in writing to the employer and employee. In the case of removal, the physician shall state the required probable duration of removal from occupational exposure to benzene above the action level and the requirements for future medical examinations to review the decision.

(iii) For any employee who is removed pursuant to paragraph (i)(8)(ii) of this section, the employer shall provide a follow-up examination. The physician, in consultation with the hematologist/internist, shall make a decision within 6 months of the date the employee was removed as to whether the employee shall be returned to the usual job or whether the employee should be removed permanently.

(iv) Whenever an employee is temporarily removed from benzene exposure pursuant to paragraph (i)(8)(i) or (i)(8)(ii) of this section, the employer shall transfer the employee to a comparable job for which the employee is qualified (or can be trained for in a short period) and where benzene exposures are as low as possible, but in no event higher than the action level. The employer shall maintain the employee's current wage rate, seniority and other benefits. If there is no such job available, the employer shall provide medical removal protection benefits until such a job becomes available or for 6 months, whichever comes first.

(v) Whenever an employee is removed permanently from benzene exposure based on a physician's recommendation pursuant to paragraph (i)(8)(iii) of this section, the employee shall be given the opportunity to transfer to another position which is available or later becomes available for which the employee is qualified (or can be trained for in a short period) and where

benzene exposures are as low as possible but in no event higher than the action level. The employer shall assure that such employee suffers no reduction in current wage rate, seniority or other benefits as a result of the transfer.

(9) Medical removal protection benefits.

(i) The employer shall provide to an employee 6 months of medical removal protection benefits immediately following each occasion an employee is removed from exposure to benzene because of hematological findings pursuant to paragraphs (i)(8) (i) and (ii) of this section, unless the employee has been transferred to a comparable job where benzene exposures are below the action level.

(ii) For the purposes of this section, the requirement that an employer provide medical removal protection benefits means that the employer shall maintain the current wage rate, seniority and other benefits of an employee as though the employee had not been removed.

(iii) The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or from employment with another employer made possible by virtue of the employee's removal.

(j) ~~Communication of benzene hazards to employees~~ Communication of hazards

(1) Hazard communication—general.

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for benzene.

(ii) In classifying the hazards of benzene at least the following hazards are to be addressed: Cancer; central nervous system effects; blood effects; aspiration; skin, eye, and respiratory tract irritation; and flammability.

(iii) Employers shall include benzene in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of benzene and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j)(3) of this section.

~~(1)(2) Signs and labels.~~ Warning signs and labels.

(i) The employer shall post signs at entrances to regulated areas. The signs shall bear the following legend:

~~DANGER~~
~~BENZENE~~
~~CANCER HAZARD~~
~~FLAMMABLE—NO SMOKING~~
~~AUTHORIZED PERSONNEL ONLY~~
~~RESPIRATOR REQUIRED~~
DANGER
BENZENE
MAY CAUSE CANCER
HIGHLY FLAMMABLE LIQUID AND VAPOR; DO NOT SMOKE
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(ii) ~~The employer shall ensure that labels or other appropriate forms of warning are provided for containers of benzene within the workplace. There is no requirement to label pipes. The labels shall comply with the requirements of 29 CFR 1910.1200(f) and in addition shall include the following legend: Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(2)(i) of this section:~~

~~DANGER~~
~~CONTAINS BENZENE~~
~~CANCER HAZARD~~
DANGER
BENZENE
CANCER HAZARD
FLAMMABLE--NO SMOKING
AUTHORIZED PERSONNEL ONLY
RESPIRATOR REQUIRED

(iii) The employer shall ensure that labels or other appropriate forms of warning are provided for containers of benzene within the workplace. There is no requirement to label pipes. The labels shall comply with the requirements of paragraph (j)(1) of this section and § 1910.1200(f).

(iv) Prior to June 1, 2015, employers shall include the following legend or similar language on the labels or other appropriate forms of warning:

DANGER
CONTAINS BENZENE
CANCER HAZARD

~~(2) Material safety data sheets.~~

~~-(i) Employers shall obtain or develop, and shall provide access to their employees, to a material safety data sheet (MSDS) which addresses benzene and complies with 29 CFR 1910.1200.—~~

~~-(ii) Employers who are manufacturers or importers shall:~~

~~-~~

~~-(A) Comply with paragraph (a) of this section, and~~

~~-(B) Comply with the requirement in OSHA's Hazard Communication Standard, 29 CFR 1910.1200, that they deliver to downstream employers an MSDS which addresses benzene.~~

(3) Information and training.

(i) The employer shall provide employees with information and training at the time of their initial assignment to a work area where benzene is present. If exposures are above the action level, employees shall be provided with information and training at least annually thereafter.

(ii) The training program shall be in accordance with the requirements of 29 CFR 1910.1200(h) (1) and (2), and shall include specific information on benzene for each category of information included in that section.

(iii) In addition to the information required under 29 CFR 1910.1200, the employer shall:

(A) Provide employees with an explanation of the contents of this section, including Appendices A and B, and indicate to them where the standard is available; and

(B) Describe the medical surveillance program required under paragraph (i) of this section, and explain the information contained in Appendix C.

(k) Recordkeeping

(1) Exposure measurements.

(i) The employer shall establish and maintain an accurate record of all measurements required by paragraph (e) of this section, in accordance with 29 CFR 1910.1020. /SAVE

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the procedure used to determine representative employee exposures;

(B) A description of the sampling and analytical methods used;

(C) A description of the type of respiratory protective devices worn, if any; and

(D) The name, social security number, job classification and exposure levels of the employee monitored and all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 30 years, in accordance with 29 CFR 1910.1020.

(2) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance required by paragraph (i) of this section, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The name and social security number of the employee;

(B) The employer's copy of the physician's written opinion on the initial, periodic and special examinations, including results of medical examinations and all tests, opinions and recommendations;

(C) Any employee medical complaints related to exposure to benzene;

(D) A copy of the information provided to the physician as required by paragraphs (i)(6)(ii) through (v) of this section; and

(E) A copy of the employee's medical and work history related to exposure to benzene or any other hematologic toxins.

(iii) The employer shall maintain this record for at least the duration of employment plus 30 years, in accordance with 29 CFR 1910.1020.

(3) Availability.

(i) The employer shall assure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure monitoring records required by this paragraph shall be provided upon request for examination and copying to employees, employee representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a) through (e) and (g) through (i).

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying, to the subject employee, to anyone having the specific written consent of the subject employee, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

(4) Transfer of records.

(i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three (3) months prior to disposal, and transmit them to the Director if required by the Director within that period.

(l) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees, or their designated representatives, an opportunity to observe the measuring or monitoring of employee exposure to benzene conducted pursuant to paragraph (e) of this section. /SAVE

(2) Observation procedures. When observation of the measuring or monitoring of employee exposure to benzene requires entry into areas where the use of protective clothing and equipment or respirators is required, the employer shall provide the observer with personal protective clothing and equipment or respirators required to be worn by employees working in the area, assure the use of such clothing and equipment or respirators, and require the observer to comply with all other applicable safety and health procedures.

(m) [Reserved]

(n) **Appendices.** The information contained in Appendices A, B, C, and D is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligations.

1910.1028 App A Substance safety data sheet, Benzene

APPENDIX A to 1910.1028 - SUBSTANCE SAFETY DATA SHEET, BENZENE

I. Substance Identification

A. Substance: Benzene.

B. Permissible Exposure: Except as to the use of gasoline, motor fuels and other fuels subsequent to discharge from bulk terminals and other exemptions specified in 1910.1028(a)(2):

1. Airborne: The maximum time-weighted average (TWA) exposure limit is 1 part of benzene vapor per million parts of air (1 ppm) for an 8-hour workday and the maximum short-term exposure limit (STEL) is 5 ppm for any 15-minute period.

2. Dermal: Eye contact shall be prevented and skin contact with liquid benzene shall be limited.

C. Appearance and odor: Benzene is a clear, colorless liquid with a pleasant, sweet odor. The odor of benzene does not provide adequate warning of its hazard.

II. Health Hazard Data

A. Ways in which benzene affects your health. Benzene can affect your health if you inhale it, or if it comes in contact with your skin or eyes. Benzene is also harmful if you happen to swallow it.

B. Effects of overexposure.

1. Short-term (acute) overexposure: If you are overexposed to high concentrations of benzene, well above the levels where its odor is first recognizable, you may feel breathless, irritable, euphoric, or giddy; you may experience irritation in eyes, nose, and respiratory tract. You may develop a headache, feel dizzy, nauseated, or intoxicated. Severe exposures may lead to convulsions and loss of consciousness.

2. Long-term (chronic) exposure. Repeated or prolonged exposure to benzene, even at relatively low concentrations, may result in various blood disorders, ranging from anemia to leukemia, an irreversible, fatal disease. Many blood disorders associated with benzene exposure may occur without symptoms.

III. Protective Clothing and Equipment

A. Respirators. Respirators are required for those operations in which engineering controls or work practice controls are not feasible to reduce exposure to the permissible level. However, where employers can document that benzene is present in the workplace less than 30 days a year, respirators may be used in lieu of engineering controls. If respirators are worn, they must have joint Mine Safety and Health Administration and the National Institute for Occupational Safety and Health (NIOSH) seal of approval, and cartridge or canisters must be replaced before the end

of their service life, or the end of the shift, whichever occurs first. If you experience difficulty breathing while wearing a respirator, you may request a positive pressure respirator from your employer. You must be thoroughly trained to use the assigned respirator, and the training will be provided by your employer.

B. Protective Clothing. You must wear appropriate protective clothing (such as boots, gloves, sleeves, aprons, etc.) over any parts of your body that could be exposed to liquid benzene.

C. Eye and Face Protection. You must wear splash-proof safety goggles if it is possible that benzene may get into your eyes. In addition, you must wear a face shield if your face could be splashed with benzene liquid.

IV. Emergency and First Aid Procedures

A. Eye and face exposure. If benzene is splashed in your eyes, wash it out immediately with large amounts of water. If irritation persists or vision appears to be affected see a doctor as soon as possible.

B. Skin exposure. If benzene is spilled on your clothing or skin, remove the contaminated clothing and wash the exposed skin with large amounts of water and soap immediately. Wash contaminated clothing before you wear it again.

C. Breathing. If you or any other person breathes in large amounts of benzene, get the exposed person to fresh air at once. Apply artificial respiration if breathing has stopped. Call for medical assistance or a doctor as soon as possible. Never enter any vessel or confined space where the benzene concentration might be high without proper safety equipment and at least one other person present who will stay outside. A life line should be used.

D. Swallowing. If benzene has been swallowed and the patient is conscious, do not induce vomiting. Call for medical assistance or a doctor immediately.

V. Medical Requirements

If you are exposed to benzene at a concentration at or above 0.5 ppm as an 8-hour time-weighted average, or have been exposed at or above 10 ppm in the past while employed by your current employer, your employer is required to provide a medical examination and history and laboratory tests within 60 days of the effective date of this standard and annually thereafter. These tests shall be provided without cost to you. In addition, if you are accidentally exposed to benzene (either by ingestion, inhalation, or skin/eye contact) under emergency conditions known or suspected to constitute toxic exposure to benzene, your employer is required to make special laboratory tests available to you.

VI. Observation of Monitoring

Your employer is required to perform measurements that are representative of your exposure to benzene and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the s taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear the protective clothing and equipment.

VII. Access to Records

You or your representative are entitled to see the records of measurements of your exposure to benzene upon written request to your employer. Your medical examination records can be furnished to yourself, your physician or designated representative upon request by you to your employer.

VIII. Precautions for Safe Use, Handling and Storage

Benzene liquid is highly flammable. It should be stored in tightly closed containers in a cool, well ventilated area. Benzene vapor may form explosive mixtures in air. All sources of ignition must be controlled. Use nonsparking tools when opening or closing benzene containers. Fire extinguishers, where provided, must be readily available. Know where they are located and how to operate them. Smoking is prohibited in areas where benzene is used or stored. Ask your supervisor where benzene is used in your area and for additional plant safety rules.

1910.1028 App B Substance technical guidelines, Benzene

APPENDIX B to 1910.1028 - SUBSTANCE TECHNICAL GUIDELINES, BENZENE

I. Physical and Chemical Data

A. Substance identification.

1. Synonyms: Benzol, benzole, coal naphtha, cyclohexatriene, phene, phenyl hydride, pyrobenzol. (Benzin, petroleum benzin and Benzine do not contain benzene).

2. Formula: C(6)H(6) (CAS Registry Number: 71-43-2)

B. Physical data.

1. Boiling Point (760 mm Hg); 80.1 deg. C (176 deg. F)

2. Specific Gravity (water = 1): 0.879

3. Vapor Density (air = 1): 2.7
4. Melting Point: 5.5 deg. C (42 deg. F)
5. Vapor Pressure at 20 deg. C (68 deg. F): 75 mm Hg
6. Solubility in Water: .06%
7. Evaporation Rate (ether = 1): 2.8
8. Appearance and Odor: Clear, colorless liquid with a distinctive sweet odor.

II. Fire, Explosion, and Reactivity Hazard Data

A. Fire.

1. Flash Point (closed cup): - 11 deg. C (12 deg. F)
2. Autoignition Temperature: 580 deg. C (1076 deg. F)
3. Flammable limits in Air. % by Volume: Lower: 1.3%, Upper: 7.5%
4. Extinguishing Media: Carbon dioxide, dry chemical, or foam.
5. Special Fire-Fighting procedures: Do not use solid stream of water, since stream will scatter and spread fire. Fine water spray can be used to keep fire-exposed containers cool.
6. Unusual fire and explosion hazards: Benzene is a flammable liquid. Its vapors can form explosive mixtures. All ignition sources must be controlled when benzene is used, handled, or stored. Where liquid or vapor may be released, such areas shall be considered as hazardous locations. Benzene vapors are heavier than air; thus the vapors may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which benzene is handled.
7. Benzene is classified as a 1 B flammable liquid for the purpose of conforming to the requirements of 29 CFR 1910.106. A concentration exceeding 3,250 ppm is considered a potential fire explosion hazard. Locations where benzene may be present in quantities sufficient to produce explosive or ignitable mixtures are considered Class I Group D for the purposes of conforming to the requirements of 29 CFR 1910.309.

B. Reactivity.

1. Conditions contributing to instability: Heat.
2. Incompatibility: Heat and oxidizing materials.
3. Hazardous decomposition products: Toxic gases and vapors (such as carbon monoxide).

III. Spill and Leak Procedures

A. s to be taken if the material is released or spilled. As much benzene as possible should be absorbed with suitable materials, such as dry sand or earth. That remaining must be flushed with large amounts of water. Do not flush benzene into a confined space, such as a sewer, because of explosion danger. Remove all ignition sources. Ventilate enclosed places.

B. Waste disposal method. Disposal methods must conform to other jurisdictional regulations. If allowed, benzene may be disposed of: (a) By absorbing it in dry sand or earth and disposing in a sanitary landfill; (b) if small quantities, by removing it to a safe location from buildings or other combustible sources, pouring it in dry sand or earth and cautiously igniting it; and (c) if large quantities, by atomizing it in a suitable combustion chamber.

IV. Miscellaneous Precautions

A. High exposure to benzene can occur when transferring the liquid from one container to another. Such operations should be well ventilated and good work practices must be established to avoid spills.

B. Use non-sparking tools to open benzene containers which are effectively grounded and bonded prior to opening and pouring.

C. Employers must advise employees of all plant areas and operations where exposure to benzene could occur. Common operations in which high exposures to benzene may be encountered are: the primary production and utilization of benzene, and transfer of benzene.

1910.1028 App C Medical surveillance guidelines for Benzene

APPENDIX C to 1910.1028 - MEDICAL SURVEILLANCE GUIDELINES FOR BENZENE

I. Route of Entry

Inhalation; skin absorption.

II. Toxicology

Benzene is primarily an inhalation hazard. Systemic absorption may cause depression of the

hematopoietic system, pancytopenia, aplastic anemia, and leukemia. Inhalation of high concentrations can affect central nervous system function. Aspiration of small amounts of liquid benzene immediately causes pulmonary edema and hemorrhage of pulmonary tissue. There is some absorption through the skin. Absorption may be more rapid in the case of abraded skin, and benzene may be more readily absorbed if it is present in a mixture or as a contaminant in solvents which are readily absorbed. The defatting action of benzene may produce primary irritation due to repeated or prolonged contact with the skin. High concentrations are irritating to the eyes and the mucous membranes of the nose, and respiratory tract.

III. Signs and Symptoms

Direct skin contact with benzene may cause erythema. Repeated or prolonged contact may result in drying, scaling dermatitis, or development of secondary skin infections. In addition, there is benzene absorption through the skin. Local effects of benzene vapor or liquid on the eye are slight. Only at very high concentrations is there any smarting sensation in the eye. Inhalation of high concentrations of benzene may have an initial stimulatory effect on the central nervous system characterized by exhilaration, nervous excitation, and/or giddiness, followed by a period of depression, drowsiness, or fatigue. A sensation of tightness in the chest accompanied by breathlessness may occur and ultimately the victim may lose consciousness. Tremors, convulsions and death may follow from respiratory paralysis or circulatory collapse in a few minutes to several hours following severe exposures.

The detrimental effect on the blood-forming system of prolonged exposure to small quantities of benzene vapor is of extreme importance. The hematopoietic system is the chief target for benzene's toxic effects which are manifested by alterations in the levels of formed elements in the peripheral blood. These effects have occurred at concentrations of benzene which may not cause irritation of mucous membranes, or any unpleasant sensory effects. Early signs and symptoms of benzene morbidity are varied, often not readily noticed and non-specific. Subjective complaints of headache, dizziness, and loss of appetite may precede or follow clinical signs. Rapid pulse and low blood pressure, in addition to a physical appearance of anemia, may accompany a subjective complaint of shortness of breath and excessive tiredness. Bleeding from the nose, gums, or mucous membranes, and the development of purpuric spots (small bruises) may occur as the condition progresses. Clinical evidence of leukopenia, anemia, and thrombocytopenia, singly or in combination, has been frequently reported among the first signs.

Bone marrow may appear normal, aplastic, or hyperplastic, and may not, in all situations, correlate with peripheral blood forming tissues. Because of variations in the susceptibility to benzene morbidity, there is no "typical" blood picture. The onset of effects of prolonged benzene exposure may be delayed for many months or years after the actual exposure has ceased and identification or correlation with benzene exposure must be sought out in the occupational history.

IV. Treatment of Acute Toxic Effects

Remove from exposure immediately. Make sure you are adequately protected and do not risk being overcome by fumes. Give oxygen or artificial resuscitation if indicated. Flush eyes, wash skin if contaminated and remove all contaminated clothing. Symptoms of intoxication may persist following severe exposures. Recovery from mild exposures is usually rapid and complete.

V. Surveillance and Preventive Considerations

A. General

The principal effects of benzene exposure which form the basis for this regulation are pathological changes in the hematopoietic system, reflected by changes in the peripheral blood and manifesting clinically as pancytopenia, aplastic anemia, and leukemia. Consequently, the medical surveillance program is designed to observe, on a regular basis, blood indices for early signs of these effects, and although early signs of leukemia are not usually available, emerging diagnostic technology and innovative regimes make consistent surveillance for leukemia, as well as other hematopoietic effects, essential.

Initial examinations are to be provided within 60 days of the effective date of this standard, or at the time of initial assignment, and periodic examinations annually thereafter. There are special provisions for medical tests in the event of hematologic abnormalities or for emergency situations.

The blood values which require referral to a hematologist or internist are noted in the standard in paragraph (i)(5). The standard specifies that blood abnormalities that persist must be referred "unless the physician has good reason to believe such referral is unnecessary" (paragraph (i)(5)). Examples of conditions that could make a referral unnecessary despite abnormal blood limits are iron or folate deficiency, menorrhagia, or blood loss due to some unrelated medical abnormality.

Symptoms and signs of benzene toxicity can be non-specific. Only a detailed history and appropriate investigative procedures will enable a physician to rule out or confirm conditions that place the employee at increased risk. To assist the examining physician with regard to which laboratory tests are necessary and when to refer an employee to the specialist, OSHA has established the following guidelines.

B. Hematology Guidelines

A minimum battery of tests is to be performed by strictly standardized methods.

1. Red cell, white cell, platelet counts, white blood cell differential, hematacrit and red cell indices must be performed by an accredited laboratory. The normal ranges for the red cell and white cell counts are influenced by altitude, race, and sex, and therefore should be determined by

the accredited laboratory in the specific area where the tests are performed.

Either a decline from an absolute normal or an individual's base line to a subnormal value or a rise to a supra-normal value, are indicative of potential toxicity, particularly if all blood parameters decline. The normal total white blood count is approximately 7,200/mm³ plus or minus 3,000. For cigarette smokers the white count may be higher and the upper range may be 2,000 cells higher than normal for the laboratory. In addition, infection, allergies and some drugs may raise the white cell count. The normal platelet count is approximately 250,000 with a range of 140,000 to 400,000. Counts outside this range should be regarded as possible evidence of benzene toxicity.

Certain abnormalities found through routine screening are of greater significance in the benzene-exposed worker and require prompt consultation with a specialist, namely:

a. Thrombocytopenia.

b. A trend of decreasing white cell, red cell, or platelet indices in an individual over time is more worrisome than an isolated abnormal finding at one test time. The importance of trend highlights the need to compare an individual's test results to baseline and/or previous periodic tests.

c. A constellation or pattern of abnormalities in the different blood indices is of more significance than a single abnormality. A low white count not associated with any abnormalities in other cell indices may be a normal statistical variation, whereas if the low white count is accompanied by decreases in the platelet and/or red cell indices, such a pattern is more likely to be associated with benzene toxicity and merits thorough investigation.

Anemia, leukopenia, macrocytosis or an abnormal differential white blood cell count should alert the physician to further investigate and/or refer the patient if repeat tests confirm the abnormalities. If routine screening detects an abnormality, follow-up tests which may be helpful in establishing the etiology of the abnormality are the peripheral blood smear and the reticulocyte count.

The extreme range of normal for reticulocytes is 0.4 to 2.5 percent of the red cells, the usual range being 0.5 to 1.2 percent of the red cells, but the typical value is in the range of 0.8 to 1.0 percent. A decline in reticulocytes to levels of less than 0.4 percent is to be regarded as possible evidence (unless another specific cause is found) of benzene toxicity requiring accelerated surveillance. An increase in reticulocyte levels to about 2.5 percent may also be consistent with (but is not as characteristic of) benzene toxicity.

2. An important diagnostic test is a careful examination of the peripheral blood smear. As with reticulocyte count the smear should be with fresh uncoagulated blood obtained from a needle tip following venipuncture or from a drop of earlobe blood (capillary blood). If necessary,

the smear may, under certain limited conditions, be made from a blood sample anticoagulated with EDTA (but never with oxalate or heparin). When the smear is to be prepared from a specimen of venous blood which has been collected by a commercial Vacutainer type tube containing neutral EDTA, the smear should be made as soon as possible after the venesection. A delay of up to 12 hours is permissible between the drawing of the blood specimen into EDTA and the preparation of the smear if the blood is stored at refrigerator (not freezing) temperature.

3. The minimum mandatory observations to be made from the smear are:

- a. The differential white blood cell count.
- b. Description of abnormalities in the appearance of red cells.
- c. Description of any abnormalities in the platelets.

d. A careful search must be made throughout of every blood smear for immature white cells such as band forms (in more than normal proportion, i.e., over 10 percent of the total differential count), any number of metamyelocytes, myelocytes or myeloblasts. Any nucleate or multinucleated red blood cells should be reported. Large "giant" platelets or fragments of megakaryocytes must be recognized.

An increase in the proportion of band forms among the neutrophilic granulocytes is an abnormality deserving special mention, for it may represent a change which should be considered as an early warning of benzene toxicity in the absence of other causative factors (most commonly infection). Likewise, the appearance of metamyelocytes, in the absence of another probable cause, is to be considered a possible indication of benzene-induced toxicity.

An upward trend in the number of basophils, which normally do not exceed about 2.0 percent of the total white cells, is to be regarded as possible evidence of benzene toxicity. A rise in the eosinophil count is less specific but also may be suspicious of toxicity if the rises above 6.0 percent of the total white count.

The normal range of monocytes is from 2.0 to 8.0 percent of the total white count with an average of about 5.0 percent. About 20 percent of individuals reported to have mild but persisting abnormalities caused by exposure to benzene show a persistent monocytosis. The findings of a monocyte count which persists at more than 10 to 12 percent of the normal white cell count (when the total count is normal) or persistence of an absolute monocyte count in excess of 800/mm³ should be regarded as a possible sign of benzene-induced toxicity.

A less frequent but more serious indication of benzene toxicity is the finding in the peripheral blood of the so-called "pseudo" (or acquired) Pelger-Huet anomaly. In this anomaly many, or sometimes the majority, of the neutrophilic granulocytes possess two round nuclear segments - less often one or three round segments - rather than three normally elongated segments. When this anomaly is not hereditary, it is often but not invariably predictive of subsequent leukemia.

However, only about two percent of patients who ultimately develop acute myelogenous leukemia show the acquired Pelger-Huet anomaly. Other tests that can be administered to investigate blood abnormalities are discussed below; however, such procedures should be undertaken by the hematologist.

An uncommon sign, which cannot be detected from the smear, but can be elicited by a "sucrose water test" of peripheral blood, is transient paroxysmal nocturnal hemoglobinuria (PNH), which may first occur insidiously during a period of established aplastic anemia, and may be followed within one to a few years by the appearance of rapidly fatal acute myelogenous leukemia. Clinical detection of PNH, which occurs in only one or two percent of those destined to have acute myelogenous leukemia, may be difficult; if the "sucrose water test" is positive, the somewhat more definitive Ham test, also known as the acid-serum hemolysis test, may provide confirmation.

e. Individuals documented to have developed acute myelogenous leukemia years after initial exposure to benzene may have progressed through a preliminary phase of hematologic abnormality. In some instances pancytopenia (i.e., a lowering in the counts of all circulating blood cells of bone marrow origin, but not to the extent implied by the term "aplastic anemia") preceded leukemia for many years. Depression of a single blood cell type or platelets may represent a harbinger of aplasia or leukemia. The finding of two or more cytopenias, or pancytopenia in a benzene-exposed individual, must be regarded as highly suspicious of more advanced although still reversible, toxicity. "Pancytopenia" coupled with the appearance of immature cells (myelocytes, myeloblasts, erythroblasts, etc.), with abnormal cells (pseudo Pelger-Huet anomaly, atypical nuclear heterochromatin, etc.), or unexplained elevations of white blood cells must be regarded as evidence of benzene overexposure unless proved otherwise. Many severely aplastic patients manifested the ominous finding of 5-10 percent myeloblasts in the marrow, occasional myeloblasts and myelocytes in the blood and 20-30% monocytes. It is evident that isolated cytopenias, pancytopenias, and even aplastic anemias induced by benzene may be reversible and complete recovery has been reported on cessation of exposure. However, since any of these abnormalities is serious, the employee must immediately be removed from any possible exposure to benzene vapor. Certain tests may substantiate the employee's prospects for progression or regression. One such test would be an examination of the bone marrow, but the decision to perform a bone marrow aspiration or needle biopsy is made by the hematologist.

The findings of basophilic stippling in circulating red blood cells (usually found in 1 to 5% of red cells following marrow injury), and detection in the bone marrow of what are termed "ringed sideroblasts" must be taken seriously, as they have been noted in recent years to be premonitory signs of subsequent leukemia.

Recently peroxidase-staining of circulating or marrow neutrophil granulocytes, employing benzidine dihydrochloride, have revealed the disappearance of, or diminution in, peroxidase in a sizable proportion of the granulocytes, and this has been reported as an early sign of leukemia. However, relatively few patients have been studied to date. Granulocyte granules are normally

strongly peroxidase positive. A steady decline in leukocyte alkaline phosphatase has also been reported as suggestive of early acute leukemia. Exposure to benzene may cause an early rise in serum iron, often but not always associated with a fall in the reticulocyte count. Thus, serial measurements of serum iron levels may provide a means of determining whether or not there is a trend representing sustained suppression of erythropoiesis.

Measurement of serum iron, determination of peroxidase and of alkaline phosphatase activity in peripheral granulocytes can be performed in most pathology laboratories. Peroxidase and alkaline phosphatase staining are usually undertaken when the index of suspicion for leukemia is high.

1910.1028 App D Sampling and analytical methods for Benzene monitoring and measurement procedures

APPENDIX D to 1910.1028 - SAMPLING AND ANALYTICAL METHODS FOR BENZENE MONITORING AND MEASUREMENT PROCEDURES

Measurements taken for the purpose of determining employee exposure to benzene are best taken so that the representative average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Short-time interval samples (or grab samples) may also be used to determine average exposure level if a minimum of five measurements are taken in a random manner over the 8-hour work shift. Random sampling means that any portion of the work shift has the same chance of being sampled as any other. The arithmetic average of all such random samples taken on one work shift is an estimate of an employee's average level of exposure for that work shift. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee). Sampling and analysis must be performed with procedures meeting the requirements of the standard.

There are a number of methods available for monitoring employee exposures to benzene. The sampling and analysis may be performed by collection of the benzene vapor or charcoal absorption tubes, with subsequent chemical analysis by gas chromatography. Sampling and analysis may also be performed by portable direct reading instruments, real-time continuous monitoring systems, passive dosimeters or other suitable methods. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring must have an accuracy, to a 95 percent confidence level, of not less than plus or minus 25 percent for concentrations of benzene greater than or equal to 0.5 ppm.

The OSHA Laboratory modified NIOSH Method S311 and evaluated it at a benzene air concentration of 1 ppm. A procedure for determining the benzene concentration in bulk material samples was also evaluated. This work, reported in OSHA Laboratory Method No. 12, includes the following two analytical procedures:

I. OSHA Method 12 for Air Samples

Analyte: Benzene Matrix: Air Procedure: Adsorption on charcoal, desorption with carbon disulfide, analysis by GC. Detection limit: 0.04 ppm Recommended air volume and sampling rate: 10L to 0.2 L/min.

1. Principle of the Method.

1.1 A known volume of air is drawn through a charcoal tube to trap the organic vapors present.

1.2. The charcoal in the tube is transferred to a small, stoppered vial, and the analyte is desorbed with carbon disulfide.

1.3. An aliquot of the desorbed sample is injected into a gas chromatograph.

1.4 The area of the resulting peak is determined and compared with areas obtained from standards.

2. Advantages and disadvantages of the method.

2.1 The sampling device is small, portable, and involved no liquids. Interferences are minimal, and most of those which do occur can be eliminated by altering chromatographic conditions. The samples are analyzed by means of a quick, instrumental method.

2.2 The amount of sample which can be taken is limited by the number of milligrams that the tube will hold before overloading. When the sample value obtained for the backup section of the charcoal tube exceeds 25 percent of that found on the front section, the possibility of sample loss exists.

3. Apparatus.

3.1 A calibrated personal sampling pump whose flow can be determined within (+ or -) 5 percent at the recommended flow rate.

3.2. Charcoal tubes: Glass with both ends flame sealed, 7 cm long with a 6-mm O.D. and a 4-mm I.D., containing 2 sections of 20/40 mesh activated charcoal separated by a 2-mm portion of urethane foam. The activated charcoal is prepared from coconut shells and is fired at 600 deg. C prior to packing. The adsorbing section contains 100 mg of charcoal, the back-up section 50 mg. A 3-mm portion of urethane foam is placed between the outlet end of the tube and the back-up section. A plug of silanized glass wool is placed in front of the adsorbing section. The pressure drop across the tube must be less than one inch of mercury at a flow rate of 1 liter per minute.

3.3. Gas chromatograph equipped with a flame ionization detector.

3.4. Column (10-ft X 1/8 -in stainless steel) packed with 80/100 Supelcoport coated with 20 percent SP 2100, 0.1 percent CW 1500.

- 3.5. An electronic integrator or some other suitable method for measuring peak area.
- 3.6. Two-milliliter sample vials with Teflon-lined caps.
- 3.7. Microliter syringes: 10-microliter (10-uL syringe, and other convenient sizes for making standards, 1-uL syringe for sample injections.
- 3.8. Pipets: 1.0 mL delivery pipets
- 3.9. Volumetric flasks: convenient sizes for making standard solutions.

4. Reagents.

4.1. Chromatographic quality carbon disulfide (CS₂). Most commercially available carbon disulfide contains a trace of benzene which must be removed. It can be removed with the following procedure:

Heat under reflux for 2 to 3 hours, 500 mL of carbon disulfide, 10 mL concentrated sulfuric acid, and 5 drops of concentrated nitric acid. The benzene is converted to nitrobenzene. The carbon disulfide layer is removed, dried with anhydrous sodium sulfate, and distilled. The recovered carbon disulfide should be benzene free. (It has recently been determined that benzene can also be removed by passing the carbon disulfide through 13x molecular sieve).

4.2. Benzene, reagent grade.

4.3. p-Cymene, reagent grade, (internal standard).

4.4. Desorbing reagent. The desorbing reagent is prepared by adding 0.05 mL of p-cymene per milliliter of carbon disulfide. (The internal standard offers a convenient means correcting analytical response for slight inconsistencies in the size of sample injections. If the external standard technique is preferred, the internal standard can be eliminated).

4.5. Purified GC grade helium, hydrogen and air.

5. Procedure.

5.1. Cleaning of equipment. All glassware used for the laboratory analysis should be properly cleaned and free of organics which could interfere in the analysis.

5.2. Calibration of personal pumps. Each pump must be calibrated with a representative charcoal tube in the line.

5.3. Collection and shipping of samples.

5.3.1. Immediately before sampling, break the ends of the tube to provide an opening at least one-half the internal diameter of the tube (2 mm).

5.3.2. The smaller section of the charcoal is used as the backup and should be placed nearest the sampling pump.

5.3.3. The charcoal tube should be placed in a vertical position during sampling to minimize channeling through the charcoal.

5.3.4 Air being sampled should not be passed through any hose or tubing before entering the charcoal tube.

5.3.5. A sample size of 10 liters is recommended. Sample at a flow rate of approximately 0.2 liters per minute. The flow rate should be known with an accuracy of at least (+ or -) 5 percent.

5.3.6. The charcoal tubes should be capped with the supplied plastic caps immediately after sampling.

5.3.7. Submit at least one blank tube (a charcoal tube subjected to the same handling procedures, without having any air drawn through it) with each set of samples.

5.3.8. Take necessary shipping and packing precautions to minimize breakage of samples.

5.4. Analysis of samples.

5.4.1. Preparation of samples. In preparation for analysis, each charcoal tube is scored with a file in front of the first section of charcoal and broken open. The glass wool is removed and discarded. The charcoal in the first (larger) section is transferred to a 2-ml vial. The separating section of foam is removed and discarded; the second section is transferred to another capped vial. These two sections are analyzed separately.

5.4.2. Desorption of samples. Prior to analysis, 1.0 mL of desorbing solution is pipetted into each sample container. The desorbing solution consists of 0.05 uL internal standard per mL of carbon disulfide. The sample vials are capped as soon as the solvent is added. Desorption should be done for 30 minutes with occasional shaking.

5.4.3. GC conditions. Typical operating conditions for the gas chromatograph are:

1.30 mL/min (60 psig) helium carrier gas flow.

2.30 mL/min (40 psig) hydrogen gas flow to detector.

3.240 mL/min (40 psig) air flow to detector.

4.150 deg. C injector temperature.

5.250 deg. C detector temperature.

6.100 deg. C column temperature.

5.4.4. Injection size. 1 uL.

5.4.5. Measurement of area. The peak areas are measured by an electronic integrator or some other suitable form of area measurement.

5.4.6. An internal standard procedure is used. The integrator is calibrated to report results in ppm for a 10 liter air sample after correction for desorption efficiency.

5.5. Determination of desorption efficiency.

5.5.1. Importance of determination. The desorption efficiency of a particular compound can vary from one laboratory to another and from one lot of chemical to another. Thus, it is necessary to determine, at least once, the percentage of the specific compound that is removed in the desorption process, provided the same batch of charcoal is used.

5.5.2. Procedure for determining desorption efficiency. The reference portion of the charcoal tube is removed. To the remaining portion, amounts representing 0.5X, 1X, and 2X and (X represents target concentration) based on a 10 L air sample are injected into several tubes at each level. Dilutions of benzene with carbon disulfide are made to allow injection of measurable quantities. These tubes are then allowed to equilibrate at least overnight. Following equilibration they are analyzed following the same procedure as the samples. Desorption efficiency is determined by dividing the amount of benzene found by amount spiked on the tube.

6. Calibration and standards. A series of standards varying in concentration over the range of interest is prepared and analyzed under the same GC conditions that will be used on the samples. A calibration curve is prepared by plotting concentration (ug/mL) versus peak area.

7. Calculations. Benzene air concentration can be calculated from the following equation:

$$\text{mg/m}^3 = (A)(B)/(C)(D)$$

Where: A = ug/mL benzene, obtained from the calibration curve

B = desorption volume (1 mL)

C = Liters of air sampled

D = desorption efficiency

The concentration in mg/m³ can be converted to ppm (at 25 deg. and 760 mm) with following equation:

$$\text{ppm} = (\text{mg/m}^3)(24.46)/(78.11)$$

Where: 24.46 = molar volume of an ideal gas 25 deg. C and 760 mm

78.11 = molecular weight of benzene

8. Backup Data.

8.1 Detection limit-Air Samples.

The detection limit for the analytical procedure is 1.28 ng with a coefficient of variation of 0.023 at this level. This would be equivalent to an air concentration of 0.04 ppm for a 10 L air sample. This amount provided a chromatographic peak that could be identifiable in the presence of possible interferences. The detection limit data were obtained by making 1 uL injections of a 1.283 ug/mL standard.

| Injection | Area Count | |
|-----------|------------|------------|
| 1 | 655.4 | |
| 2 | 617.5 | |
| 3 | 662.0 | X = 640.2 |
| 4 | 641.1 | SD = 14.9 |
| 5 | 636.4 | CV = 0.023 |
| 6 | 629.2 | |

8.2. Pooled coefficient of variation - Air Samples. The pooled coefficient of variation for the analytical procedure was determined by 1 uL replicate injections of analytical standards. The standards were 16.04, 32.08, and 64.16 ug/mL, which are equivalent to 0.5, 1.0, and 2.0 ppm for a 10 L air sample respectively.

| Injection | Area Counts | | |
|-------------|-------------|---------|---------|
| | 0.5 ppm | 1.0 ppm | 2.0 ppm |
| 1 | 3996.5 | 8130.2 | 16481 |
| 2 | 4059.4 | 8235.6 | 16493 |
| 3 | 4052.0 | 8307.9 | 16535 |
| 4 | 4027.2 | 8263.2 | 16609 |
| 5 | 4046.8 | 8291.1 | 16552 |
| 6 | 4137.9 | 8288.8 | 16618 |
| X = | 4053.3 | 8254.0 | 16548.3 |
| SD = | 47.2 | 62.5 | 57.1 |
| CV = | 0.0116 | 0.0076 | 0.0034 |
| CV = 0.008. | | | |

8.3. Storage data - Air Samples

Samples were generated at 1.03 ppm benzene at 80% relative humidity, 22 deg. C, and 643 mm. All samples were taken for 50 minutes at 0.2 L/min. Six samples were analyzed immediately and the rest of the samples were divided into two groups by fifteen samples each. One group was stored at refrigerated temperature of 25 deg. C, and the other group was stored at ambient temperature (approximately 23 deg. C). These samples were analyzed over a period of fifteen days. The results are tabulated below.

PERCENT RECOVERY

| Day analyzed | Refrigerated | | | Ambient | | |
|--------------|--------------|------|------|---------|------|------|
| | 0 | 97.4 | 98.7 | 98.9 | 97.4 | 98.7 |

| | | | | | | |
|----------|------|-------|-------|------|-------|-------|
| 0 | 97.1 | 100.6 | 100.9 | 97.1 | 100.6 | 100.9 |
| 2 | 95.8 | 96.4 | 95.4 | 95.4 | 96.6 | 96.9 |
| 5 | 93.9 | 93.7 | 92.4 | 92.4 | 94.3 | 94.1 |
| 9 | 93.6 | 95.5 | 94.6 | 95.2 | 95.6 | 96.6 |
| 13 | 94.3 | 95.3 | 93.7 | 91.0 | 95.0 | 94.6 |
| 15 | 96.8 | 95.8 | 94.2 | 92.9 | 96.3 | 95.9 |

8.4. Desorption data.

Samples were prepared by injecting liquid benzene onto the A section of charcoal tubes. Samples were prepared that would be equivalent to 0.5, 1.0, and 2.0 ppm for a 10 L air sample.

PERCENT RECOVERY

| Sample | 0.5 ppm | 1.0 ppm | 2.0 ppm |
|------------|------------|------------|------------|
| 1 | 99.4 | 98.8 | 99.5 |
| 2 | 99.5 | 98.7 | 99.7 |
| 3 | 99.2 | 98.6 | 99.8 |
| 4 | 99.4 | 99.1 | 100.0 |
| 5 | 99.2 | 99.0 | 99.7 |
| 6 | 99.8 | 99.1 | 99.9 |
| X = | 99.4 | 98.9 | 99.8 |
| SD = | 0.22 | 0.21 | 0.18 |
| CV = | 0.0022 | 0.0021 | 0.0018 |
| X = 99.4 | | | |

8.5. Carbon disulfide.

Carbon disulfide from a number of sources was analyzed for benzene contamination. The results are given in the following table. The benzene contaminant can be removed with the procedures given in section 4.1.

| Sample | ug Benzene/mL | ppm equivalent (for 10 L air sample) |
|-------------------------|------------------|---|
| Aldrich Lot 83017 | 4.20. | 0.13 |
| Baker Lot 720364 | 1.01. | 0.03 |
| Baker Lot 822351 | 1.01. | 0.03 |
| Malinkrodt Lot WEMP .. | 1.74. | 0.05 |
| Malinkrodt Lot WDSJ .. | 5.65. | 0.18 |
| Malinkrodt Lot WHGA .. | 2.90. | 0.09 |
| Treated CS2 | | |

II. OSHA LABORATORY METHOD NO. 12 FOR BULK SAMPLES

Analyte: Benzene.

Matrix: Bulk Samples.

Procedure: Bulk Samples are analyzed directly by high performance liquid chromatography (HPLC).

Detection limits: 0.01% by volume.

1. Principle of the method.

1.1. An aliquot of the bulk sample to be analyzed is injected into a liquid chromatograph.

1.2. The peak area for benzene is determined and compared to areas obtained from standards.

2. Advantages and disadvantages of the method.

2.1. The analytical procedure is quick, sensitive, and reproducible.

2.2. Reanalysis of samples is possible.

2.3. Interferences can be circumvented by proper selection of HPLC parameters.

2.4. Samples must be free of any particulates that may clog the capillary tubing in the liquid chromatograph. This may require distilling the sample or clarifying with a clarification kit.

3. Apparatus.

3.1. Liquid chromatograph equipped with a UV detector.

3.2. HPLC Column that will separate benzene from other components in the bulk sample being analyzed. The column used for validation studies was a Waters uBondapack C18, 30 cm x 3.9 mm.

3.3. A clarification kit to remove any particulates in the bulk if necessary.

3.4. A micro-distillation apparatus to distill any samples if necessary.

3.5. An electronic integrator or some other suitable method of measuring peak areas.

3.6. Microliter syringes - 10 uL syringe and other convenient sizes for making standards. 10 uL syringe for sample injections.

3.7. Volumetric flasks, 5 mL and other convenient sizes for preparing standards and making dilutions.

4. Reagents.

4.1. Benzene, reagent grade.

4.2. HPLC grade water, methyl alcohol, and isopropyl alcohol.

5. Collection and shipment of samples.

5.1. Samples should be transported in glass containers with Teflon-lined caps.

5.2. Samples should not be put in the same container used for air samples.

6. Analysis of samples.

6.1. Sample preparation.

If necessary, the samples are distilled or clarified. Samples are analyzed undiluted. If the benzene concentration is out of the working range, suitable dilutions are made with isopropyl alcohol.

6.2. HPLC conditions.

The typical operating conditions for the high performance liquid chromatograph are:

1. Mobile phase - Methyl alcohol/water, 50/50

1. Analytical wavelength - 254 nm

3. Injection size - 10 uL

6.3. Measurement of peak area and calibration.

Peak areas are measured by an integrator or other suitable means. The integrator is calibrated to report results % in benzene by volume.

7. Calculations.

Since the integrator is programmed to report results in % benzene by volume in an undiluted sample, the following equation is used:

% Benzene by Volume = A x B

Where: A = % by volume on report

B = Dilution Factor

(B = 1 for undiluted sample)

8. Backup Data.

8.1. Detection limit - Bulk Samples.

The detection limit for the analytical procedure for bulk samples is 0.88 ug, with a coefficient of variation of 0.019 at this level. This amount provided a chromatographic peak that could be identifiable in the presence of possible interferences. The detection limit data were obtained by making 10 uL injections of a 0.10% by volume standard.

| Injection | Area Count | |
|-----------|------------|-------------|
| 1 | 45386 | |
| 2 | 44214 | |
| 3 | 43822 | X = 44040.1 |
| 4 | 44062 | SD = 852.5 |
| 6 | 42724 | CV = 0.019 |

8.2. Pooled coefficient of variation - Bulk Samples.

The pooled coefficient of variation for analytical procedure was determined by 50 uL replicate injections of analytical standards. The standards were 0.01, 0.02, 0.04, 0.10, 1.0, and 2.0% benzene by volume.

AREA COUNT (PERCENT)

| Injection No. | 0.01 | 0.02 | 0.04 | 0.10 | 1.0 | 2.0 |
|---------------|---------|---------|--------|--------|---------|---------|
| 1 | 45386 | 84737 | 166097 | 448497 | 4395380 | 9339150 |
| 2 | 44241 | 84300 | 170832 | 441299 | 4590800 | 9484900 |
| 3 | 43822 | 83835 | 164160 | 443719 | 4593200 | 9557580 |
| 4 | 44062 | 84381 | 164445 | 444842 | 4642350 | 9677060 |
| 5 | 44006 | 83012 | 168398 | 442564 | 4646430 | 9766240 |
| 6 | 42724 | 81957 | 173002 | 443975 | 4646260 | |
| X = | 44040.1 | 83703.6 | 167872 | 444149 | 4585767 | 9564986 |
| SD = | 852.5 | 1042.2 | 3589.8 | 2459.1 | 96839.3 | 166233 |
| CV = | 0.0194 | 0.0125 | 0.0213 | 0.0055 | 0.0211 | 0.0174 |
| CV = | 0.017 | | | | | |

1910.1028 App E Qualitative and Quantitative fit testing procedures [Reserved]

APPENDIX E to 1910.1028 - QUALITATIVE AND QUANTITATIVE FIT TESTING PROCEDURES [Reserved]

1910.1029 Coke oven emissions. CPL 2-2.28A

(a) Scope and application. This section applies to the control of employee exposure to coke oven emissions, except that this section shall not apply to working conditions with regard to which other Federal agencies exercise statutory authority to prescribe or enforce standards affecting occupational safety and health.

(b) Definitions. For the purpose of this section: "Authorized person" means any person

specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring and measuring procedures under paragraph (n) of this section.

"Beehive oven" means a coke oven in which the products of carbonization other than coke are not recovered, but are released into the ambient air.

"Coke oven" means a retort in which coke is produced by the destructive distillation or carbonization of coal.

"Coke oven battery" means a structure containing a number of slot-type coke ovens.

"Coke oven emissions" means the benzene-soluble fraction of total particulate matter present during the destructive distillation or carbonization of coal for the production of coke.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or his or her designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure which is likely to, or does, result in any massive release of coke oven emissions.

"Existing coke oven battery" means a battery in operation or under construction on January 20, 1977, and which is not a rehabilitated coke oven battery.

"Rehabilitated coke oven battery" means a battery which is rebuilt, overhauled, renovated, or restored such as from the pad up, after January 20, 1977.

"Secretary" means the Secretary of Labor, U.S. Department of Labor, or his or her designee.

"Stage charging" means a procedure by which a predetermined volume of coal in each larry car hopper is introduced into an oven such that no more than two hoppers are discharging simultaneously.

"Sequential charging" means a procedure, usually automatically timed, by which a predetermined volume of coal in each larry car hopper is introduced into an oven such that no more than two hoppers commence or finish discharging simultaneously although, at some point, all hoppers are discharging simultaneously.

"Pipeline charging" means any apparatus used to introduce coal into an oven which uses a pipe or duct permanently mounted onto an oven and through which coal is charged.

"Green plush" means coke which when removed from the oven results in emissions due to the

presence of unvolatilized coal.

(c) Permissible exposure limit. The employer shall assure that no employee in the regulated area is exposed to coke oven emissions at concentrations greater than 150 micrograms per cubic meter of air (150 ug/m³), averaged over any 8-hour period.

(d) Regulated areas.

(1) The employer shall establish regulated areas and shall limit access to them to authorized persons.

(2) The employer shall establish the following as regulated areas:

(i) The coke oven battery including topside and its machinery, pushside and its machinery, coke side and its machinery, and the battery ends; the wharf; and the screening station;

(ii) The beehive oven and its machinery.

(e) Exposure monitoring and measurement

(1) Monitoring program.

(i) Each employer who has a place of employment where coke oven emissions are present shall monitor employees employed in the regulated area to measure their exposure to coke oven emissions.

(ii) The employer shall obtain measurements which are representative of each employee's exposure to coke oven emissions over an eight-hour period. All measurements shall determine exposure without regard to the use of respiratory protection. STD 1-4.3

(iii) The employer shall collect fullshift (for at least seven continuous hours) personal samples, including at least one sample during each shift for each battery and each job classification within the regulated areas including at least the following job classifications:

(A) Lidman;

(B) Tar chaser;

(C) Larry car operator;

(D) Luterman;

(E) Machine operator, coke side;

- (F) Benchman, coke side;
- (G) Benchman, pusher side;
- (H) Heater;
- (I) Quenching car operator;
- (J) Pusher machine operator;
- (K) Screening station operator;
- (L) Wharfman;
- (M) Oven patcher;
- (N) Oven repairman;
- (O) Spellman; and
- (P) Maintenance personnel.

(iv) The employer shall repeat the monitoring and measurements required by this paragraph (e)(1) at least every three months.

(2) Redetermination. Whenever there has been a production, process, or control change which may result in new or additional exposure to coke oven emissions, or whenever the employer has any other reason to suspect an increase in employee exposure, the employer shall repeat the monitoring and measurements required by paragraph (e)(1) of this section for those employees affected by such change or increase.

(3) Employee notification.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) Whenever such results indicate that the representative employee exposure exceeds the permissible exposure limit, the employer shall, in such notification, inform each employee of that fact and of the corrective action being taken to reduce exposure to or below the permissible exposure limit.

(4) Accuracy of measurement. The employer shall use a method of monitoring and measurement which has an accuracy (with a confidence level of 95%) of not less than plus or minus 35% for concentrations of coke oven emissions greater than or equal to 150 ug/m(3).

(f) Methods of compliance. The employer shall control employee exposure to coke oven emissions by the use of engineering controls, work practices and respiratory protection as follows: STD 1-4.3

(1) Priority of compliance methods

(i) Existing coke oven batteries.

(a) The employer shall institute the engineering and work practice controls listed in paragraphs (f)(2), (f)(3) and (f)(4) of this section in existing coke oven batteries at the earliest possible time, but not later than January 20, 1980, except to the extent that the employer can establish that such controls are not feasible. In determining the earliest possible time for institution of engineering and work practice controls, the requirement, effective August 27, 1971, to implement feasible administrative or engineering controls to reduce exposures to coal tar pitch volatiles, shall be considered. Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section. STD 1-4.3

(b) The engineering and work practice controls required under paragraphs (f)(2), (f)(3) and (f)(4) of this section are minimum requirements generally applicable to all existing coke oven batteries. If, after implementing all controls required by paragraphs (f)(2), (f)(3) and (f)(4) of this section, or after January 20, 1980, whichever is sooner, employee exposures still exceed the permissible exposure limit, employers shall implement any other engineering and work practice controls necessary to reduce exposure to or below the permissible exposure limit except to the extent that the employer can establish that such controls are not feasible. Whenever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section. STD 1.43

(ii) New or rehabilitated coke oven batteries.

(a) The employer shall institute the best available engineering and work practice controls on all new or rehabilitated coke oven batteries to reduce and maintain employee exposures at or below the permissible exposure limit, except to the extent that the employer can establish that such controls are not feasible. Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure

limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section. STD 1.43

(b) If, after implementing all the engineering and work practice controls required by paragraph (f)(1)(ii)(a) of this section, employee exposures still exceed the permissible exposure limit, the employer shall implement any other engineering and work practice controls necessary to reduce exposure to or below the permissible exposure limit except to the extent that the employer can establish that such controls are not feasible. Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section. STD 1.43

(iii) Beehive ovens.

(a) The employer shall institute engineering and work practice controls on all beehive ovens at the earliest possible time to reduce and maintain employee exposures at or below the permissible exposure limit, except to the extent that the employer can establish that such controls are not feasible. In determining the earliest possible time for institution of engineering and work practice controls, the requirement, effective August 27, 1971, to implement feasible administrative or engineering controls to reduce exposures to coal tar pitch volatiles, shall be considered. Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section. STD 1.43

(b) If, after implementing all engineering and work practice controls required by paragraph (f)(1)(iii)(a) of this section, employee exposures still exceed the permissible exposure limit, the employer shall implement any other engineering and work practice controls necessary to reduce exposures to or below the permissible exposure limit except to the extent that the employer can establish that such controls are not feasible. Whenever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section. STD 1.43

(2) Engineering controls

(i) Charging. The employer shall equip and operate existing coke oven batteries with all of

the following engineering controls to control coke oven emissions during charging operations:

(a) One of the following methods of charging:

(1) Stage charging as described in paragraph (f)(3)(i)(b) of this section; or

(2) Sequential charging as described in paragraph (f)(3)(i)(b) of this section except that paragraph (f)(3)(i)(b)(3)(iv) of this section does not apply to sequential charging; or

(3) Pipeline charging or other forms of enclosed charging in accordance with paragraph (f)(2)(i) of this section, except that paragraphs (f)(2)(i)(b), (d), (e), (f) and (h) of this section do not apply;

(b) Drafting from two or more points in the oven being charged, through the use of double collector mains, or a fixed or movable jumper pipe system to another oven, to effectively remove the gases from the oven to the collector mains;

(c) Aspiration systems designed and operated to provide sufficient negative pressure and flow volume to effectively move the gases evolved during charging into the collector mains, including sufficient steam pressure, and steam jets of sufficient diameter;

(d) Mechanical volumetric controls on each larry car hopper to provide the proper amount of coal to be charged through each charging hole so that the tunnel head will be sufficient to permit the gases to move from the oven into the collector mains;

(e) Devices to facilitate the rapid and continuous flow of coal into the oven being charged, such as stainless steel liners, coal vibrators or pneumatic shells;

(f) Individually operated larry car drop sleeves and slide gates designed and maintained so that the gases are effectively removed from the oven into the collector mains;

(g) Mechanized gooseneck and standpipe cleaners;

(h) Air seals on the pusher machine leveler bars to control air infiltration during charging; and

(i) Roof carbon cutters or a compressed air system or both on the pusher machine rams to remove roof carbon.

(ii) Coking. The employer shall equip and operate existing coke oven batteries with all of the following engineering controls to control coke oven emissions during coking operations;

- (a) A pressure control system on each battery to obtain uniform collector main pressure;
- (b) Ready access to door repair facilities capable of prompt and efficient repair of doors, door sealing edges and all door parts;
- (c) An adequate number of spare doors available for replacement purposes;
- (d) Chuck door gaskets to control chuck door emissions until such door is repaired, or replaced; and
- (e) Heat shields on door machines.

(3) Work practice controls

(i) Charging. The employer shall operate existing coke oven batteries with all of the following work practices to control coke oven emissions during the charging operation:

(a) Establishment and implementation of a detailed, written inspection and cleaning procedure for each battery consisting of at least the following elements:

- (1) Prompt and effective repair or replacement of all engineering controls;
- (2) Inspection and cleaning of goosenecks and standpipes prior to each charge to a specified minimum diameter sufficient to effectively move the evolved gases from the oven to the collector mains;
- (3) Inspection for roof carbon build-up prior to each charge and removal of roof carbon as necessary to provide an adequate gas channel so that the gases are effectively moved from the oven into the collector mains;
- (4) Inspection of the steam aspiration system prior to each charge so that sufficient pressure and volume is maintained to effectively move the gases from the oven to the collector mains;
- (5) Inspection of steam nozzles and liquor sprays prior to each charge and cleaning as necessary so that the steam nozzles and liquor sprays are clean;
- (6) Inspection of standpipe caps prior to each charge and cleaning and luting or both as necessary so that the gases are effectively moved from the oven to the collector mains; and
- (7) Inspection of charging holes and lids for cracks, warpage and other defects prior to each charge and removal of carbon to prevent emissions, and application of luting

material to standpipe and charging hole lids where necessary to obtain a proper seal.

(b) Establishment and implementation of a detailed written charging procedure, designed and operated to eliminate emissions during charging for each battery, consisting of at least the following elements:

(1) Larry car hoppers filled with coal to a predetermined level in accordance with the mechanical volumetric controls required under paragraph (f)(2)(i)(d) of this section so as to maintain a sufficient gas passage in the oven to be charged;

(2) The larry car aligned over the oven to be charged, so that the drop sleeves fit tightly over the charging holes; and

(3) The oven charged in accordance with the following sequence of requirements:

(i) The aspiration system turned on;

(ii) Coal charged through the outermost hoppers, either individually or together depending on the capacity of the aspiration system to collect the gases involved;

(iii) The charging holes used under paragraph (f)(3)(i)(b)(3)(ii) of this section relidded or otherwise sealed off to prevent leakage of coke oven emissions;

(iv) If four hoppers are used, the third hopper discharged and relidded or otherwise sealed off to prevent leakage of coke oven emissions;

(v) The final hopper discharged until the gas channel at the top of the oven is blocked and then the chuck door opened and the coal leveled;

(vi) When the coal from the final hopper is discharged and the leveling operation complete, the charging hole relidded or otherwise sealed off to prevent leakage of coke oven emissions; and

(vii) The aspiration system turned off only after the charging holes have been closed.

(c) Establishment and implementation of a detailed written charging procedure, designed and operated to eliminate emissions during charging of each pipeline or enclosed charged battery.

(ii) Coking. The employer shall operate existing coke oven batteries pursuant to a detailed written procedure established and implemented for the control of coke oven emissions during coking, consisting of at least the following elements:

(a) Checking oven back pressure controls to maintain uniform pressure conditions in the collecting main;

(b) Repair, replacement and adjustment of oven doors and chuck doors and replacement of door jambs so as to provide a continuous metal-to-metal fit;

(c) Cleaning of oven doors, chuck doors and door jambs each coking cycle so as to provide an effective seal;

(d) An inspection system and corrective action program to control door emissions to the maximum extent possible; and

(e) Luting of doors that are sealed by luting each coking cycle and reluting, replacing or adjusting as necessary to control leakage.

(iii) Pushing. The employer shall operate existing coke oven batteries with the following work practices to control coke oven emissions during pushing operations:

(a) Coke and coal spillage quenched as soon as practicable and not shoveled into a heated oven; and

(b) A detailed written procedure for each battery established and implemented for the control of emissions during pushing consisting of the following elements:

(1) Dampering off the ovens and removal of charging hole lids to effectively control coke oven emissions during the push;

(2) Heating of the coal charge uniformly for a sufficient period so as to obtain proper coking including preventing green pushes;

(3) Prevention of green pushes to the maximum extent possible;

(4) Inspection, adjustment and correction of heating flue temperatures and defective flues at least weekly and after any green push, so as to prevent green pushes;

(5) Cleaning of heating flues and related equipment to prevent green pushes, at least weekly and after any green push.

(iv) Maintenance and repair. The employer shall operate existing coke oven batteries pursuant to a detailed written procedure of maintenance and repair established and implemented for the effective control of coke oven emissions consisting of the following elements:

(a) Regular inspection of all controls, including goosenecks, standpipes, standpipe caps, charging hold lids and castings, jumper pipes and air seals for cracks, misalignment or other defects and prompt implementation of the necessary repairs as soon as possible;

(b) Maintaining the regulated area in a neat, orderly condition free of coal and coke spillage and debris;

(c) Regular inspection of the damper system, aspiration system and collector main for cracks or leakage, and prompt implementation of the necessary repairs;

(d) Regular inspection of the heating system and prompt implementation of the necessary repairs;

(e) Prevention of miscellaneous fugitive topside emissions;

(f) Regular inspection and patching of oven brickwork;

(g) Maintenance of battery equipment and controls in good working order;

(h) Maintenance and repair of coke oven doors, chuck doors, door jambs and seals; and

(i) Repairs instituted and completed as soon as possible, including temporary repair measures instituted and completed where necessary, including but not limited to:

(1) Prevention of miscellaneous fugitive topside emissions; and

(2) Chuck door gaskets, which shall be installed prior to the start of the next coking cycle.

(4) Filtered air.

(i) The employer shall provided positive-pressure, temperature controlled filtered air for larry car, pusher machine, door machine, and quench car cabs.

(ii) The employer shall provide standby pulpits on the battery topside, at the wharf, and at the screening station, equipped with positive-pressure, temperature controlled filtered air.

(5) Emergencies. Whenever an emergency occurs, the next coking cycle may not begin until the cause of the emergency is determined and corrected, unless the employer can establish that it is necessary to initiate the next coking cycle in order to determine the cause of the emergency.

(6) Compliance program.

(i) Each employer shall establish and implement a written program to reduce exposures

solely by means of the engineering and work practice controls required in paragraph (f) of this section.

(ii) The written program shall include at least the following:

(a) A description of each coke oven operation by battery, including work force and operating crew, coking time, operating procedures and maintenance practices;

(b) Engineering plans and other studies used to determine the controls for the coke battery;

(c) A report of the technology considered in meeting the permissible exposure limit;

(d) Monitoring data obtained in accordance with paragraph (e) of this section;

(e) A detailed schedule for the implementation of the engineering and work practice controls required in paragraph (f) of this section; and

(f) Other relevant information.

(iii) If, after implementing all controls required by paragraph (f)(2) - (f)(4) of this section, or after January 20, 1980, whichever is sooner, or after completion of a new or rehabilitated battery the permissible exposure limit is still exceeded, the employer shall develop a detailed written program and schedule for the implementation of any additional engineering controls and work practices necessary to reduce exposure to or below the permissible exposure limit.

(iv) Written plans for such programs shall be submitted, upon request, to the Secretary and the Director, and shall be available at the worksite for examination and copying by the Secretary, the Director, and the authorized employee representative. The plans required under paragraph (f)(6) of this section shall be revised and updated at least annually to reflect the current status of the program.

(7) Training in compliance procedures. The employer shall incorporate all written procedures and schedules required under this paragraph (f) in the information and training program required under paragraph (k) of this section and, where appropriate, post in the regulated area.

(g) Respiratory protection

(1) General.

For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Compliance with the permissible exposure limit may not be achieved by the use of respirators except during:

(i) Periods necessary to install or implement feasible engineering and work-practice controls.

(ii) Work operations, such as maintenance and repair activity, for which engineering and work-practice controls are technologically not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the permissible exposure limit.

(iv) Emergencies.

(2) Respirator program. The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(3) Respirator selection. Employers must select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers may use a filtering facepiece respirator only when it functions as a filter respirator for coke oven emissions particulates.

(h) Protective clothing and equipment

(1) Provision and use. The employer shall provide and assure the use of appropriate protective clothing and equipment, such as but not limited to:

(i) Flame resistant jacket and pants;

(ii) Flame resistant gloves;

(iii) Face shields or vented goggles which comply with 1910.133(a)(2) of this part;

(iv) Footwear providing insulation from hot surfaces for footwear;

(v) Safety shoes which comply with 1910.136 of this part; and

(vi) Protective helmets which comply with 1910.135 of this part.

(2) Cleaning and replacement.

(i) The employer shall provide the protective clothing required by paragraphs (h)(1) (i) and (ii) of this section in a clean and dry condition at least weekly. STD 1-6.4

(ii) The employer shall clean, launder, or dispose of protective clothing required by paragraphs (h)(1) (i) and (ii) of this section.

STD 1-6.4

(iii) The employer shall repair or replace the protective clothing and equipment as needed to maintain their effectiveness.

STD 1-6.4

(iv) The employer shall assure that all protective clothing is removed at the completion of a work shift only in change rooms prescribed in paragraph (i)(1) of this section.

(v) The employer shall assure that contaminated protective clothing which is to be cleaned, laundered, or disposed of, is placed in a closable container in the change room.

(vi) The employer shall inform any person who cleans or launders protective clothing required by this section, of the potentially harmful effects of exposure to coke oven emissions.

(i) Hygiene facilities and practices

(1) Change rooms. The employer shall provide clean change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing and equipment whenever employees are required to wear protective clothing and equipment in accordance with paragraph (h)(1) of this section.

(2) Showers.

(i) The employer shall assure that employees working in the regulated area shower at the end of the work shift.

(ii) The employer shall provide shower facilities in accordance with 1910.141(d)(3) of this part.

(3) Lunchrooms. The employer shall provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees working in the regulated area.

(4) Lavatories.

(i) The employer shall assure that employees working in the regulated area wash their hands and face prior to eating.

(ii) The employer shall provide lavatory facilities in accordance with 1910.141(d) (1) and (2) of this part.

(5) Prohibition of activities in the regulated area.

(i) The employer shall assure that in the regulated area, food or beverages are not present or consumed, smoking products are not present or used, and cosmetics are not applied, except that these activities may be conducted in the lunchrooms, change rooms and showers required under paragraphs (i)(1) - (i)(3) of this section.

(ii) Drinking water may be consumed in the regulated area.

(j) Medical surveillance

(1) General requirements.

(i) Each employer shall institute a medical surveillance program for all employees who are employed in a regulated area at least 30 days per year.

(ii) This program shall provide each employee covered under paragraph (j)(1)(i) of this section with an opportunity for medical examinations in accordance with this paragraph (j).

(iii) The employer shall inform any employee who refuses any required medical examination of the possible health consequences of such refusal and shall obtain a signed statement from the employee indicating that the employee understands the risk involved in the refusal to be examined.

(iv) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and are provided without cost to the employee.

(2) Initial examinations. At the time of initial assignment to a regulated area or upon the institution of the medical surveillance program, the employer shall provide a medical examination for employees covered under paragraph (j)(1)(i) of this section including at least the following elements:

(i) A work history and medical history which shall include smoking history and the presence and degree of respiratory symptoms, such as breathlessness, cough, sputum production, and wheezing; STD 1.43

(ii) A standard posterior-anterior chest x-ray;

(iii) Pulmonary function tests including forced vital capacity (FVC) and forced expiratory volume at one second (FEV 1.0) with recording of type of equipment used;

(iv) Weight;

- (v) A skin examination;
- (vi) Urinalysis for sugar, albumin, and hematuria; and
- (vii) A urinary cytology examination.

(3) Periodic examinations.

(i) The employer shall provide the examinations specified in paragraphs (j)(2) (i) - (vi) of this section at least annually for employees covered under paragraph (j)(1)(i) of this section.

(ii) The employer must provide the examinations specified in paragraphs (j)(2)(i) through (j)(2)(vii) of this section at least annually for employees 45 years of age or older or with five (5) or more years employment in the regulated area.

(iii) Whenever an employee who is 45 years of age or older or with five (5) or more years employment in a regulated area transfers or is transferred from employment in a regulated area, the employer must continue to provide the examinations specified in paragraphs (j)(2)(i) through (j)(2)(vii) of this section at least annually as long as that employee is employed by the same employer or a successor employer.

(iv) Whenever an employee has not taken the examinations specified in paragraphs (j)(3) (i) - (iii) of this section with the six (6) months preceding the termination of employment the employer shall provide such examinations to the employee upon termination of employment.

(4) Information provided to the physician. The employer shall provide the following information to the examining physician:

- (i) A copy of this regulation and its Appendixes;
- (ii) A description of the affected employee's duties as they relate to the employee's exposure;
- (iii) The employee's exposure level or estimated exposure level;
- (iv) A description of any personal protective equipment used or to be used; and
- (v) Information from previous medical examinations of the affected employee which is not readily available to the examining physician.

(5) Physician's written opinion.

(i) The employer shall obtain a written opinion from the examining physician which shall include:

(a) The results of the medical examinations;

(b) The physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of the employee's health from exposure to coke oven emissions;

(c) Any recommended limitations upon the employee's exposure to coke oven emissions or upon the use of protective clothing or equipment such as respirators; and STD 1.43

(d) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further explanation or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure.

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(k) Employee information and training

(1) Training program.

(i) The employer shall train each employee who is employed in a regulated area in accordance with the requirements of this section. The employer shall institute a training program and ensure employee participation in the program.

(ii) The training program shall be provided as of January 27, 1977 for employees who are employed in the regulated area at that time or at the time of initial assignment to a regulated area.

(iii) The training program shall be provided at least annually for all employees who are employed in the regulated area, except that training regarding the occupational safety and health hazards associated with exposure to coke oven emissions and the purpose, proper use, and limitations of respiratory protective devices shall be provided at least quarterly until January 20, 1978. STD 1.43

(iv) The training program shall include informing each employee of:

(a) The information contained in the substance information sheet for coke oven emissions (Appendix A);

(b) The purpose, proper use, and limitations of respiratory protective devices required in accordance with paragraph (g) of this section; STD 1.43

(c) The purpose for and a description of the medical surveillance program required by

paragraph (j) of this section including information on the occupational safety and health hazards associated with exposure to coke oven emissions;

(d) A review of all written procedures and schedules required under paragraph (f) of this section; and

(e) A review of this standard.

(2) Access to training materials.

(i) The employer shall make a copy of this standard and its appendixes readily available to all employees who are employed in the regulated area.

(ii) The employer shall provide upon request all materials relating to the employee information and training program to the Secretary and the Director.

(1) ~~Precautionary signs and labels~~ Communication of hazards

(1) ~~General.~~ Hazard communication—general.

(i) ~~The employer may use labels or signs required by other statutes, regulations or ordinances in addition to, or in combination with, signs and labels required by this paragraph.~~ The employer shall include coke oven emissions in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of chemicals and substances associated with coke oven processes and to safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (k) of this section. The employer shall ensure that at least the following hazard is addressed: Cancer.

(ii) ~~The employer shall assure that no statement appears on or near any sign required by this paragraph which contradicts or detracts from the effects of the required sign.~~

~~(iii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.~~

(2) Signs.

(i) The employer shall post signs in the regulated area bearing the legends:

~~DANGER
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
NO SMOKING OR EATING
DANGER~~

COKE OVEN EMISSIONS
MAY CAUSE CANCER
DO NOT EAT, DRINK OR SMOKE
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(ii) ~~In addition, not later than January 20, 1978, the employer shall post signs in the areas where the permissible exposure limit is exceeded bearing the legend:— STD 1.43~~ In addition, the employer shall post signs in the areas where the permissible exposure limit is exceeded bearing the legend:

~~DANGER~~
~~RESPIRATOR REQUIRED~~ WEAR RESPIRATORY PROTECTION IN THIS AREA

(iii) The employer shall ensure that no statement appears on or near any sign required by this paragraph (l) which contradicts or detracts from the effects of the required sign.

(iv) The employer shall ensure that signs required by this paragraph (l)(2) are illuminated and cleaned as necessary so that the legend is readily visible.

(v) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (l)(2)(i) of this section:

DANGER
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
NO SMOKING OR EATING

(vi) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (l)(2)(ii) of this section:

DANGER
RESPIRATOR REQUIRED

(3) ~~Labels. The employer shall apply precautionary labels to all containers of protective clothing contaminated with coke oven emissions bearing the legend:~~

(i) The employer shall ensure that labels of containers of contaminated protective clothing and equipment include the following information:

CAUTION
~~CLOTHING CONTAMINATED WITH COKE EMISSIONS~~
~~DO NOT REMOVE DUST BY BLOWING OR SHAKING~~

CONTAMINATED WITH COKE EMISSIONS
MAY CAUSE CANCER
DO NOT REMOVE DUST BY BLOWING OR SHAKING

(ii) Prior to June 1, 2015, employers may include the following information on contaminated protective clothing and equipment in lieu of the labeling requirements in paragraph (1)(3)(i) of this section:

CAUTION
CLOTHING CONTAMINATED WITH COKE EMISSIONS
DO NOT REMOVE DUST BY BLOWING OR SHAKING

(m) Recordkeeping

(1) Exposure measurements. The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to coke oven emissions required in paragraph (e) of this section.

(i) This record shall include:

(a) Name, social security number, and job classification of the employees monitored;

(b) The date(s), number, duration and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure where applicable;

(c) The type of respiratory protective devices worn, if any;
STD 1.43

(d) A description of the sampling and analytical methods used and evidence of their accuracy; and

(e) The environmental variables that could affect the measurement of employee exposure.

(ii) The employer shall maintain this record for at least 40 years or for the duration of employment plus 20 years, whichever is longer.

(2) Medical surveillance. The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (j) of this section.

(i) The record shall include:

- (a) The name, social security number, and description of duties of the employee;
 - (b) A copy of the physician's written opinion;
 - (c) The signed statement of any refusal to take a medical examination under paragraph (j)(1)(ii) of this section; and
 - (d) Any employee medical complaints related to exposure to coke oven emissions.
- (ii) The employer shall keep, or assure that the examining physician keeps, the following medical records:
- (a) A copy of the medical examination results including medical and work history required under paragraph (j)(2) of this section;
 - (b) A description of the laboratory procedures used and a copy of any standards or guidelines used to interpret the test results;
 - (c) The initial x-ray;
 - (d) The x-rays for the most recent five (5) years;
 - (e) Any x-ray with a demonstrated abnormality and all subsequent x-rays;
 - (f) The initial cytologic examination slide and written description;
 - (g) The cytologic examination slide and written description for the most recent 10 years;
- and
- (h) Any cytologic examination slides with demonstrated atypia, if such atypia persists for 3 years, and all subsequent slides and written descriptions.
- (iii) The employer shall maintain medical records required under paragraph (m)(2) of this section for at least 40 years, or for the duration of employment plus 20 years, whichever is longer.
- (3) Availability.
- (i) The employer shall make available upon request all records required to be maintained by paragraph (m) of this section to the Secretary and the Director for examination and copying.
 - (ii) Employee exposure measurement records and employee medical records required by this

paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020(a) - (e) and (g) - (i).

(4) Transfer of records.

(i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (m) of this section.

(ii) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(n) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees or their representatives an opportunity to observe any measuring or monitoring of employee exposure to coke oven emissions conducted pursuant to paragraph (e) of this section.

(2) Observation procedures.

(i) Whenever observation of the measuring or monitoring of employee exposure to coke oven emissions requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with and assure the use of such equipment and shall require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the measurement, observers shall be entitled to:

(a) An Explanation of the measurement procedures;

(b) Observe all s related to the measurement of coke oven emissions performed at the place of exposure; and

(c) Record the results obtained.

(o) [Reserved]

(p) Appendices. The information contained in the appendixes to this section is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

1910.1029 App A Coke oven emissions substance information sheet

APPENDIX A to 1910.1029 - COKE OVEN EMISSIONS SUBSTANCE INFORMATION SHEET

I. SUBSTANCE IDENTIFICATION

A. Substance: Coke Oven Emissions

B. Definition: The benzene-soluble fraction of total particulate matter present during the destructive distillation or carbonization of coal for the production of coke.

C. Permissible Exposure Limit: 150 micrograms per cubic meter of air determined as an average over an 8-hour period.

D. Regulated areas: Only employees authorized by your employer should enter a regulated area. The employer is required to designate the following areas as regulated areas: the coke oven battery, including topside and its machinery, pushside and its machinery, cokeside and its machinery, and the battery ends; the screening station; and the wharf; and the beehive ovens and their machinery.

II. HEALTH HAZARD DATA

Exposure to coke oven emissions is a cause of lung cancer, and kidney cancer, in humans. Although there have not been an excess number of skin cancer cases in humans, repeated skin contact with coke oven emissions should be avoided.

III. PROTECTIVE CLOTHING AND EQUIPMENT

A. Respirators: Respirators will be provided by your employer for routine use if your employer is in the process of implementing engineering and work practice controls or where engineering and work practice controls are not feasible or insufficient to reduce exposure to or below the PEL. You must wear respirators for non-routine activities or in emergency situations where you are likely to be exposed to levels of coke oven emissions in excess of the permissible exposure limit. Until January 20, 1978, the routine wearing of respirators is voluntary. Until that date, if you choose not to wear a respirator you do not have to do so. You must still have your respirator with you and you must still wear it if you are near visible emissions. Since how well your respirator fits your face is very important, your employer is required to conduct fit tests to make sure the respirator seals properly when you wear it. These tests are simple and rapid and will be explained to you during your training sessions. STD 1.43

B. Protective clothing: Your employer is required to provide, and you must wear, appropriate, clean, protective clothing and equipment to protect your body from repeated skin contact with coke oven emissions and from the heat generated during the coking process. This clothing should include such items as jacket and pants and flame resistant gloves. Protective equipment should include face shield or vented goggles, protective helmets and safety shoes, insulated from hot surfaces where appropriate.

IV. HYGIENE FACILITIES AND PRACTICES

You must not eat, drink, smoke, chew gum or tobacco, or apply cosmetics in the regulated area, except that drinking water is permitted. Your employer is required to provide lunchrooms and other areas for these purposes.

Your employer is required to provide showers, washing facilities, and change rooms. If you work in a regulated area, you must wash your face, and hands before eating. You must shower at the end of the work shift. Do not take used protective clothing out of the change rooms without your employer's permission. Your employer is required to provide for laundering or cleaning of your protective clothing.

V. SIGNS AND LABELS

Your employer is required to post warning signs and labels for your protection. Signs must be posted in regulated areas. The signs must warn that a cancer hazard is present, that only authorized employees may enter the area, and that no smoking or eating is allowed. In regulated areas where coke oven emissions are above the permissible exposure limit, the signs should also warn that respirators must be worn. STD 1.43

VI. MEDICAL EXAMINATIONS

If you work in a regulated area at least 30 days per year, your employer is required to provide you with a medical examination every year. The medical examination must include a medical history, a chest x-ray, pulmonary function test, weight comparison, skin examination, a urinalysis, and a urine cytology exam for the early detection of urinary cancer. The urine cytology exam is only included in the initial exam until you are either 45 years or older or have 5 or more years employment in the regulated areas when the medical exams including this test, but excepting the x-ray exam, are to be given every six months; under these conditions, you are to be given an x-ray exam at least once a year. The examining physician will provide a written opinion to your employer containing the results of the medical exams. You should also receive a copy of this opinion.

VII. OBSERVATION OF MONITORING

Your employer is required to monitor your exposure to coke oven emissions and you are entitled to observe the monitoring procedure. You are entitled to receive an explanation of the measurement procedure, observe the s taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you must also be provided with and must wear the protective clothing and equipment. STD 1.43

VIII. ACCESS TO RECORDS

You or your representative are entitled to records of your exposure to coke oven emissions upon request to your employer. Your medical examination records can be furnished to your physician upon request to your employer.

IX. TRAINING AND EDUCATION

Additional information on all of these items plus training as to hazards of coke oven emissions and the engineering and work practice controls associated with your job will also be provided by your employer.

1910.1029 App B Industrial hygiene and medical surveillance guidelines

APPENDIX B to 1910.1029 - INDUSTRIAL HYGIENE AND MEDICAL SURVEILLANCE GUIDELINES

I. INDUSTRIAL HYGIENE GUIDELINES

A. Sampling (Benzene-Soluble Fraction Total Particulate Matter).

Samples collected should be full shift (at least 7-hour) samples. Sampling should be done using a personal sampling pump with pulsation damper at a flow rate of 2 liters per minute. Samples should be collected on 0.8 micrometer pore size silver membrane filters (37 mm diameter) preceded by Gelman glass fiber type A-E filters encased in three-piece plastic (polystyrene) field monitor cassettes. The cassette face cap should be on and the plug removed. The rotameter should be checked every hour to ensure that proper flow rates are maintained.

A minimum of three full-shift samples should be collected for each job classification on each battery, at least one from each shift. If disparate results are obtained for particular job classification, sampling should be repeated. It is advisable to sample each shift on more than one day to account for environmental variables (wind, precipitation, etc.) which may affect sampling. Differences in exposures among different work shifts may indicate a need to improve work practices on a particular shift. Sampling results from different shifts for each job classification should not be averaged. Multiple samples from same shift on each battery may be used to calculate an average exposure for a particular job classification.

B. Analysis.

1. All extraction glassware is cleaned with dichromic acid cleaning solution, rinsed with tap water, then de-ionized water, acetone, and allowed to dry completely. The glassware is rinsed with nanograde benzene before use. The Teflon cups are cleaned with benzene then with acetone.

2. Pre-weigh the 2 ml Teflon cups to one hundredth of a milligram (0.01 mg) on a autobalance AD 2 Tare weight of the cups is about 50 mg.
3. Place the silver membrane filter and glass fiber filter into a 15 ml test tube.
4. Extract with 5 ml of benzene for five minutes in an ultrasonic cleaner.
5. Filter the extract in 15 ml medium glass fritted funnels.
6. Rinse test tube and filters with two 1.5 ml aliquots of benzene and filter through the fritted glass funnel.
7. Collect the extract and two rinses in a 10 ml Kontes graduated evaporative concentrator.
8. Evaporate down to 1 ml while rinsing the sides with benzene.
9. Pipet 0.5 ml into the Teflon cup and evaporate to dryness in a vacuum oven at 40 deg. C for 3 hours.
10. Weigh the Teflon cup and the weight gain is due to the benzene soluble residue in half the Sample.

II. MEDICAL SURVEILLANCE GUIDELINES

A. General.

The minimum requirements for the medical examination for coke oven workers are given in paragraph (j) of the standard. The initial examination is to be provided to all coke oven workers who work at least 30 days in the regulated area. The examination includes at posterior-anterior chest x-ray, pulmonary function tests (FVC and FEV 1.0), weight, urinalysis, skin examination and a urinary cytologic examination. These tests are needed to serve as the baseline for comparing the employee's future test results. Periodic exams include all the elements of the initial exams, except that the urine cytologic test is to be performed only on those employees who are 45 years or older or who have worked for 5 or more years in the regulated area; periodic exams, with the exception of x-rays, are to be performed semiannually for this group instead of annually; for this group, x-rays will continue to be given at least annually. The examination contents are minimum requirements, additional tests such as lateral and oblique x-rays or additional pulmonary function tests may be performed if deemed necessary.

B. Pulmonary function tests.

Pulmonary function tests should be performed in a manner which minimizes subject and operator bias. There has been shown to be learning effects with regard to the results obtained

from certain tests, such as FEV 1.0. Best results can be obtained by multiple trials for each subject. The best of three trials or the average of the last three of five trials may be used in obtaining reliable results. The type of equipment used (manufacturer, model, etc.) should be recorded with the results as reliability and accuracy varies and such information may be important in the evaluation of test results. Care should be exercised to obtain the best possible testing equipment.

[41 FR 46784, Oct. 22, 1976, as amended at 42 FR 3304, Jan. 18, 1977; 45 FR 35283, May 23, 1980; 50 FR 37353, 37354, Sept. 13, 1985; 54 FR 24334, June 7, 1989]

1910.1030 Bloodborne Pathogens. CPL 2-2.44C

(a) **Scope and Application** This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) **Definitions.** For purposes of this section, the following shall apply:

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

"Blood" means human blood, human blood components, and products made from human blood.

"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

"Clinical Laboratory" means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

"Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

"Contaminated Laundry" means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

"Contaminated Sharps" means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or

disposal.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

"Engineering Controls" means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

"Exposure Incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

"Handwashing Facilities" means a facility providing an adequate supply of running potable water, soap and single use towels or air drying machines.

"HBV" means hepatitis B virus.

"HIV" means human immunodeficiency virus.

"Licensed Healthcare Professional" is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

"Needleless systems" means a device that does not use needles for:

- (1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;
- (2) The administration of medication or fluids; or
- (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

"Occupational Exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

"Other Potentially Infectious Materials" means

- (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

"Parenteral" means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

"Personal Protective Equipment" is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

"Production Facility" means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

"Regulated Waste" means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

"Research Laboratory" means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

"Sharps with engineered sharps injury protections" means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

"Source Individual" means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

"Sterilize" means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

"Universal Precautions" is an approach to infection control. According to the concept of

Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

"Work Practice Controls" means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

(c) Exposure Control

(1) Exposure Control Plan

(i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

(ii) The Exposure Control Plan shall contain at least the following elements:

(A) The exposure determination required by paragraph (c)(2),

(B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

(C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

(A) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

(B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(v) An employer, who is required to establish an Exposure Control Plan shall solicit input

from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

(vi) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

(2) Exposure Determination

(i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

(A) A list of all job classifications in which all employees in those job classifications have occupational exposure;

(B) A list of job classifications in which some employees have occupational exposure, and

(C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

(ii) This exposure determination shall be made without regard to the use of personal protective equipment.

(d) Methods of Compliance

(1) General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

(2) Engineering and Work Practice Controls

(i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

(ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(iii) Employers shall provide handwashing facilities which are readily accessible to employees.

(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

(v) Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

(A) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.

(B) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(A) puncture resistant;

(B) labeled or color-coded in accordance with this standard;

(C) leakproof on the sides and bottom; and

(D) in accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

(x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

(xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

(xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

(B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

(C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

(A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

(B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(3) Personal Protective Equipment

(i) Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

(ii) Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(iii) Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iv) Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

(v) Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

(vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

(vii) All personal protective equipment shall be removed prior to leaving the work area.

(viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(ix) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous

membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

(B) Disposable (single use) gloves shall not be washed or decontaminated for re-use.

(C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

(1) Periodically reevaluate this policy;

(2) Make gloves available to all employees who wish to use them for phlebotomy;

(3) Not discourage the use of gloves for phlebotomy; and

(4) Require that gloves be used for phlebotomy in the following circumstances:

(i) When the employee has cuts, scratches, or other breaks in his or her skin;

(ii) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

(iii) When the employee is receiving training in phlebotomy.

(x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

(xi) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will

depend upon the task and degree of exposure anticipated.

(xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

(4) Housekeeping

(i) General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

(ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

(C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

(E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

(iii) Regulated Waste.

(A) Contaminated Sharps Discarding and Containment.

(1) Contaminated sharps shall be discarded immediately or as soon as feasible in containers

that are:

- (i) Closable;
- (ii) Puncture resistant;
- (iii) Leakproof on sides and bottom; and
- (iv) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(2) During use, containers for contaminated sharps shall be:

(i) Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

(ii) Maintained upright throughout use; and

(iii) Replaced routinely and not be allowed to overfill.

(3) When moving containers of contaminated sharps from the area of use, the containers shall be:

(i) Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

(ii) Placed in a secondary container if leakage is possible. The second container shall be:

(A) Closable;

(B) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

(C) Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

(4) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

(B) Other Regulated Waste Containment.

(1) Regulated waste shall be placed in containers which are:

(i) Closable;

(ii) Constructed to contain all contents and prevent leakage of fluids

during handling, storage, transport or shipping;

(iii) Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and

(iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(2) If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

(a) Closable;

(b) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

(c) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

(d) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

(iv) Laundry.

(A) Contaminated laundry shall be handled as little as possible with a minimum of agitation.

(1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

(2) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

(3) Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

(B) The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

(C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

(e) HIV and HBV Research Laboratories and Production Facilities

(1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

(2) Research laboratories and production facilities shall meet the following criteria:

(i) Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(ii) Special Practices

(A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

(B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

(C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

(E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module.

No work with these other potentially infectious materials shall be conducted on the open bench.

(F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

(G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

(H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

(K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

(L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(iii) Containment Equipment.

(A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective

clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

(3) HIV and HBV research laboratories shall meet the following criteria:

(i) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

(ii) An autoclave for decontamination of regulated waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:

(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

(iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(iv) Access doors to the work area or containment module shall be self-closing.

(v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(5) Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph

(g)(2)(ix).

(f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up

(1) General

(i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

(A) Made available at no cost to the employee;

(B) Made available to the employee at a reasonable time and place;

(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

(2) Hepatitis B Vaccination

(i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

(ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

(iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination

offered by the employer sign the statement in Appendix A.

(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(3) Post-exposure Evaluation and Follow-up Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(iii) Collection and testing of blood for HBV and HIV serological status;

(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) Information Provided to the Healthcare Professional

(i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(A) A copy of this regulation;

(B) A description of the exposed employee's duties as they relate to the exposure incident;

(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(D) Results of the source individual's blood testing, if available; and

(E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

(5) Healthcare Professional's Written Opinion The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

(i) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

(A) That the employee has been informed of the results of the evaluation; and

(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(6) Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) Communication of Hazards to Employees

(1) Labels and Signs

(i) Labels.

(A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

(B) Labels required by this section shall include the following legend:



(C) These fluorescent orange predominantly so, symbols in a contrasting color.

labels shall be or orange-red or with lettering and

(D) Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels.

(F) Containers of blood, blood components, or blood products that are labeled as to

their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(ii) Signs.

(A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:



BIOHAZARD

(Name of the
Infectious Agent)
(Special

requirements for entering the area)

(Name, telephone number of the laboratory director or other responsible person.)

(B) These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

(2) Information and Training

(i) The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

(ii) Training shall be provided as follows:

(A) At the time of initial assignment to tasks where occupational exposure may take place;

(B) At least annually thereafter.

(iii) [Reserved]

(iv) Annual training for all employees shall be provided within one year of their previous training.

(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(vii) The training program shall contain at a minimum the following elements:

(A) An accessible copy of the regulatory text of this standard and an explanation of its contents;

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective

equipment;

(G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(H) An explanation of the basis for selection of personal protective equipment;

(I) Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

(M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

(N) An opportunity for interactive questions and answers with the person conducting the training session.

(viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

(C) The employer shall provide a training program to employees who have no prior

experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) Recordkeeping

(1) Medical Records

(i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The name and social security number of the employee;

(B) A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

(E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

(iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

(A) Kept confidential; and

(B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

(2) Training Records

(i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

(D) The names and job titles of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(3) Availability

(i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

(4) Transfer of Records

(i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

(5) Sharps injury log.

(i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

- (A) The type and brand of device involved in the incident,
- (B) The department or work area where the exposure incident occurred, and
- (C) An explanation of how the incident occurred.

(ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

(i) Dates

(1) Effective Date. The standard shall become effective on March 6, 1992.

(2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on May 5, 1992.

(3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on June 4, 1992.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g) (1) Labels and Signs, shall take effect on July 6, 1992.

1910.1030 App. A Hepatitis B Vaccine Declination (Mandatory)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

[56 FR 64175, Dec. 6th, 1991]

1910.1043 Cotton dust. (Not applicable in Wyoming)

1910.1044 1,2-dibromo-3-chloropropane.

(a) Scope and application.

(1) This section applies to occupational exposure to 1,2-dibromo-3-chloropropane (DBCP).

(2) This section does not apply to:

(i) Exposure to DBCP which results solely from the application and use of DBCP as a pesticide; or

(ii) The storage, transportation, distribution or sale of DBCP in intact containers sealed in such a manner as to prevent exposure to DBCP vapors or liquid, except for the requirements of paragraphs (i), (n) and (o) of this section.

(b) Definitions.

(1) "Administrator" means the Administrator of the State of Wyoming Occupational Health and Safety Department, or designee.

(2) "Authorized person" means any person required by his duties to be present in regulated areas and authorized to do so by his employer, by this section, or by the Act. "Authorized person" also includes any person entering such areas as a designated representative of employees exercising an opportunity to observe employee exposure monitoring.

(3) "DBCP" means 1,2-dibromo-3-chloropropane, Chemical Abstracts Service Registry Number 96-12-8, and includes all forms of DBCP.

(4) "Department" means the Occupational Health and Safety Department; Cheyenne, Wyoming, 82002.

(5) "Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education and Welfare, or designee.

(6) "Emergency" means any occurrence such as, but not limited to equipment failure, rupture of containers, or failure of control equipment which may, or does, result in an unexpected release of DBCP

(7) "Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

(c) Permissible exposure limit

(1) Inhalation. The employer shall assure that no employee is exposed to an airborne concentration of DBCP in excess of 1 part DBCP per billion parts of air (ppb) as an 8-hour

time-weighted average.

(2) Dermal and eye exposure. The employer shall assure that no employee is exposed to eye or skin contact with DBCP.

(d) [Reserved]

(e) Regulated areas.

(1) The employer shall establish, within each place of employment, regulated areas wherever DBCP concentrations are in excess of the permissible exposure limit.

(2) The employer shall limit access to regulated areas to authorized persons.

(f) Exposure monitoring

(1) General.

(i) Determinations of airborne exposure levels shall be made from air sample that are representative of each employee's exposure to DBCP over an 8-hour period.

(ii) For the purposes of this paragraph, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) Initial. Each employer who has a place of employment in which DBCP is present, shall monitor each workplace and work operation to accurately determine the airborne concentrations of DBCP to which employees may be exposed.

(3) Frequency.

(i) If the monitoring required by this section reveals employee exposures to be at or below the permissible exposure limit, the employer must repeat these measurements at least every 6 months.

(ii) If the monitoring required by this section reveals employee exposures to be in excess of the permissible exposure limit, the employer must repeat these measurements for each such employee at least quarterly. The employer must continue quarterly monitoring until at least two consecutive measurements, taken at least seven (7) days apart, are at or below the permissible exposure limit. Thereafter the employer must monitor at least every 6 months.

(4) Additional. Whenever there has been a production, process, control, or personnel change which may result in any new or additional exposure to DBCP, or whenever the employer has any reason to suspect new or additional exposures to DBCP, the employer shall monitor the

employees potentially affected by such change for the purpose of redetermining their exposure.

(5) Employee notification.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) Whenever the results indicate that employee exposure exceeds the permissible exposure limit, the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limit.

(6) Accuracy of measurement. The employer shall use a method of measurement which has an accuracy, to a confidence level of 95 percent, of not less than plus or minus 25 percent for concentrations of DBCP at or above the permissible exposure limit.

(g) Methods of compliance

(1) Priority of compliance methods. The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to DBCP at or below the permissible exposure limit, except to the extent that the employer establishes that such controls are not feasible. Where feasible engineering and work practice controls are not sufficient to reduce employee exposures to within the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls, and shall supplement them by use of respiratory protection.

(2) Compliance program.

(i) The employer shall establish and implement a written program to reduce employee exposures to DBCP to or below the permissible exposure limit solely by means of engineering and work practice controls as required by paragraph (g)(1) of this section.

(ii) The written program shall include a detailed schedule for development and implementation of the engineering and work practice controls. These plans must be revised at least annually to reflect the current status of the program.

(iii) Written plans for these compliance programs shall be submitted upon request to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and any affected employee or designated representative of employees.

(iv) The employer shall institute and maintain at least the controls described in his most recent written compliance program.

(h) Respirator protection.

(1) General. For employees who are required to use respirators by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work-practice controls.

(ii) Maintenance and repair activities for which engineering and work-practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the permissible exposure limit.

(iv) Emergencies.

(2) Respirator program. The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(3) Respirator selection. Employers must:

(i) Select, and provide to employees, the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(ii) Provide employees with one of the following respirator options to use for entry into, or escape from, unknown DBCP concentrations:

(A) A combination respirator that includes a supplied-air respirator with a full facepiece operated in a pressure-demand or other positive-pressure or continuous-flow mode, as well as an auxiliary self-contained breathing apparatus (SCBA) operated in a pressure-demand or positive-pressure mode.

(B) An SCBA with a full facepiece operated in a pressure-demand or other positive-pressure mode.

(i) Emergency situations

(1) Written plans.

(i) A written plan for emergency situations shall be developed for each workplace in which DBCP is present.

(ii) Appropriate portions of the plan shall be implemented in the event of an emergency.

(2) Employees engaged in correcting emergency conditions shall be equipped as required in paragraphs (h) and (j) of this section until the emergency is abated.

(3) Evacuation. Employees not engaged in correcting the emergency shall be removed and restricted from the area and normal operations in the affected area shall not be resumed until the emergency is abated.

(4) Alerting employees. Where there is a possibility of employee exposure to DBCP due to the occurrence of an emergency, a general alarm shall be installed and maintained to promptly alert employees of such occurrences.

(5) Medical surveillance. For any employee exposed to DBCP in an emergency situation, the employer shall provide medical surveillance in accordance with paragraph (m)(6) of this section.

(6) Exposure monitoring.

(i) Following an emergency, the employer shall conduct monitoring which complies with paragraph (f) of this section.

(ii) In workplaces not normally subject to periodic monitoring, the employer may terminate monitoring when two consecutive measurements indicate exposures below the permissible exposure limit.

(j) Protective clothing and equipments

(1) Provision and use. Where there is any possibility of eye or dermal contact with liquid or solid DBCP, the employer shall provide, at no cost to the employee, and assure that the employee wears impermeable protective clothing and equipment to protect the area of the body which may come in contact with DBCP. Eye and face protection shall meet the requirements of 1910.133 of this part.

(2) Removal and storage.

(i) The employer shall assure that employees remove DBCP contaminated work clothing only in change rooms provided in accordance with paragraph (l)(1) of this section.

(ii) The employer shall assure that employees promptly remove any protective clothing and equipment which becomes contaminated with DBCP-containing liquids and solids. This clothing shall not be reworn until the DBCP has been removed from the clothing or equipment.

(iii) The employer shall assure that no employee takes DBCP contaminated protective devices and work clothing out of the change room, except those employees authorized to do so for the purpose of laundering, maintenance, of disposal.

(iv) DBCP-contaminated protective devices and work clothing shall be placed and stored in closed containers which prevent dispersion of the DBCP outside the container.

~~(v) Containers of DBCP-contaminated protective devices or work clothing which are to be taken out of change rooms or the workplace for cleaning, maintenance or disposal, shall bear labels in accordance with paragraph (o)(3) of this section.~~ Containers of DBCP-contaminated protective devices or work clothing which are to be taken out of change rooms or the workplace for cleaning, maintenance or disposal shall bear labels with the following information: CONTAMINATED WITH 1,2-Dibromo-3-chloropropane (DBCP), MAY CAUSE CANCER.

(3) Cleaning and replacement.

(i) The employer shall clean, launder, repair, or replace protective clothing and equipment required by this paragraph to maintain their effectiveness. The employer shall provide clean

protective clothing and equipment at least daily to each affected employee.

(ii) The employer shall inform any person who launders or clean DBCP-contaminated protective clothing or equipment of the potentially harmful effects of exposure to DBCP.

(iii) The employer shall prohibit the removal of DBCP from protective clothing and equipment by blowing or shaking.

(k) Housekeeping

(1) Surfaces.

(i) All workplace surfaces shall be maintained free of visible accumulations of DBCP.

(ii) Dry sweeping and the use of compressed air for the cleaning of floors and other surfaces is prohibited where DBCP dusts or liquids are present.

(iii) Where vacuuming methods are selected to clean floors and other surfaces, either portable units or a permanent system may be used.

(a) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters or other appropriate means of contaminant removal, so that DBCP is not reintroduced into the workplace air; and

~~(b) Portable vacuum units used to collect DBCP may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (o)(3) of this section. Portable vacuum units used to collect DBCP may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (j)(2)(v) of this section.~~

(iv) Cleaning of floors and other surfaces contaminated with DBCP-containing dusts shall not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) Liquids. Where DBCP is present in a liquid form, or as a resultant vapor, all containers or vessels containing DBCP shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(3) Waste disposal. DBCP waste scrap, debris, containers or equipment, shall be disposed of in sealed bags or other closed containers which prevent dispersion of DBCP outside the container.

(l) Hygiene facilities and practices

(1) Change rooms. The employer shall provide clean change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing and equipment whenever employees are required to wear protective clothing and equipment in accordance with paragraphs (h) and (j) of this section.

(2) Showers.

(i) The employer shall assure that employees working in the regulated area shower at the end of the work shift.

(ii) The employer shall assure that employees whose skin becomes contaminated with DBCP-containing liquids or solids immediately wash or shower to remove any DBCP from the skin.

(iii) The employer shall provide shower facilities in accordance with 29 CFR 1910.141(d)(3).

(3) Lunchrooms. The employer shall provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees working in regulated areas.

(4) Lavatories.

(i) The employer shall assure that employees working in the regulated area remove protective clothing and wash their hands and face prior to eating.

(ii) The employer shall provide a sufficient number of lavatory facilities which comply with 29 CFR 1910.141(d) (1) and (2).

(5) Prohibition of activities in regulated areas. The employer shall assure that, in regulated areas, food or beverages are not present or consumed, smoking products and implements are not present or used, and cosmetics are not present or applied.

(m) Medical surveillance

(1) General.

(i) The employer shall make available a medical surveillance program for employees who work in regulated areas and employees who are subjected to DBCP exposures in an emergency situation.

(ii) All medical examinations and procedures shall be performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(2) Frequency and content. At the time of initial assignment, and annually thereafter, the employer shall provide a medical examination for employees who work in regulated areas, which includes at least the following:

(i) A medical and occupational history including reproductive history.

(ii) A physical examination, including examination of the genitourinary tract, testicle size and body habitus, including a determination of sperm count.

(iii) A serum specimen shall be obtained and the following determinations made by radioimmunoassay techniques utilizing National Institutes of Health (NIH) specific antigen or one of equivalent sensitivity:

(a) Serum follicle stimulating hormone (FSH);

(b) Serum luteinizing hormone (LH); and

(c) Serum total estrogen (females).

(iv) Any other tests deemed appropriate by the examining physician.

(3) Additional examinations. If the employee for any reason develops signs or symptoms commonly associated with exposure to DBCP, the employer shall provide the employee with a medical examination which shall include those elements considered appropriate by the examining physician.

(4) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this regulation and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The level of DBCP to which the employee is exposed; and

(iv) A description of any personal protective equipment used or to be used.

(5) Physician's written opinion.

(i) For each examination under this section, the employer shall obtain and provide the employee with a written opinion from the examining physician which shall include:

(a) The results of the medical tests performed;

(b) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of health from exposure to DBCP; and

(c) Any recommended limitations upon the employee's exposure to DBCP or upon the use of protective clothing and equipment such as respirators.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure.

(6) Emergency situations. If the employee is exposed to DBCP in an emergency situation, the employer shall provide the employee with a sperm count test as soon as practicable, or, if the employee has been vasectomized or is unable to produce a semen specimen, the hormone tests contained in paragraph (m)(2)(iii) of this section. The employer shall provide these same tests three months later.

(n) Employee information and training

(1) Training program.

(i) The employer shall train each employee who may be exposed to DBCP in accordance with the requirements of this section. The employer shall institute a training program and ensure employee participation in the program.

(ii) The employer shall assure that each employee is informed of the following:

(a) The information contained in Appendix A;

(b) The quantity, location, manner of use, release or storage of DBCP and the specific nature of operations which could result in exposure to DBCP as well as any necessary protective measures;

(c) The purpose, proper use, and limitations of respirators;

(d) The purpose and description of the medical surveillance program required by paragraph (m) of this section; and

(e) A review of this standard, including appendices.

(2) Access to training materials.

(i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(o) ~~Signs and labels~~ Communication of hazards

(1) ~~General.~~ Hazard communication—general

(i) ~~The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to or in combination with, signs and labels required by this paragraph.~~ Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for DBCP.

(ii) ~~The employer shall assure that no statement appears on or near any sign or label required by this paragraph which contradicts or detracts from the required sign or label.~~ In classifying the hazards of DBCP at least the following hazards are to be addressed: Cancer; reproductive effects; liver effects; kidney effects; central nervous system effects; skin, eye and respiratory tract irritation; and acute toxicity effects.

(iii) Employers shall include DBCP in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of DBCP and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (n) of this section.

(iv) The employer shall ensure that no statement appears on or near any sign or label required by this paragraph (o) which contradicts or detracts from the meaning of the required sign or label.

(2) Signs.

(i) The employer shall post signs to clearly indicate all regulated areas. These signs shall bear the legend:

DANGER
1,2-Dibromo-3-chloropropane
(Insert appropriate trade or common names)
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATOR REQUIRED

(ii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in

paragraph (o)(2) of this section:

DANGER

1,2-Dibromo-3-chloropropane

(Insert appropriate trade or common names)

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

RESPIRATOR REQUIRED

(3) Labels.

(i) The employer shall assure that precautionary labels are affixed to all containers of DBCP and of products containing DBCP in the workplace, and that the labels remain affixed when the DBCP or products containing DBCP are sold, distributed, or otherwise leave the employer's workplace. Where DBCP or products containing DBCP are sold, distributed or otherwise leave the employer's workplace bearing appropriate labels required by EPA under the regulations in 40 CFR Part 162, the labels required by this paragraph need not be affixed. Where DBCP or products containing DBCP are sold, distributed or otherwise leave the employer's workplace bearing appropriate labels required by EPA under the regulations in 40 CFR Part 162, the labels required by this paragraph (o)(3) need not be affixed.

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend: The employer shall ensure that the precautionary labels required by this paragraph (o)(3) are readily visible and legible.

DANGER

1,2-Dibromo-3-chloropropane

CANCER HAZARD

(iii) Prior to June 1, 2015, employers may include the following information on containers of DBCP or products containing DBCP, DBCP-contaminated protective devices or work clothing or DBCP-contaminated portable vacuums in lieu of the labeling requirements in paragraphs (j)(2)(v), (k)(1)(iii)(b) and (o)(1)(i) of this section:

DANGER

1,2-Dibromo-3-chloropropane

CANCER HAZARD

(p) Recordkeeping

(1) Exposure monitoring.

(i) The employer shall establish and maintain an accurate record of all monitoring required

by paragraph (f) of this section.

(ii) This record shall include:

(a) The dates, number, duration and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(b) A description of the sampling and analytical methods used;

(c) Type of respiratory protective devices worn, if any; and

(d) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(2) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance required by paragraph (m) of this section.

(ii) This record shall include:

(a) The name and social security number of the employee;

(b) A copy of the physician's written opinion;

(c) Any employee medical complaints related to exposure to DBCP;

(d) A copy of the information provided the physician as required by paragraphs (m)(4)(ii) through (m)(4)(iv) of this section; and

(e) A copy of the employee's medical and work history.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(3) Availability.

(i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure monitoring records and employee medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020(a) - (e) and (g) - (i).

(4) Transfer of records.

(i) If the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (p) of this section for the prescribed period.

(ii) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(q) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees, or their designated representatives, with an opportunity to observe any monitoring of employee exposure to DBCP required by this section.

(2) Observation procedures.

(i) Whenever observation of the measuring or monitoring of employee exposure to DBCP requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring or measurement, observers shall be entitled to:

(a) Receive an explanation of the measurement procedures;

(b) Observe all s related to the measurement of airborne concentrations of DBCP performed at the place of exposure; and

(c) Record the results obtained.

(r) Appendices. The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

* (Approved by the Office of Management and Budget under control number 1218-0101)

1910.1044 App A Substance safety data sheet for DBCP

APPENDIX A to 1910.1044 - SUBSTANCE SAFETY DATA SHEET FOR DBCP

I. SUBSTANCE IDENTIFICATION

A. Synonyms and trades names: DBCP; Dibromochloropropane; Fumazone (Dow Chemical Company TM); Nemaflume; Nemagon (Shell Chemical Co. TM); Nemaset; BBC 12; and OS 1879.

B. Permissible exposure:

1. Airborne. 1 part DBCP vapor per billion parts of air (1 ppb); time-weighted average (TWA) for an 8-hour workday.

2. Dermal. Eye contact and skin contact with DBCP are prohibited.

C. Appearance and odor: Technical grade DBCP is a dense yellow or amber liquid with a pungent odor. It may also appear in granular form, or blended in varying concentrations with other liquids.

D. Uses: DBCP is used to control nematodes, very small worm-like plant parasites, on crops including cotton, soybeans, fruits, nuts, vegetables and ornamentals.

II. HEALTH HAZARD DATA

A. Routes of entry: Employees may be exposed:

1. Through inhalation (breathing);

2. Through ingestion (swallowing);

3. Skin contact; and

4. Eye contact.

B. Effects of exposure:

1. Acute exposure. DBCP may cause drowsiness, irritation of the eyes, nose, throat and skin, nausea and vomiting. In addition, overexposure may cause damage to the lungs, liver or kidneys.

2. Chronic exposure. Prolonged or repeated exposure to DBCP has been shown to cause sterility in humans. It also has been shown to produce cancer and sterility in laboratory animals and has been determined to constitute an increased risk of cancer in man.

3. Reporting Signs and Symptoms. If you develop any of the above signs or symptoms that you think are caused by exposure to DBCP, you should inform your employer.

III. EMERGENCY FIRST AID PROCEDURES

A. Eye exposure. If DBCP liquid or dust containing DBCP gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with DBCP.

B. Skin exposure. If DBCP liquids or dusts containing DBCP get on your skin, immediately wash using soap or mild detergent and water. If DBCP liquids or dusts containing DBCP penetrate through your clothing, remove the clothing immediately and wash. If irritation is present after washing get medical attention.

C. Breathing. If you or any person breathe in large amounts of DBCP, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Do not use mouth-to-mouth. Keep the affected person warm and at rest. Get medical attention as soon as possible.

D. Swallowing. When DBCP has been swallowed and the person is conscious, give the person large amounts of water immediately. After the water has been swallowed, try to get the person to vomit by having him touch the back of his throat with his finger. Do not make an unconscious person vomit. Get medical attention immediately.

E. Rescue. Notify someone. Put into effect the established emergency rescue procedures. Know the locations of the emergency rescue equipment before the need arises.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

A. Respirators. You may be required to wear a respirator in emergencies and while your employer is in the process of reducing DBCP exposures through engineering controls. If respirators are worn, they must have a National Institute for Occupational Safety and Health (NIOSH) approval label (Older respirators may have a Bureau of Mines Approval label). For effective protection, a respirator must fit your face and head snugly. The respirator should not be loosened or removed in work situations where its use is required. DBCP does not have a detectable odor except at 1,000 times or more above the permissible exposure limit. If you can

smell DBCP while wearing a respirator, the respirator is not working correctly; go immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. Protective clothing. When working with DBCP you must wear for your protection impermeable work clothing provided by your employer. (Standard rubber and neoprene protective clothing do not offer adequate protection).

DBCPC must never be allowed to remain on the skin. Clothing and shoes must not be allowed to become contaminated with DBCP, and if they do, they must be promptly removed and not worn again until completely free of DBCP. Turn in impermeable clothing that has developed leaks for repair or replacement.

C. Eye protection. You must wear splash-proof safety goggles where there is any possibility of DBCP liquid or dust contacting your eyes.

V. PRECAUTIONS FOR SAFE USE, HANDLING, AND STORAGE

A. DBCP must be stored in tightly closed containers in a cool, well-ventilated area.

B. If your work clothing may have become contaminated with DBCP, or liquids or dusts containing DBCP, you must change into uncontaminated clothing before leaving the work premises.

C. You must promptly remove any protective clothing that becomes contaminated with DBCP. This clothing must not be reworn until the DBCP is removed from the clothing.

D. If your skin becomes contaminated with DBCP, you must immediately and thoroughly wash or shower with soap or mild detergent and water to remove any DBCP from your skin.

E. You must not keep food, beverages, cosmetics, or smoking materials, nor eat or smoke, in regulated areas.

F. If you work in a regulated area, you must wash your hands thoroughly with soap or mild detergent and water, before eating, smoking or using toilet facilities.

G. If you work in a regulated area, you must remove any protective equipment or clothing before leaving the regulated area.

H. Ask your supervisor where DBCP is used in your work area and for any additional safety and health rules.

VI. ACCESS TO INFORMATION

A. Each year, your employer is required to inform you of the information contained in this Substance Safety Data Sheet for DBCP. In addition, your employer must instruct you in the safe use of DBCP, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to DBCP. You or your representative have the right to observe employee exposure measurements and to record the result obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he is required to inform you of the actions which are being taken to reduce your exposure.

C. Your employer is required to keep records of your exposure and medical examinations. Your employer is required to keep exposure and medical data for at least 40 years or the duration of your employment plus 20 years, whichever is longer.

D. Your employer is required to release exposure and medical records to you, your physician, or other individual designated by you upon your written request.

1910.1044 App B Substance technical guidelines for DBCP

APPENDIX B to 1910.1044 - SUBSTANCE TECHNICAL GUIDELINES FOR DBCP

I. PHYSICAL AND CHEMICAL DATA

A. Substance Identification

1. Synonyms: 1,2-dibromo-3-chloropropane; DBCP, Fumazone; Nemaforme; Nemagon; Nemaset; BBC 12; OS 1879. DBCP is also included in agricultural pesticides and fumigants which include the phrase "Nema---" in their name.

2. Formula: C₃H₅Br₂ Cl.

3. Molecular Weight: 236.

B. Physical Data:

1. Boiling point (760 mm HG): 195C (383F)

2. Specific gravity (water=1): 2.093.

3. Vapor density (air=1 at boiling point of DBCP): Data not available.
4. Melting point: 6C (43F).
5. Vapor pressure at 20C (68F): 0.8 mm Hg
6. Solubility in water: 1000 ppm.
7. Evaporation rate (Butyl Acetate=1): very much less than 1.
8. Appearance and odor: Dense yellow or amber liquid with a pungent odor at high concentrations. Any detectable odor of DBCP indicates overexposure.

II. FIRE EXPLOSION AND REACTIVITY HAZARD DATA

A. Fire

1. Flash point: 170F (77C)
2. Autoignition temperature: Data not available.
3. Flammable limits in air, percent by volume: Data not available.
4. Extinguishing media: Carbon dioxide, dry chemical.
5. Special fire-fighting procedures: Do not use a solid stream of water since a stream will scatter and spread the fire. Use water spray to cool containers exposed to a fire.
6. Unusual fire and explosion hazards: None known.
7. For purposes of complying with the requirements of 1910.106, liquid DBCP is classified as a Class III A combustible liquid.
8. For the purpose of complying with 1910.309, the classification of hazardous locations as described in article 500 of the National Electrical Code for DBCP shall be Class I, Group D.
9. For the purpose of compliance with 1910.157, DBCP is classified as a Class B fire hazard.
10. For the purpose of compliance with 1910.178, locations classified as hazardous locations due to the presence of DBCP shall be Class I, Group D.

11. Sources of ignition are prohibited where DBCP presents a fire or explosion hazard.

B. Reactivity

1. Conditions contributing to instability: None known.

2. Incompatibilities: Reacts with chemically active metals, such as aluminum, magnesium and tin alloys.

3. Hazardous decomposition products: Toxic gases and vapors (such as HBr, HCl and carbon monoxide) may be released in a fire involving DBCP.

4. Special precautions: DBCP will attack some rubber materials and coatings.

III. SPILL, LEAK AND DISPOSAL PROCEDURES

A. If DBCP is spilled or leaked, the following s should be taken:

1. The area should be evacuated at once and re-entered only after thorough ventilation.

2. Ventilate area of spill or leak.

3. If in liquid form, collect for reclamation or absorb in paper, vermiculite, dry sand, earth or similar material.

4. If in solid form, collect spilled material in the most convenient and safe manner for reclamation or for disposal.

B. Persons not wearing protective equipment must be restricted from areas of spills or leaks until cleanup has been completed.

C. Waste Disposal Methods:

1. For small quantities of liquid DBCP, absorb on paper towels, remove to a safe place (such as a fume hood) and burn the paper. Large quantities can be reclaimed or collected and atomized in a suitable combustion chamber equipped with an appropriate effluent gas cleaning device. If liquid DBCP is absorbed in vermiculite, dry sand, earth or similar material and placed in sealed containers it may be disposed of in a State-approved sanitary landfill.

2. If in solid form, for small quantities, place on paper towels, remove to a safe place (such as a fume hood) and burn. Large quantities may be reclaimed. However, if this is not practical,

dissolve in a flammable solvent (such as alcohol) and atomize in a suitable combustion chamber equipped with an appropriate effluent gas cleaning device. DBCP in solid form may also be disposed in a state-approved sanitary landfill.

IV. MONITORING AND MEASUREMENT PROCEDURES

A. Exposure above the permissible exposure limit.

1. Eight Hour Exposure Evaluation: Measurements taken for the purpose of determining employee exposure under this section are best taken so that the average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

2. Monitoring Techniques: The sampling and analysis under this section may be performed by collecting the DBCP vapor on petroleum based charcoal absorption tubes with subsequent chemical analyses. The method of measurement chosen should determine the concentration of airborne DBCP at the permissible exposure limit to an accuracy of plus or minus 25 percent. If charcoal tubes are used, a total volume of 10 liters should be collected at a flow rate of 50 cc. per minute for each tube. Analyze the resultant samples as you would samples of halogenated solvent.

B. Since many of the duties relating to employee protection are dependent on the results of monitoring and measuring procedures, employers should assure that the evaluation of employee exposures is performed by a competent industrial hygienist or other technically qualified person.

V. PROTECTIVE CLOTHING

Employees should be required to wear appropriate protective clothing to prevent any possibility of skin contact with DBCP. Because DBCP is absorbed through the skin, it is important to prevent skin contact with both liquid and solid forms of DBCP. Protective clothing should include impermeable coveralls or similar fullbody work clothing, gloves, headcoverings, and workshoes or shoe coverings. Standard rubber and neoprene gloves do not offer adequate protection and should not be relied upon to keep DBCP off the skin. DBCP should never be allowed to remain on the skin. Clothing and shoes should not be allowed to become contaminated with the material, and if they do, they should be promptly removed and not worn again until completely free of the material. Any protective clothing which has developed leaks or is otherwise found to be defective should be repaired or replaced. Employees should also be required to wear splash-proof safety goggles where there is any possibility of DBCP contacting

the eyes.

VI. HOUSEKEEPING AND HYGIENE FACILITIES

1. The workplace must be kept clean, orderly and in a sanitary condition;
2. Dry sweeping and the use of compressed air is unsafe for the cleaning of floors and other surfaces where DBCP dust or liquids are found. To minimize the contamination of air with dust, vacuuming with either portable or permanent systems must be used. If a portable unit is selected, the exhaust must be attached to the general workplace exhaust ventilation system, or collected within the vacuum unit equipped with high efficiency filters or other appropriate means of contamination removal and not used for other purposes. Units used to collect DBCP must be labeled.
3. Adequate washing facilities with hot and cold water must be provided, and maintained in a sanitary condition. Suitable cleansing agents should also be provided to assure the effective removal of DBCP from the skin.
4. Change or dressing rooms with individual clothes storage facilities must be provided to prevent the contamination of street clothes with DBCP. Because of the hazardous nature of DBCP, contaminated protective clothing must be stored in closed containers for cleaning or disposal.

VII. MISCELLANEOUS PRECAUTIONS

- A. Store DBCP in tightly closed containers in a cool, well ventilated area.
- B. Use of supplied-air suits or other impervious clothing (such as acid suits) may be necessary to prevent skin contact with DBCP. Supplied-air suits should be selected, used, and maintained under the supervision of persons knowledgeable in the limitations and potential life-endangering characteristics of supplied-air suits.
- C. The use of air-conditioned suits may be necessary in warmer climates.
- D. Advise employees of all areas and operations where exposure to DBCP could occur.

VIII. COMMON OPERATIONS

Common operations in which exposure to DBCP is likely to occur are: during its production; and during its formulation into pesticides and fumigants.

1910.1044 App C Medical surveillance guidelines for DBCP

APPENDIX C to 1910.1044 - MEDICAL SURVEILLANCE GUIDELINES FOR DBCP

I. ROUTE OF ENTRY

Inhalation; skin absorption

II. TOXICOLOGY

Recent data collected on workers involved in the manufacture and formulation of DBCP has shown that DBCP can cause sterility at very low levels of exposure. This finding is supported by studies showing that DBCP causes sterility in animals. Chronic exposure to DBCP resulted in pronounced necrotic action on the parenchymatous organs (i.e., liver, kidney, spleen) and on the testicles of rats at concentrations as low as 5 ppm. Rats that were chronically exposed to DBCP also showed changes in the composition of the blood, showing low ABC, hemoglobin, and WBC, and high reticulocyte levels as well as functional hepatic disturbance, manifesting itself in a long prothrombin time. Reznik et al. noted a single dose of 100 mg produced profound depression of the nervous system of rats. Their condition gradually improved. Acute exposure also resulted in the destruction of the sex gland activity of male rats as well as causing changes in the estrous cycle in female rats. Animal studies have also associated DBCP with an increased incidence of carcinoma. Olson, et al. orally administered DBCP to rats and mice 5 times per week at experimentally predetermined maximally tolerated doses and at half those doses. As early as ten weeks after initiation of treatment, DBCP induce a high incidence of squamous cell carcinomas of the stomach with metastases in both species. DBCP also induced mammary adenocarcinomas in the female rats at both dose levels.

III. SIGNS AND SYMPTOMS

A. Inhalation: Nausea, eye irritation, conjunctivitis, respiratory irritation, pulmonary congestion or edema, CNS depression with apathy, sluggishness, and ataxia.

B. Dermal: Erythema or inflammation and dermatitis on repeated exposure.

IV. SPECIAL TESTS

A. Semen analysis: The following information excerpted from the document "Evaluation of Testicular Function", submitted by the Corporate Medical Department of the Shell Oil Company (exhibit 39-3), may be useful to physicians conducting the medical surveillance program;

In performing semen analyses certain minimal but specific criteria should be met:

1. It is recommended that a minimum of three valid semen analyses be obtained in order to make a determination of an individual's average sperm count.

2. A period of sexual abstinence is necessary prior to the collection of each masturbatory sample. It is recommended that intercourse or masturbation be performed 48 hours before the actual specimen collection. A period of 48 hours of abstinence would follow; then the masturbatory sample would be collected.

3. Each semen specimen should be collected in a clean, widemouthed, glass jar (not necessarily pre-sterilized) in a manner designated by the examining physician. Any part of the seminal fluid exam should be initialed only after liquefaction is complete, i.e., 30 to 45 minutes after collection.

4. Semen volume should be measured to the nearest 1/10 of a cubic centimeter.

5. Sperm density should be determined using routine techniques involving the use of a white cell pipette and a hemocytometer chamber. The immobilizing fluid most effective and most easily obtained for this process is distilled water.

6. Thin, dry smears of the semen should be made for a morphologic classification of the sperm forms and should be stained with either hematoxylin or the more difficult, yet more precise, Papanicolaou technique. Also of importance to record is obvious sperm agglutination, pyospermia, delayed liquefaction (greater than 30 minutes), and hyperviscosity. In addition, pH, using nitrazine paper, should be determined.

7. A total morphology evaluation should include percentages of the following:

- a. Normal (oval) forms,
- b. Tapered forms,
- c. Amorphous forms (include large and small sperm shapes),
- d. Duplicated (either heads or tails) forms, and
- e. Immature forms.

8. Each sample should be evaluated for sperm viability (percent viable sperm moving at the time of examination) as well as sperm motility (subjective characterization of "purposeful forward sperm progression" of the majority of those viable sperm analyzed) within two hours after collection, ideally by the same or equally qualified examiner.

B. Serum determinations: The following serum determinations should be performed by radioimmuno-assay techniques using National Institutes of Health (NIH) specific antigen or antigen preparations of equivalent sensitivity:

1. Serum follicle stimulating hormone (FSH);
2. Serum luteinizing hormone (LH); and
3. Serum total estrogen (females only).

V. TREATMENT

Remove from exposure immediately, give oxygen or artificial resuscitation if indicated. Contaminated clothing and shoes should be removed immediately. Flush eyes and wash contaminated skin. If swallowed and the person is conscious, induce vomiting. Recovery from mild exposures is usually rapid and complete.

VI. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. Other considerations. DBCP can cause both acute and chronic effects. It is important that the physician become familiar with the operating conditions in which exposure to DBCP occurs. Those with respiratory disorders may not tolerate the wearing of negative pressure respirators.

B. Surveillance and screening. Medical histories and laboratory examinations are required for each employee subject to exposure to DBCP. The employer should screen employees for history of certain medical conditions (listed below) which might place the employee at increased risk from exposure.

1. Liver disease. The primary site of biotransformation and detoxification of DBCP is the liver. Liver dysfunctions likely to inhibit the conjugation reactions will tend to promote the toxic actions of DBCP. These precautions should be considered before exposing persons with impaired liver function to DBCP.
2. Renal disease. Because DBCP has been associated with injury to the kidney it is important that special consideration be given to those with possible impairment of renal function.
3. Skin disease. DBCP can penetrate the skin and can cause erythema on prolonged exposure. Persons with pre-existing skin disorders may be more susceptible to the effects of DBCP.
4. Blood dyscrasias. DBCP has been shown to decrease the content of erythrocytes, hemoglobin, and leukocytes in the blood, as well as increase the prothrombin time. Persons with existing blood disorders may be more susceptible to the effects of DBCP.
5. Reproductive disorders. Animal studies have associated DBCP with various effects on the reproductive organs. Among these effects are atrophy of the testicles and changes in the estrous cycle. Persons with pre-existing reproductive disorders may be at increased risk to these effects of DBCP.

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- [43 FR 11527, Mar. 17, 1978, as amended at 45 FR 35283, May 23, 1980; 49 FR 18295, Apr. 30, 1984; 54 FR 24334, June 7, 1989; 61 FR 5507, Feb. 13, 1996]

1910.1045 Acrylonitrile.

(a) Scope and application.

(1) This section applies to all occupational exposures to acrylonitrile (AN), Chemical Abstracts Service Registry No. 000107131, except as provided in paragraphs (a)(2) and (a)(3) of this section.

(2) This section does not apply to exposures which result solely from the processing, use, and handling of the following materials:

(i) ABS resins, SAN resins, nitrile barrier resins, solid nitrile elastomers, and acrylic and modacrylic fibers, when these listed materials are in the form of finished polymers, and products fabricated from such finished polymers;

(ii) Materials made from and/or containing AN for which objective data is reasonably relied upon to demonstrate that the material is not capable of releasing AN in airborne concentrations in excess of 1 ppm as an eight (8)-hour time-weighted average, under the expected conditions of processing, use, and handling which will cause the greatest possible release; and

(iii) Solid materials made from and/or containing AN which will not be heated above 170 deg. F during handling, use, or processing.

(3) An employer relying upon exemption under paragraph (a)(2)(ii) shall maintain records of the objective data supporting that exemption, and of the basis of the employer's reliance on the data, as provided in paragraph (q) of this section.

(b) Definitions.

"Acrylonitrile" or "AN" means acrylonitrile monomer, chemical formula $\text{CH}_2=\text{CHCN}$.

"Action level" means a concentration of AN of 1 ppm as an eight (8) -hour time-weighted average.

"Administrator" means the Administrator of the State of Wyoming Occupational Health and Safety Division, or designee.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring procedures under paragraph r. of this section.

"Decontamination" means treatment of materials and surfaces by water washdown, ventilation, or other means, to assure that the materials will not expose employees to airborne concentrations of AN above 1 means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or designee.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which results in an unexpected massive release of AN.

"Liquid AN" means AN monomer in liquid form, and liquid or semiliquid polymer intermediates, including slurries, suspensions, emulsions, and solutions, produced during the polymerization of AN.

"WOHS" means the Office of the Wyoming Occupational Health and Safety Department.

(c) Permissible exposure limits

(1) Inhalation.

(i) Time weighted average limit (TWA). The employer shall assure that no employee is exposed to an airborne concentration of acrylonitrile in excess of two (2) parts acrylonitrile per million parts of air (2 ppm) as an eight (8)-hour time-weighted average.

(ii) Ceiling limit. The employer shall assure that no employee is exposed to an airborne concentration of acrylonitrile in excess of ten (10) ppm as averaged over any fifteen (15)-minute period during the work day.

(2) Dermal and eye exposure. The employer shall assure that no employee is exposed to skin contact or eye contact with liquid AN.

(d) [Reserved]

(e) Exposure monitoring

(1) General.

(i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to AN over an eight (8)-hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) Initial monitoring. Each employer who has a place of employment in which AN is present shall monitor each such workplace and work operation to accurately determine the airborne concentrations of AN to which employees may be exposed.

(3) Frequency.

(i) If the monitoring required by this section reveals employee exposure to be below the action level, the employer may discontinue monitoring for that employee.

(ii) If the monitoring required by this section reveals employee exposure to be at or above the action level but at or below the permissible exposure limits, the employer must repeat such monitoring for each such employee at least every 6 months. The employer must continue these measurements every 6 months until at least two consecutive measurements taken at least seven (7) days apart, are below the action level, and thereafter the employer may discontinue monitoring for that employee.

(iii) If the monitoring required by this section reveals employee exposure to be in excess of the permissible exposure limits, the employer must repeat these determinations for each such employee at least quarterly. The employer must continue these quarterly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are at or below the permissible exposure limits, and thereafter the employer must monitor at least every 6 months.

(4) Additional monitoring. Whenever there has been a production, process, control, or personnel change which may result in new or additional exposures to AN, or whenever the

employer has any other reason to suspect a change which may result in new or additional exposures to AN, additional monitoring which complies with this paragraph shall be conducted.

(5) Employee notification.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that the permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

(6) Accuracy of measurement. The method of measurement of employee exposures shall be accurate to a confidence level of 95 percent, to within plus or minus 35 percent for concentrations of AN at or above the permissible exposure limits, and plus or minus 50 percent for concentrations of AN below the permissible exposure limits.

(f) Regulated areas.

(1) The employer shall establish regulated areas where AN concentrations are in excess of the permissible exposure limits.

(2) Regulated areas shall be demarcated and segregated from the rest of the workplace, in any manner that minimizes the number of persons who will be exposed to AN.

(3) Access to regulated areas shall be limited to authorized persons or to persons otherwise authorized by the act or regulations issued pursuant thereto.

(4) The employer shall assure that food or beverages are not present or consumed, tobacco products are not present or used, and cosmetics are not applied in the regulated area.

(g) Methods of compliance

(1) Engineering and work practice controls.

(i) By November 2, 1980, the employer shall institute engineering and work practice controls to reduce and maintain employee exposures to AN, to or below the permissible exposure limits, except to the extent that the employer establishes that such controls are not feasible.

(ii) Wherever the engineering and work practice controls which can be instituted are not

sufficient to reduce employee exposures to or below the permissible exposure limits, the employer shall nonetheless use them to reduce exposures to the lowest levels achievable by these controls, and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (h) of this section.

(2) Compliance program.

(i) The employer shall establish and implement a written program to reduce employee exposures to or below the permissible exposure limits solely by means of engineering and work practice controls, as required by paragraph (g)(1) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation or process resulting in employee exposure to AN above the permissible exposure limits;

(B) An outline of the nature of the engineering controls and work practices to be applied to the operation or process in question;

(C) A report of the technology considered in meeting the permissible exposure limits;

(D) A schedule for implementation of engineering and work practice controls for the operation or process, which shall project completion no later than November 2, 1980; and

(E) Other relevant information.

(iii) The employer shall complete the set forth in the compliance program by the dates in the schedule.

(iv) Written plans shall be submitted upon request to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, or any affected employee or representative.

(v) The plans required by this paragraph must be revised and updated at least annually to reflect the current status of the program.

(h) Respiratory protection

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work-practice

controls.

(ii) Work operations, such as maintenance and repair activities or reactor cleaning, for which the employer establishes that engineering and work-practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the permissible exposure limits.

(iv) Emergencies.

(2) Respirator program.

(i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) If air-purifying respirators (chemical-cartridge or chemical-canister types) are used:

(A) The air-purifying canister or cartridge must be replaced prior to the expiration of its service life or at the completion of each shift, whichever occurs first.

(B) A label must be attached to the cartridge or canister to indicate the date and time at which it is first installed on the respirator.

(3) Respirator selection. Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(ii) For escape, provide employees with any organic vapor respirator or any self-contained breathing apparatus permitted for use under paragraph (h)(3)(i) of this standard.

(i) Emergency situations

(1) Written plans.

(i) A written plan for emergency situations shall be developed for each workplace where liquid AN is present. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped as required in paragraph (h) of this section until the emergency is abated.

(iii) Employees not engaged in correcting the emergency shall be evacuated from the area and shall not be permitted to return until the emergency is abated.

(2) Alerting employees. Where there is the possibility of employee exposure to AN in excess of the ceiling limit, a general alarm shall be installed and used to promptly alert employees of such occurrences.

(j) Protective clothing and equipment

(1) Provision and use. Where eye or skin contact with liquid AN may occur, the employer shall provide at no cost to the employee, and assure that employees wear, impermeable protective clothing or other equipment to protect any area of the body which may come in contact with liquid AN. The provision of 1910.132 and 1910.133 shall be complied with.

(2) Cleaning and replacement.

(i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this section as needed to maintain their effectiveness.

(ii) The employer shall assure that impermeable protective clothing which contacts or is likely to have contacted liquid AN shall be decontaminated before being removed by the employee.

(iii) The employer shall assure that an employee whose nonimpermeable clothing becomes wetted with liquid AN shall immediately remove that clothing and proceed to shower. The clothing shall be decontaminated before it is removed from the regulated area.

(iv) The employer shall assure that no employee removes protective clothing or equipment from the change room, except for those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(v) The employer shall inform any person who launders or cleans protective clothing or equipment of the potentially harmful effects of exposure to AN.

(k) Housekeeping.

(1) All surfaces shall be maintained free of visible accumulations of liquid AN.

(2) For operations involving liquid AN, the employer shall institute a program for detecting leaks and spills of liquid AN, including regular visual inspections.

(3) Where spills of liquid AN are detected, the employer shall assure that surfaces contacted by the liquid AN are decontaminated. Employees not engaged in decontamination activities shall

leave the area of the spill, and shall not be permitted in the area until decontamination is completed.

(l) Waste disposal. AN waste, scrap, debris, bags, containers, or equipment shall be decontaminated before being incorporated in the general waste disposal system.

(m) Hygiene facilities and practices.

(1) Where employees are exposed to airborne concentrations of AN above the permissible exposure limits, or where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, the facilities required by 29 CFR 1910.141, including clean change rooms and shower facilities, shall be provided by the employer for the use of those employees, and the employer shall assure that the employees use the facilities provided.

(2) The employer shall assure that employees wearing protective clothing or equipment for protection from skin contact with liquid AN shall shower at the end of the work shift.

(3) The employer shall assure that, in the event of skin or eye exposure to liquid AN, the affected employee shall shower immediately to minimize the danger of skin absorption.

(4) The employer shall assure that employees working in the regulated area wash their hands and faces prior to eating.

(n) Medical surveillance

(1) General.

(i) The employer shall institute a program of medical surveillance for each employee who is or will be exposed to AN at or above the action level, without regard to the use of respirators. The employer shall provide each such employee with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and that they shall be provided without cost to the employee.

(2) Initial examinations. At the time of initial assignment, or upon institution of the medical surveillance program, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history and medical history with special attention to skin, respiratory, and gastrointestinal systems, and those nonspecific symptoms, such as headache, nausea, vomiting, dizziness, weakness, or other central nervous system dysfunctions that may be associated with

acute or with chronic exposure to AN;

(ii) A complete physical examination giving particular attention to the peripheral and central nervous system, gastrointestinal system, respiratory system, skin, and thyroid;

(iii) A 14- by 17-inch posteroanterior chest X-ray; and

(iv) Further tests of the intestinal tract, including fecal occult blood screening, for all workers 40 years of age or older, and for any other affected employees for whom, in the opinion of the physician, such testing is appropriate.

(3) Periodic examinations.

(i) The employer shall provide the examinations specified in paragraph (n)(2) of this section at least annually for all employees specified in paragraph (n)(1) of this section.

(ii) If an employee has not had the examination specified in paragraph (n)(2) of this section within 6 months preceding termination of employment, the employer shall make such examination available to the employee prior to such termination.

(4) Additional examinations. If the employee for any reason develops signs or symptoms which may be associated with exposure to AN, the employer shall provide an appropriate examination and emergency medical treatment.

(5) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its appendixes;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level;

(iv) The employee's anticipated or estimated exposure level (for preplacement examinations or in cases of exposure due to an emergency);

(v) A description of any personal protective equipment used or to be used; and

(vi) Information from previous medical examinations of the affected employee, which is not otherwise available to the examining physician.

(6) Physician's written opinion.

(i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical examination and test performed;

(B) The physician's opinion as to whether the employee has any detected medical condition(s) which would place the employee at an increased risk of material impairment of the employee's health from exposure to AN;

(C) Any recommended limitations upon the employee's exposure to AN or upon the use of protective clothing and equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to AN.

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) Employee information and training

(1) Training program.

(i) The employer shall train each employee exposed to AN above the action level, each employee whose exposures are maintained below the action level by engineering and work practice controls, and each employee subject to potential skin or eye contact with liquid AN in accordance with the requirements of this section. The employer shall institute a training program and ensure employee participation in the program.

(ii) Training shall be provided at the time of initial assignment, or upon institution of the training program, and at least annually thereafter, and the employer shall assure that each employee is informed of the following:

(A) The information contained in appendixes A and B;

(B) The quantity, location, manner of use, release, or storage of AN, and the specific nature of operations which could result in exposure to AN, as well as any necessary protective s;

(C) The purpose, proper use, and limitations of respirators and protective clothing;

(D) The purpose and a description of the medical surveillance program required by

paragraph (n) of this section;

(E) The emergency procedures developed, as required by paragraph (i) of this section;

(F) Engineering and work practice controls, their function, and the employee's relationship to these controls; and

(G) A review of this standard.

(2) Access to training materials.

(i) The employer shall make a copy of this standard and its appendixes readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) ~~Signs and labels~~ Communication of hazards

(1) ~~General~~ Hazard communication—general.

(i) ~~The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.~~ Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for AN and AN-based materials not exempted under paragraph (a)(2) of this section.

(ii) ~~The employer shall assure that no statement appears on or near any sign or label required by this paragraph which contradicts or detracts from the required sign or label.~~ In classifying the hazards of AN and AN-based materials at least the following hazards are to be addressed: Cancer; central nervous system effects; liver effects; skin sensitization; skin, respiratory, and eye irritation; acute toxicity effects; and flammability.

(iii) Employers shall include AN and AN-based materials in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of AN and AN-based materials and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (o) of this section.

(iv) The employer shall ensure that no statement appears on or near any sign or label required by this paragraph (p) that contradicts or detracts from the required sign or label.

(2) Signs.

(i) The employer shall post signs to clearly indicate all workplaces where AN concentrations exceed the permissible exposure limits. The signs shall bear the following legend:

~~DANGER
ACRYLONITRILE (AN)
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS MAY BE REQUIRED~~
DANGER
ACRYLONITRILE (AN)
MAY CAUSE CANCER
RESPIRATORY PROTECTION MAY BE REQUIRED IN THIS AREA
AUTHORIZED PERSONNEL ONLY

~~(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible. The employer shall ensure that signs required by this paragraph (p)(2) are illuminated and cleaned as necessary so that the legend is readily visible.~~

~~(iii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (p)(2)(i) of this section:~~

~~DANGER
ACRYLONITRILE (AN)
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS MAY BE REQUIRED~~

(3) Labels.

~~(i) The employer shall assure that precautionary labels are affixed to all containers of liquid AN and AN-based materials not exempted under paragraph (a)(2) of this standard. The employer shall assure that the labels remain affixed when the materials are sold, distributed, or otherwise leave the employer's workplace. The employer shall ensure that precautionary labels are in compliance with paragraph (p)(1)(i) of this section and are affixed to all containers of liquid AN and AN-based materials not exempted under paragraph (a)(2) of this section. The employer shall ensure that the labels remain affixed when the materials are sold, distributed, or otherwise leave the employer's workplace.~~

~~(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend: Prior to June 1, 2015, employers may include the following information on precautionary labels required by this~~

paragraph (p)(3) in lieu of the labeling requirements in paragraph (p)(1) of this section:

DANGER
CONTAINS ACRYLONITRILE (AN)
CANCER HAZARD

(iii) The employer shall ensure that the precautionary labels required by this paragraph (p)(3) are readily visible and legible..

(q) Recordkeeping

(1) Objective data for exempted operations.

(i) Where the processing, use, and handling of materials made from or containing AN are exempted pursuant to paragraph (a)(2)(ii) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The material qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of AN;

(D) A description of the operation exempted and how the data supports the exemption;
and

(E) Other data relevant to the operations, materials, and processing covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) Exposure monitoring.

(i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a

description of the sampling procedure used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used and the data relied upon to establish that the methods used meet the accuracy and precision requirements of paragraph (e)(6) of this section;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least forty (40) years, or for the duration of employment plus twenty (20) years, whichever is longer.

(3) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physician's written opinions;

(B) Any employee medical complaints related to exposure to AN;

(C) A copy of the information provided to the physician as required by paragraph (n)(5) of this section; and

(D) A copy of the employee's medical and work history.

(iii) The employer shall assure that this record be maintained for at least forty (40) years, or for the duration of employment plus twenty (20) years, whichever is longer.

(4) Availability.

(i) The employer shall make all records required to be maintained by this section available, upon request, to the Assistant Secretary and the Director for examination and copying.

(ii) Records required by paragraphs (q)(1) - (q)(3) of this section shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a) - (e) and (q) - (i). Records required by paragraph (q)(1) shall be provided in the same manner as exposure monitoring records.

(5) Transfer of records.

(i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by this section for the prescribed period.

(ii) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(r) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to AN conducted pursuant to paragraph (e) of this section.

(2) Observation procedures.

(i) Whenever observation of the monitoring of employee exposure to AN requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing and equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled:

(A) To receive an explanation of the measurement procedures;

(B) To observe all s related to the measurement of airborne concentrations of AN performed at the place of exposure; and

(C) To record the results obtained.

(s) [Reserved]

(t) Appendixes. The information contained in the appendixes is not intended, by itself, to create any additional obligation not otherwise imposed, or to detract from any obligation.

1910.1045 App A Substance safety data sheet for acrylonitrile

APPENDIX A to 1910.1045 - SUBSTANCE SAFETY DATA SHEET FOR ACRYLONITRILE

I. SUBSTANCE IDENTIFICATION

A. Substance: Acrylonitrile (CH₂CHCN).

B. Synonyms: Propenenitrile; vinyl cyanide; cyanoethylene; AN; VCN; acylon; carbacryl; fumigian; ventox.

C. Acrylonitrile can be found as a liquid or vapor, and can also be found in polymer resins, rubbers, plastics, polyols, and other polymers having acrylonitrile as a raw or intermediate material.

D. AN is used in the manufacture of acrylic and modiacrylic fibers, acrylic plastics and resins, speciality polymers, nitrile rubbers, and other organic chemicals. It has also been used as a fumigant.

E. Appearance and odor: Colorless to pale yellow liquid with a pungent odor which can only be detected at concentrations above the permissible exposure level, in a range of 13-19 parts AN per million parts of air (13-19 ppm).

F. Permissible exposure: Exposure may not exceed either:

1. Two parts AN per million parts of air (2 ppm) averaged over the 8-hour workday; or
2. Ten parts AN per million parts of air (10 ppm) averaged over any 15-minute period in the workday.
3. In addition, skin and eye contact with liquid AN is prohibited.

II. HEALTH HAZARD DATA

A. Acrylonitrile can affect your body if you inhale the vapor (breathing), if it comes in contact with your eyes or skin, or if you swallow it. It may enter your body through your skin.

B. Effects of overexposure: 1. Short-term exposure: Acrylonitrile can cause eye irritation, nausea, vomiting, headache, sneezing, weakness, and lightheadedness. At high concentrations, the effects of exposure may go on to loss of consciousness and death. When acrylonitrile is held in contact with the skin after being absorbed into shoe leather or clothing, it may produce blisters following several hours of no apparent effect. Unless the shoes or clothing are removed immediately and the area washed, blistering will occur. Usually there is no pain or inflammation associated with blister formation.

2. Long-term exposure: Acrylonitrile has been shown to cause cancer in laboratory animals and has been associated with higher incidences of cancer in humans. Repeated or prolonged exposure of the skin to acrylonitrile may produce irritation and dermatitis.

3. Reporting signs and symptoms: You should inform your employer if you develop any signs or symptoms and suspect they are caused by exposure to acrylonitrile.

III. EMERGENCY FIRST AID PROCEDURES

A. Eye exposure: If acrylonitrile gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.

B. Skin exposure: If acrylonitrile gets on your skin, immediately wash the contaminated skin with water. If acrylonitrile soaks through your clothing, especially your shoes, remove the clothing immediately and wash the skin with water. If symptoms occur after washing, get medical attention immediately. Thoroughly wash the clothing before reusing. Contaminated leather shoes or other leather articles should be discarded.

C. Inhalation: If you or any other person breathes in large amounts of acrylonitrile, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.

D. Swallowing: When acrylonitrile has been swallowed, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him touch the back of his throat with his finger. Do not make an unconscious person vomit. Get medical attention immediately.

E. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, notify someone else and put into effect the established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the emergency equipment before the need arises.

F. Special first aid procedures: First aid kits containing an adequate supply (at least two dozen) of amyl nitrite pearls, each containing 0.3 ml, should be maintained at each site where acrylonitrile is used. When a person is suspected of receiving an overexposure to acrylonitrile, immediately remove that person from the contaminated area using established rescue procedures. Contaminated clothing must be removed and the acrylonitrile washed from the skin immediately. Artificial respiration should be started at once if breathing has stopped. If the person is unconscious, amyl nitrite may be used as an antidote by a properly trained individual in accordance with established emergency procedures. Medical aid should be obtained immediately.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

A. Respirators. You may be required to wear a respirator for nonroutine activities, in emergencies, while your employer is in the process of reducing acrylonitrile exposures through engineering controls, and in areas where engineering controls are not feasible. If respirators are worn, they must have a label issued by the National Institute for Occupational Safety and Health under the provisions of 42 CFR part 84 stating that the respirators have been approved for use with organic vapors. For effective protection, respirators must fit your face and head snugly. Respirators must not be loosened or removed in work situations where their use is required.

B. Supplied-air suits: In some work situations, the wearing of supplied-air suits may be necessary. Your employer must instruct you in their proper use and operation.

C. Protective clothing: You must wear impervious clothing, gloves, face shield, or other appropriate protective clothing to prevent skin contact with liquid acrylonitrile. Where protective clothing is required, your employer is required to provide clean garments to you as necessary to assume that the clothing protects you adequately.

Replace or repair impervious clothing that has developed leaks.

Acrylonitrile should never be allowed to remain on the skin. Clothing and shoes which are not impervious to acrylonitrile should not be allowed to become contaminated with acrylonitrile, and if they do the clothing and shoes should be promptly removed and decontaminated. The clothing should be laundered or discarded after the AN is removed. Once acrylonitrile penetrates shoes or other leather articles, they should not be worn again.

D. Eye protection: You must wear splashproof safety goggles in areas where liquid acrylonitrile may contact your eyes. In addition, contact lenses should not be worn in areas where eye contact with acrylonitrile can occur.

V. PRECAUTIONS FOR SAFE USE, HANDLING, AND STORAGE

A. Acrylonitrile is a flammable liquid, and its vapors can easily form explosive mixtures in air.

B. Acrylonitrile must be stored in tightly closed containers in a cool, well-ventilated area, away from heat, sparks, flames, strong oxidizers (especially bromine), strong bases, copper, copper alloys, ammonia, and amines.

C. Sources of ignition such as smoking and open flames are prohibited wherever acrylonitrile is handled, used, or stored in a manner that could create a potential fire or explosion hazard.

D. You should use non-sparking tools when opening or closing metal containers of acrylonitrile, and containers must be bonded and grounded when pouring or transferring liquid acrylonitrile.

E. You must immediately remove any non-impervious clothing that becomes wetted with acrylonitrile, and this clothing must not be reworn until the acrylonitrile is removed from the clothing.

F. Impervious clothing wet with liquid acrylonitrile can be easily ignited. This clothing must be washed down with water before you remove it.

G. If your skin becomes wet with liquid acrylonitrile, you must promptly and thoroughly wash or shower with soap or mild detergent to remove any acrylonitrile from your skin.

H. You must not keep food, beverages, or smoking materials, nor are you permitted to eat or smoke in regulated areas where acrylonitrile concentrations are above the permissible exposure limits.

I. If you contact liquid acrylonitrile, you must wash your hands thoroughly with soap or mild detergent and water before eating, smoking, or using toilet facilities.

J. Fire extinguishers and quick drenching facilities must be readily available, and you should know where they are and how to operate them.

K. Ask your supervisor where acrylonitrile is used in your work area and for any additional plant safety and health rules.

VI. ACCESS TO INFORMATION

A. Each year, your employer is required to inform you of the information contained in this Substance Safety Data Sheet for acrylonitrile. In addition, your employer must instruct you in the proper work practices for using acrylonitrile, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to acrylonitrile. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits.

C. Your employer is required to keep records of your exposures and medical examinations. These records must be kept by the employer for at least forty (40) years or for the period of your employment plus twenty (20) years, whichever is longer.

D. Your employer is required to release your exposure and medical records to you or your representative upon your request.

[63 FR 1152, Jan. 8, 1998]

1910.1045 App B Substance technical guidelines for acrylonitrile

APPENDIX B to 1910.1045 - SUBSTANCE TECHNICAL GUIDELINES FOR ACRYLONITRILE

I. PHYSICAL AND CHEMICAL DATA

A. Substance identification: 1. Synonyms: AN; VCN; vinyl cyanide; propenenitrile; cyanoethylene; Acrylon; Carbacryl; Fumigrain; Ventox.

2. Formula: $\text{CH}_2 = \text{CHCN}$.

3. Molecular weight: 53.1.

B. Physical data: 1. Boiling point (760 mm Hg): 77.3 deg. C (171 deg. F);

2. Specific gravity (water = 1): 0.81 (at 20 deg. C or 68 deg. F);
3. Vapor density (air=1 at boiling point of acrylonitrile): 1.83;
4. Melting point: -83 deg. C (-117 deg. F);
5. Vapor pressure (@20 deg. F): 83 mm Hg;
6. Solubility in water, percent by weight @20 deg. C (68 deg. F): 7.35;
7. Evaporation rate (Butyl Acetate = 1): 4.54; and
8. Appearance and odor: Colorless to pale yellow liquid with a pungent odor at concentrations above the permissible exposure level. Any detectable odor of acrylonitrile may indicate overexposure.

II. FIRE, EXPLOSION, AND REACTIVITY HAZARD DATA

- A. Fire:
 1. Flash point: -1 deg. C (30 deg. F) (closed cup).
 2. Autoignition temperature: 481 deg. C (898 deg. F).
 3. Flammable limits air, percent by volume: Lower: 3, Upper: 17.
 4. Extinguishing media: Alcohol foam, carbon dioxide, and dry chemical.
 5. Special fire-fighting procedures: Do not use a solid stream of water, since the stream will scatter and spread the fire. Use water to cool containers exposed to a fire.
 6. Unusual fire and explosion hazards: Acrylonitrile is a flammable liquid. Its vapors can easily form explosive mixtures with air. All ignition sources must be controlled where acrylonitrile is handled, used, or stored in a manner that could create a potential fire or explosion hazard. Acrylonitrile vapors are heavier than air and may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which acrylonitrile is being handled.
 7. For purposes of compliance with the requirements of 29 CFR 1910.106, acrylonitrile is classified as a class IB flammable liquid. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.
 8. For purposes of compliance with 29 CFR 1910.157, acrylonitrile is classified as a Class B

fire hazard.

9. For purpose of compliance with 29 CFR 1919.309, locations classified as hazardous due to the presence of acrylonitrile shall be Class I, Group D.

B. Reactivity:

1. Conditions contributing to instability: Acrylonitrile will polymerize when hot, and the additional heat liberated by the polymerization may cause containers to explode. Pure AN may self-polymerize, with a rapid build-up of pressure, resulting in an explosion hazard. Inhibitors are added to the commercial product to prevent self-polymerization.

2. Incompatibilities: Contact with strong oxidizers (especially bromine) and strong bases may cause fires and explosions. Contact with copper, copper alloys, ammonia, and amines may start serious decomposition.

3. Hazardous decomposition products: Toxic gases and vapors (such as hydrogen cyanide, oxides of nitrogen, and carbon monoxide) may be released in a fire involving acrylonitrile and certain polymers made from acrylonitrile.

4. Special precautions: Liquid acrylonitrile will attack some forms of plastics, rubbers, and coatings.

III. SPILL, LEAK, AND DISPOSAL PROCEDURES

A. If acrylonitrile is spilled or leaked, the following s should be taken:

1. Remove all ignition sources.
2. The area should be evacuated at once and re-entered only after the area has been thoroughly ventilated and washed down with water.
3. If liquid acrylonitrile or polymer intermediate, collect for reclamation or absorb in paper, vermiculite, dry sand, earth, or similar material, or wash down with water into process sewer system.

B. Persons not wearing protective equipment should be restricted from areas of spills or leaks until clean-up has been completed.

C. Waste disposal methods: Waste material shall be disposed of in a manner that is not hazardous to employees or to the general population. Spills of acrylonitrile and flushing of such

spills shall be channeled for appropriate treatment or collection for disposal. They shall not be channeled directly into the sanitary sewer system. In selecting the method of waste disposal, applicable local, State, and Federal regulations should be consulted.

IV. MONITORING AND MEASUREMENT PROCEDURES

A. Exposure above the Permissible Exposure Limit:

1. Eight-hour exposure evaluation: Measurements taken for the purpose of determining employee exposure under this section are best taken so that the average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee.)

2. Ceiling evaluation: Measurements taken for the purpose of determining employee exposure under this section must be taken during periods of maximum expected airborne concentrations of acrylonitrile in the employee's breathing zone. A minimum of three (3) measurements should be taken on one work shift. The average of all measurements taken is an estimate of the employee's ceiling exposure.

3. Monitoring techniques: The sampling and analysis under this section may be performed by collecting the acrylonitrile vapor on charcoal adsorption tubes or other composition adsorption tubes, with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monitoring systems, portable direct-reading instruments, or passive dosimeters. Analysis of resultant samples should be by gas chromatograph.

Appendix D lists methods of sampling and analysis which have been tested by NIOSH and OSHA for use with acrylonitrile. NIOSH and OSHA have validated modifications of NIOSH Method S-156 (See Appendix D) under laboratory conditions for concentrations below 1 ppm. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that methods of monitoring must be accurate, to a 95-percent confidence level, to + or - 35-percent for concentrations of AN at or above 2 ppm, and to + or - 50-percent for concentrations below 2ppm. In addition to the methods described in Appendix D, there are numerous other methods available for monitoring for AN in the workplace. Details on these other methods have been submitted by various companies to the rulemaking record, and are available at the OSHA Docket Office.

B. Since many of the duties relating to employee exposure are dependent on the results of monitoring and measuring procedures, employers shall assure that the evaluation of employee

exposures is performed by a competent industrial hygienist or other technically qualified person.

V. PROTECTIVE CLOTHING

Employees shall be provided with and required to wear appropriate protective clothing to prevent any possibility of skin contact with liquid AN. Because acrylonitrile is absorbed through the skin, it is important to prevent skin contact with liquid AN. Protective clothing shall include impermeable coveralls or similar full-body work clothing, gloves, head-coverings, as appropriate to protect areas of the body which may come in contact with liquid AN.

Employers should ascertain that the protective garments are impermeable to acrylonitrile. Non-impermeable clothing and shoes should not be allowed to become contaminated with liquid AN. If permeable clothing does become contaminated, it should be promptly removed, placed in a regulated area for removal of the AN, and not worn again until the AN is removed. If leather footwear or other leather garments become wet from acrylonitrile, they should be replaced and not worn again, due to the ability of leather to absorb acrylonitrile and hold it against the skin. Since there is no pain associated with the blistering which may result from skin contact with liquid AN, it is essential that the employee be informed of this hazard so that he or she can be protected.

Any protective clothing which has developed leaks or is otherwise found to be defective shall be repaired or replaced. Clean protective clothing shall be provided to the employee as necessary to assure its protectiveness. Whenever impervious clothing becomes wet with liquid AN, it shall be washed down with water before being removed by the employee. Employees are also required to wear splash-proof safety goggles where there is any possibility of acrylonitrile contacting the eyes.

VI. HOUSEKEEPING AND HYGIENE FACILITIES

For purposes of complying with 29 CFR 1910.141, the following items should be emphasized:

A. The workplace should be kept clean, orderly, and in a sanitary condition. The employer is required to institute a leak and spill detection program for operations involving liquid AN in order to detect sources of fugitive AN emissions.

B. Dry sweeping and the use of compressed air is unsafe for the cleaning of floors and other surfaces where liquid AN may be found.

C. Adequate washing facilities with hot and cold water are to be provided, and maintained in a sanitary condition. Suitable cleansing agents are also to be provided to assure the effective removal of acrylonitrile from the skin.

D. Change or dressing rooms with individual clothes storage facilities must be provided to prevent the contamination of street clothes with acrylonitrile. Because of the hazardous nature of acrylonitrile, contaminated protective clothing should be placed in a regulated area designated by the employer for removal of the AN before the clothing is laundered or disposed of.

VII. MISCELLANEOUS PRECAUTIONS

A. Store acrylonitrile in tightly-closed containers in a cool, well-ventilated area and take necessary precautions to avoid any explosion hazard.

B. High exposures to acrylonitrile can occur when transferring the liquid from one container to another.

C. Non-sparking tools must be used to open and close metal acrylonitrile containers. These containers must be effectively grounded and bonded prior to pouring.

D. Never store uninhibited acrylonitrile.

E. Acrylonitrile vapors are not inhibited. They may form polymers and clog vents of storage tanks.

F. Use of supplied-air suits or other impervious coverings may be necessary to prevent skin contact with and provide respiratory protection from acrylonitrile where the concentration of acrylonitrile is unknown or is above the ceiling limit. Supplied-air suits should be selected, used, and maintained under the immediate supervision of persons knowledgeable in the limitations and potential life-endangering characteristics of supplied-air suits.

G. Employers shall advise employees of all areas and operations where exposure to acrylonitrile could occur.

VIII. COMMON OPERATIONS

Common operations in which exposure to acrylonitrile is likely to occur include the following: Manufacture of the acrylonitrile monomer; synthesis of acrylic fibers, ABS, SAN, and nitrile barrier plastics and resins, nitrile rubber, surface coatings, specialty chemicals, use as a chemical intermediate, use as a fumigant and in the cyanoethylation of cotton.

1910.1045 App C Medical surveillance guidelines for acrylonitrile

APPENDIX C to 1910.1045 - MEDICAL SURVEILLANCE GUIDELINES FOR ACRYLONITRILE

I. ROUTE OF ENTRY

Inhalation; skin absorption; ingestion.

II. TOXICOLOGY

Acrylonitrile vapor is an asphyxiant due to inhibitory action on metabolic enzyme systems. Animals exposed to 75 or 100 ppm for 7 hours have shown signs of anoxia; in some animals which died at the higher level, cyanomethemoglobin was found in the blood. Two human fatalities from accidental poisoning have been reported; one was caused by inhalation of an unknown concentration of the vapor, and the other was thought to be caused by skin absorption or inhalation. Most cases of intoxication from industrial exposure have been mild, with rapid onset of eye irritation, headache, sneezing, and nausea. Weakness, lightheadedness, and vomiting may also occur. Exposure to high concentrations may produce profound weakness, asphyxia, and death. The vapor is a severe eye irritant. Prolonged skin contact with the liquid may result in absorption with systemic effects, and in the formation of large blisters after a latent period of several hours. Although there is usually little or no pain or inflammation, the affected skin resembles a second-degree thermal burn. Solutions spilled on exposed skin, or on areas covered only by a light layer of clothing, evaporate rapidly, leaving no irritation, or, at the most, mild transient redness. Repeated spills on exposed skin may result in dermatitis due to solvent effects.

Results after 1 year of a planned 2-year animal study on the effects of exposure to acrylonitrile have indicated that rats ingesting as little as 35 ppm in their drinking water develop tumors of the central nervous system. The interim results of this study have been supported by a similar study being conducted by the same laboratory, involving exposure of rats by inhalation of acrylonitrile vapor, which has shown similar types of tumors in animals exposed to 80 ppm.

In addition, the preliminary results of an epidemiological study being performed by duPont on a cohort of workers in their Camden, S.C. acrylic fiber plant indicate a statistically significant increase in the incidence of colon and lung cancers among employees exposed to acrylonitrile.

III. SIGNS AND SYMPTOMS OF ACUTE OVEREXPOSURE

Asphyxia and death can occur from exposure to high concentrations of acrylonitrile. Symptoms of overexposure include eye irritation, headache, sneezing, nausea and vomiting, weakness, and

lightheadedness. Prolonged skin contact can cause blisters on the skin with appearance of a second-degree burn, but with little or no pain. Repeated skin contact may produce scaling dermatitis.

IV. TREATMENT OF ACUTE OVEREXPOSURE

Remove employee from exposure. Immediately flush eyes with water and wash skin with soap or mild detergent and water. If AN has been swallowed, and person is conscious, induce vomiting. Give artificial resuscitation if indicated. More severe cases, such as those associated with loss of consciousness, may be treated by the intravenous administration of sodium nitrite, followed by sodium thiosulfate, although this is not as effective for acrylonitrile poisoning as for inorganic cyanide poisoning.

V. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. As noted above, exposure to acrylonitrile has been linked to increased incidence of cancers of the colon and lung in employees of the duPont acrylic fiber plant in Camden, S.C. In addition, the animal testing of acrylonitrile has resulted in the development of cancers of the central nervous system in rats exposed by either inhalation or ingestion. The physician should be aware of the findings of these studies in evaluating the health of employees exposed to acrylonitrile.

Most reported acute effects of occupational exposure to acrylonitrile are due to its ability to cause tissue anoxia and asphyxia. The effects are similar to those caused by hydrogen cyanide. Liquid acrylonitrile can be absorbed through the skin upon prolonged contact. The liquid readily penetrates leather, and will produce burns of the feet if footwear contaminated with acrylonitrile is not removed.

It is important for the physician to become familiar with the operating conditions in which exposure to acrylonitrile may occur. Those employees with skin diseases may not tolerate the wearing of whatever protective clothing may be necessary to protect them from exposure. In addition, those with chronic respiratory disease may not tolerate the wearing of negative-pressure respirators.

B. Surveillance and screening. Medical histories and laboratory examinations are required for each employee subject to exposure to acrylonitrile above the action level. The employer must screen employees for history of certain medical conditions which might place the employee at increased risk from exposure.

1. Central nervous system dysfunction. Acute effects of exposure to acrylonitrile generally involve the central nervous system. Symptoms of acrylonitrile exposure include headache, nausea, dizziness, and general weakness. The animal studies cited above suggest possible carcinogenic effects of acrylonitrile on the central nervous system, since rats exposed by either inhalation or ingestion have developed similar CNS tumors.

2. Respiratory disease. The du Pont data indicate an increased risk of lung cancer among employees exposed to acrylonitrile.

3. Gastrointestinal disease. The du Pont data indicate an increased risk of cancer of the colon among employees exposed to acrylonitrile. In addition, the animal studies show possible tumor production in the stomachs of the rats in the ingestion study.

4. Skin disease. Acrylonitrile can cause skin burns when prolonged skin contact with the liquid occurs. In addition, repeated skin contact with the liquid can cause dermatitis.

5. General. The purpose of the medical procedures outlined in the standard is to establish a baseline for future health monitoring. Persons unusually susceptible to the effects of anoxia or those with anemia would be expected to be at increased risk. In addition to emphasis on the CNS, respiratory and gastrointestinal systems, the cardiovascular system, liver, and kidney function should also be stressed.

1910.1045 App D Sampling and analytical methods for acrylonitrile

APPENDIX D to 1910.1045 - SAMPLING AND ANALYTICAL METHODS FOR ACRYLONITRILE

There are many methods available for monitoring employee exposures to acrylonitrile. Most of these involve the use of charcoal tubes and sampling pumps, with analysis by gas chromatograph. The essential differences between the charcoal tube methods include, among others, the use of different desorbing solvents, the use of different lots of charcoal, and the use of different equipment for analysis of the samples.

Besides charcoal, considerable work has been performed on methods using porous polymer sampling tubes and passive dosimeters. In addition, there are several portable gas analyzers and monitoring units available on the open market.

This appendix contains details for the methods which have been tested at OSHA Analytical Laboratory in Salt Lake City, and NIOSH in Cincinnati. Each is a variation on NIOSH Method S-156, which is also included for reference. This does not indicate that these methods are the only ones which will be satisfactory. There also may be workplace situations in which these methods are not adequate, due to such factors as high humidity. Copies of the other methods available to OSHA are available in the rulemaking record, and may be obtained from the OSHA Docket Office. These include, the Union Carbide, Monsanto, Dow Chemical and Dow Badische methods, as well as NIOSH Method P & CAM 127.

Employers who note problems with sample breakthrough should try larger charcoal tubes. Tubes of larger capacity are available, and are often used for sampling vinyl chloride. In addition, lower flow rates and shorter sampling times should be beneficial in minimizing breakthrough problems.

Whatever method the employer chooses, he must assure himself of the method's accuracy and precision under the unique conditions present in his workplace.

NIOSH METHOD S-156 (UNMODIFIED)

Analyte: Acrylonitrile.

Matrix: Air.

Procedure: Absorption on charcoal, desorption with methanol, GC.

1. Principle of the method (Reference 11.1).

1.1 A known volume of air is drawn through a charcoal tube to trap the organic vapors present.

1.2 The charcoal in the tube is transferred to a small, stoppered sample container, and the analyte is desorbed with methanol.

1.3 An aliquot of the desorbed sample is injected into a gas chromatograph.

1.4 The area of the resulting peak is determined and compared with areas obtained for standards.

2. Range and sensitivity.

2.1 This method was validated over the range of 17.5-70.0 mg/cu m at an atmospheric temperature and pressure of 22 deg. C and 760 MM Hg, using a 20-liter sample. Under the conditions of sample size (20-liters) the probable useful range of this method is 4.5-135 mg-cu m. The method is capable of measuring much smaller amounts if the desorption efficiency is adequate. Desorption efficiency must be determined over the range used.

2.2 The upper limit of the range of the method is dependent on the adsorptive capacity of the charcoal tube. This capacity varies with the concentrations of acrylonitrile and other substances in the air. The first section of the charcoal tube was found to hold at least 3.97 mg of acrylonitrile when a test atmosphere containing 92.0 mg/cu m of acrylonitrile in air was sampled 0.18 liter per minute for 240 minutes; at that time the concentration of acrylonitrile in the effluent was less than 5 percent of that in the influent. (The charcoal tube consists of two sections of activated charcoal separated by a section of urethane foam. See section 6.2.) If a particular atmosphere is suspected of containing a large amount of contaminant, a smaller sampling volume should be taken.

3. Interference.

3.1 When the amount of water in the air is so great that condensation actually occurs in the tube, organic vapors will not be trapped efficiently. Preliminary experiments using toluene indicate that high humidity severely decreases the breakthrough volume.

3.2 When interfering compounds are known or suspected to be present in the air, such information, including their suspected identities, should be transmitted with the sample.

3.3 It must be emphasized that any compound which has the same retention time as the analyte at the operating conditions described in this method is an interference. Retention time data on a single column cannot be considered proof of chemical identity.

3.4 If the possibility of interference exists, separation conditions (column packing, temperature, etc.) must be changed to circumvent the problem.

4. Precision and accuracy.

4.1 The Coefficient of Variation (CVT) for the total analytical and sampling method in the range of 17.5-70.0 mg/cu m was 0.073. This value corresponds to a 3.3 mg/cu m standard deviation at the (previous) OSHA standard level (20 ppm). Statistical information and details of the validation and experimental test procedures can be found in Reference 11.2.

4.2 On the average the concentrations obtained at the 20 ppm level using the overall sampling and analytical method were 6.0 percent lower than the "true" concentrations for a limited number of laboratory experiments. Any difference between the "found" and "true" concentrations may not represent a bias in the sampling and analytical method, but rather a random variation from the experimentally determined "true" concentration. Therefore, no recovery correction should be applied to the final result in section 10.5.

5. Advantages and disadvantages of the method.

5.1 The sampling device is small, portable, and involves no liquids. Interferences are minimal, and most of those which do occur can be eliminated by altering chromatographic conditions. The tubes are analyzed by means of a quick, instrumental method.

The method can also be used for the simultaneous analysis of two or more substances suspected to be present in the same sample by simply changing gas chromatographic conditions.

5.2 One disadvantage of the method is that the amount of sample which can be taken is limited by the number of milligrams that the tube will hold before overloading. When the sample value obtained for the backup section of the charcoal tube exceeds 25 percent of that found on the front section, the possibility of sample loss exists.

5.3 Furthermore, the precision of the method is limited by the reproducibility of the pressure drop across the tubes. This drop will affect the flow rate and cause the volume to be imprecise, because the pump is usually calibrated for one tube only.

6. Apparatus.

6.1 A calibrated personal sampling pump whose flow can be determined within + or - 5 percent at the recommended flow rate. (Reference 11.3).

6.2 Charcoal tubes: Glass tubes with both ends flame sealed, 7 cm long with a 6-mm O.D. and a 4-mm I.D., containing 2 sections of 20/40 mesh activated charcoal separated by a 2-mm portion of urethane foam. The activated charcoals prepared from coconut shells and is fired at 600 deg. C

prior to packing. The adsorbing section contains 100 mg of charcoal, the backup section 50 mg. A 3-mm portion of urethane foam is placed between the outlet end of the tube and the backup section. A plug of silicated glass wool is placed in front of the adsorbing section. The pressure drop across the tube must be less than 1 inch of mercury at a flow rate of 1 liter per minute.

6.3 Gas chromatograph equipped with a flame ionization detector.

6.4 Column (4-ftX 1/4 -in stainless steel) packed with 50/80 mesh Poropak, type Q.

6.5 An electronic integrator or some other suitable method for measuring peak areas.

6.6 Two-milliliter sample containers with glass stoppers or Teflon-lined caps. If an automatic sample injector is used, the associated vials may be used.

6.7 Microliter syringes: 10-microliter and other convenient sizes for making standards.

6.8 Pipets: 1.0-ml delivery pipets.

6.9 Volumetric flask: 10-ml or convenient sizes for making standard solutions.

7. Reagents.

7.1 Chromatographic quality methanol.

7.2 Acrylonitrile, reagent grade.

7.3 Hexane, reagent grade.

7.4 Purified nitrogen.

7.5 Prepurified hydrogen.

7.6 Filtered compressed air.

8. Procedure.

8.1 Cleaning of equipment. All glassware used for the laboratory analysis should be detergent washed and thoroughly rinsed with tap water and distilled water.

8.2 Calibration of personal pumps. Each personal pump must be calibrated with a representative charcoal tube in the line. This will minimize errors associated with uncertainties in the sample volume collected.

8.3 Collection and shipping of samples.

8.3.1 Immediately before sampling, break the ends of the tube to provide an opening at least one-half the internal diameter of the tube (2 mm).

8.3.2 The smaller section of charcoal is used as a backup and should be positioned nearest the sampling pump.

8.3.3 The charcoal tube should be placed in a vertical direction during sampling to minimize channeling through the charcoal.

8.3.4 Air being sampled should not be passed through any hose or tubing before entering the charcoal tube.

8.3.5 A maximum sample size of 20 liters is recommended. Sample at a flow of 0.20 liter per minute or less. The flow rate should be known with an accuracy of at least + or - 5 percent.

8.3.6 The temperature and pressure of the atmosphere being sampled should be recorded. If pressure reading is not available, record the elevation.

8.3.7 The charcoal tubes should be capped with the supplied plastic caps immediately after sampling. Under no circumstances should rubber caps be used.

8.3.8 With each batch of 10 samples submit one tube from the same lot of tubes which was used for sample collection and which is subjected to exactly the same handling as the samples except that no air is drawn through it. Label this as a blank.

8.3.9 Capped tubes should be packed tightly and padded before they are shipped to minimize tube breakage during shipping.

8.3.10 A sample of the bulk material should be submitted to the laboratory in a glass container with a Teflon-lined cap. This sample should not be transported in the same container as the charcoal tubes.

8.4 Analysis of samples.

8.4.1 Preparation of samples. In preparation for analysis, each charcoal tube is scored with a file in front of the first section of charcoal and broken open. The glass wool is removed and discarded. The charcoal in the first (larger) section is transferred to a 2-ml stoppered sample container. The separating section of foam is removed and discarded; the second section is transferred to another stoppered container. These two sections are analyzed separately.

8.4.2 Desorption of samples. Prior to analysis, 1.0 ml of methanol is pipetted into each sample container. Desorption should be done for 30 minutes. Tests indicate that this is adequate if the sample is agitated occasionally during this period. If an automatic sample injector is used, the sample vials should be capped as soon as the solvent is added to minimize volatilization.

8.4.3 GC conditions. The typical operating conditions for the gas chromatograph are:

1. 50 ml/min (60 psig) nitrogen carrier gas flow.
2. 65 ml/min (24 psig) hydrogen gas flow to detector.

3. 500 ml/min (50 psig) air flow to detector.
4. 235 deg. C injector temperature.
5. 255 deg. C manifold temperature (detector).
6. 155 deg. C column temperature.

8.4.4 Injection. The first step in the analysis is the injection of the sample into the gas chromatograph. To eliminate difficulties arising from blowback or distillation within the syringe needle, one should employ the solvent flush injection technique. The 10-microliter syringe is first flushed with solvent several times to wet the barrel and plunger. Three microliters of solvent are drawn into the syringe to increase the accuracy and reproducibility of the injected sample volume. The needle is removed from the solvent, and the plunger is pulled back about 0.2 microliter to separate the solvent flush from the sample with a pocket of air to be used as a marker. The needle is then immersed in the sample, and a 5-microliter aliquot is withdrawn, taking into consideration the volume of the needle, since the sample in the needle will be completely injected. After the needle is removed from the sample and prior to injection, the plunger is pulled back 1.2 microliters to minimize evaporation of the sample from the tip of the needle. Observe that the sample occupies 4.9-5.0 microliters in the barrel of the syringe. Duplicate injections of each sample and standard should be made. No more than a 3 percent difference in area is to be expected. An automatic sample injector can be used if it is shown to give reproducibility at least as good as the solvent flush method.

8.4.5 Measurement of area. The area of the sample peak is measured by an electronic integrator or some other suitable form of area measurement, and preliminary results are read from a standard curve prepared as discussed below.

8.5 Determination of desorption efficiency.

8.5.1 Importance of determination. The desorption efficiency of a particular compound can vary from one laboratory to another and also from one batch of charcoal to another. Thus, it is necessary to determine at least once the percentage of the specific compound that is removed in the desorption process, provided the same batch of charcoal is used.

8.5.2 Procedure for determining desorption efficiency. Activated charcoal equivalent to the amount in the first section of the sampling tube (100 mg) is measured into a 2.5 in, 4-mm I.D. glass tube, flame sealed at one end. This charcoal must be from the same batch as that used in obtaining the samples and can be obtained from unused charcoal tubes. The open end is capped with Parafilm. A known amount of hexane solution of acrylonitrile containing 0.239 g/ml is injected directly into the activated charcoal with a microliter syringe, and tube is capped with more Parafilm. When using an automatic sample injector, the sample injector vials, capped with Teflon-faced septa, may be used in place of the glass tube.

The amount injected is equivalent to that present in a 20-liter air sample at the selected level.

Six tubes at each of three levels (0.5X, 1X, and 2X of the standard) are prepared in this manner and allowed to stand for at least overnight to assure complete adsorption of the analyte onto the charcoal. These tubes are referred to as the sample. A parallel blank tube should be treated in the same manner except that no sample is added to it. The sample and blank tubes are desorbed and analyzed in exactly the same manner as the sampling tube described in section 8.4.

Two or three standards are prepared by injecting the same volume of compound into 1.0 ml of methanol with the same syringe used in the preparation of the samples. These are analyzed with the samples.

The desorption efficiency (D.E.) equals the average weight in mg recovered from the tube divided by the weight in mg added to the tube, or

$$\text{D.E.} = \frac{\text{Average weight recovered (mg)}}{\text{weight added (mg)}}$$

The desorption efficiency is dependent on the amount of analyte collected on the charcoal. Plot the desorption efficiency versus weight of analyte found. This curve is used in section 10.4 to correct for adsorption losses.

9. Calibration and standards.

It is convenient to express concentration of standards in terms of mg/1.0 ml methanol, because samples are desorbed in this amount of methanol. The density of the analyte is used to convert mg into microliters for easy measurement with a microliter syringe. A series of standards, varying in concentration over the range of interest, is prepared and analyzed under the same GC conditions and during the same time period as the unknown samples. Curves are established by plotting concentration in mg/1.0 ml versus peak area.

Note: Since no internal standard is used in the method, standard solutions must be analyzed at the same time that the sample analysis is done. This will minimize the effect of known day-to-day variations and variations during the same day of the FID response.

10. Calculations.

10.1 Read the weight, in mg, corresponding to each peak area from the standard curve. No volume corrections are needed, because the standard curve is based on mg/1.0 ml methanol and the volume of sample injected is identical to the volume of the standards injected.

10.2 Corrections for the blank must be made for each sample.

$$\text{mg} = \text{mg sample} - \text{mg blank}$$

Where:

mg sample = mg found in front section of sample tube.

mg sample = mg found in front section of blank tube.

A similar procedure is followed for the backup sections.

10.3 Add the weights found in the front and backup sections to get the total weight in the sample.

10.4 Read the desorption efficiency from the curve (see sec. 8.5.2) for the amount found in the front section. Divide the total weight by this desorption efficiency to obtain the corrected mg/sample.

$$\text{Corrected mg/sample} = \frac{\text{Total weight}}{\text{D.E.}}$$

10.5 The concentration of the analyte in the air sampled can be expressed in mg/cu m.

$$\text{mg/cu m} = \text{Corrected mg (section 10.4)} \times \frac{1,000 \text{ (liter/cu m)}}{\text{air volume sampled (liter)}}$$

10.6 Another method of expressing concentration is ppm.

$$\text{ppm} = \text{m mg/cu} \times 24.45/\text{M.W.} \times 760/\text{PX T.} + 273/298$$

Where:

P = Pressure (mm Hg) of air sampled.

T = Temperature (deg. C) of air sampled.

24.45 = Molar volume (liter/mole) at 25 deg. C and 760 mm Hg.

M.W. = Molecular weight (g/mole) of analyte.

760 = Standard pressure (mm Hg).

298 = Standard temperature (deg. K).

11. References.

11.1 White, L. D. et al., "A Convenient Optimized Method for the Analysis of Selected Solvent Vapors in the Industrial Atmosphere," Amer. Ind. Hyg. Assoc. J., 31:225 (1970).

11.2 Documentation of NIOSH Validation Tests, NIOSH Contract No. CDC-99-74-45.

11.3 Final Report, NIOSH Contract HSM-99-71-31, "Personal Sampler Pump for Charcoal Tubes," September 15, 1972.

NIOSH Modification of NIOSH Method S-156

The NIOSH recommended method for low levels for acrylonitrile is a modification of method S-156. It differs in the following respects:

(1) Samples are desorbed using 1 ml of 1 percent acetone in CS(2) rather than methanol.

(2) The analytical column and conditions are:

Column: 20 percent SP-1000 on 80/100 Supelcoport 10 feet x 1/8 inch S.S.

Conditions:

Injector temperature: 200 deg. C.
Detector temperature: 100 deg. C.
Column temperature: 85 deg. C.
Helium flow: 25 ml/min.
Air flow: 450 ml/min.
Hydrogen flow: 55 ml/min.

(3) A 2 ul injection of the desorbed analyte is used.

(4) A sampling rate of 100 ml/min is recommended.

OSHA Laboratory Modification of NIOSH Method S-156

Analyte: Acrylonitrile.

Matrix: Air.

Procedure: Adsorption on charcoal, desorption with methanol, GC.

1. Principle of the Method (Reference 1).

1.1 A known volume of air is drawn through a charcoal tube to trap the organic vapors present.

1.2 The charcoal in the tube is transferred to a small, stoppered sample vial, and the analyte is desorbed with methanol.

1.3 An aliquot of the desorbed sample is injected into a gas chromatograph.

1.4 The area of the resulting peak is determined and compared with areas obtained for standards.

2. Advantages and disadvantages of the method.

2.1 The sampling device is small, portable, and involves no liquids. Interferences are minimal, and most of those which do occur can be eliminated by altering chromatographic conditions. The tubes are analyzed by means of a quick, instrumental method.

2.2 This method may not be adequate for the simultaneous analysis of two or more substances.

2.3 The amount of sample which can be taken is limited by the number of milligrams that the tube will hold before overloading. When the sample value obtained for the backup section of the charcoal tube exceeds 25 percent of that found on the front section, the possibility of sample loss exists.

2.4 The precision of the method is limited by the reproducibility of the pressure drop across the tubes. This drop will affect the flow rate and cause the volume to be imprecise, because the pump is usually calibrated for one tube only.

3. Apparatus.

3.1 A calibrated personal sampling pump whose flow can be determined within + or - (5) percent at the recommended flow rate.

3.2 Charcoal tubes: Glass tube with both ends flame sealed, 7 cm long with a 6-mm O.D. and a 4-mm I.D., containing 2 sections of 20/40 mesh activated charcoal separated by a 2-mm portion of urethane foam. The activated charcoal is prepared from coconut shells and is fired at 600 deg. C prior to packing. The adsorbing section contains 100 mg of charcoal, the back-up section 50 mg. A 3-mm portion of urethane foam is placed between the outlet end of the tube and the back-up section. A plug of sililated glass wool is placed in front of the adsorbing section. The pressure drop across the tube must be less than one inch of mercury at a flow rate of 1 liter per minute.

3.3 Gas chromatograph equipped with a nitrogen phosphorus detector.

3.4 Column (10-ft x 1/8"-in stainless steel) packed with 100/120 Supelcoport coated with 10 percent SP 1000.

3.5 An electronic integrator or some other suitable method for measuring peak area.

3.6 Two-milliliter sample vials with Teflon-lined caps

3.7 Microliter syringes: 10-microliter, and other convenient sizes for making standards.

3.8 Pipets: 1.0-ml delivery pipets.

3.9 Volumetric flasks: convenient sizes for making standard solutions.

4. Reagents.

4.1 Chromatographic quality methanol.

4.2 Acrylonitrile, reagent grade.

4.3 Filtered compressed air.

4.4 Purified hydrogen.

4.5 Purified helium.

5. Procedure.

5.1 Cleaning of equipment. All glassware used for the laboratory analysis should be properly cleaned and free of organics which could interfere in the analysis.

5.2 Calibration of personal pumps. Each pump must be calibrated with a representative charcoal tube in the line.

5.3 Collection and shipping of samples.

5.3.1 Immediately before sampling, break the ends of the tube to provide an opening at least one-half the internal diameter of the tube (2 mm).

5.3.2 The smaller section of the charcoal is used as the backup and should be placed nearest the sampling pump.

5.3.3 The charcoal should be placed in a vertical position during sampling to minimize channeling through the charcoal.

5.3.4 Air being sampled should not be passed through any hose or tubing before entering the charcoal tube.

5.3.5 A sample size of 20 liters is recommended. Sample at a flow rate of approximately 0.2 liters per minute. The flow rate should be known with an accuracy of at least + or - (5) percent.

5.3.6 The temperature and pressure of the atmosphere being sampled should be recorded.

5.3.7 The charcoal tubes should be capped with the supplied plastic caps immediately after sampling. Rubber caps should not be used.

5.3.8 Submit at least one blank tube (a charcoal tube subjected to the same handling procedures, without having any air drawn through it) with each set of samples.

5.3.9. Take necessary shipping and packing precautions to minimize breakage of samples.

5.4 Analysis of samples.

5.4.1 Preparation of samples. In preparation for analysis, each charcoal tube is scored with a file in front of the first section of charcoal and broken open. The glass wool is removed and discarded. The charcoal in the first (larger) section is transferred to a 2-ml vial. The separating section of foam is removed and discarded; the section is transferred to another capped vial. These two sections are analyzed separately.

5.4.2 Desorption of samples. Prior to analysis, 1.0 ml of methanol is pipetted into each sample container. Desorption should be done for 30 minutes in an ultrasonic bath. The sample vials are recapped as soon as the solvent is added.

5.4.3 GC conditions. The typical operating conditions for the gas chromatograph are:

1. 30 ml/min (60 psig) helium carrier gas flow.
2. 3.0 ml/min (30 psig) hydrogen gas flow to detector.
3. 50 ml/min (60 psig) air flow to detector.
4. 200 deg. C injector temperature.
5. 200 deg. C detector temperature.
6. 100 deg. C column temperature.

5.4.4 Injection. Solvent flush technique or equivalent.

5.4.5 Measurement of area. The area of the sample peak is measured by an electronic integrator or some other suitable form of area measurement, and preliminary results are read from a standard curve prepared as discussed below.

5.5 Determination of desorption efficiency.

5.5.1 Importance of determination. The desorption efficiency of a particular compound can vary from one laboratory to another and also from one batch of charcoal to another. Thus, it is necessary to determine, at least once, the percentage of the specific compound that is removed in the desorption process, provided the same batch of charcoal is used.

5.5.2 Procedure for determining desorption efficiency. The reference portion of the charcoal tube is removed. To the remaining portion, amounts representing 0.5X, 1X, and 2X (X represents TLV) based on a 20 l air sample are injected onto several tubes at each level. Dilutions of acrylonitrile with methanol are made to allow injection of measurable quantities. These tubes are then allowed to equilibrate at least overnight. Following equilibration they are analyzed following the same procedure as the samples. A curve of the desorption efficiency amt recovered/amt added is plotted versus amount of analyte found. This curve is used to correct for adsorption losses.

6. Calibration and standards.

A series of standards, varying in concentration over the range of interest, is prepared and analyzed under the same GC conditions and during the same time period as the unknown samples. Curves are prepared by plotting concentration versus peak area.

Note: Since no internal standard is used in the method, standard solutions must be analyzed at the same time that the sample analysis is done. This will minimize the effect of known day-to-day variations and variations during the same day of the NPD response. Multiple injections are necessary.

7. Calculations.

Read the weight, corresponding to each peak area from the standard curve, correct for the blank, correct for the desorption efficiency, and make necessary air volume corrections.

8. Reference. NIOSH Method S-156.

[43 FR 45809, Oct. 3, 1978, as amended at 45 FR 35283, May 23, 1980; 54 FR 24334, June 7, 1989; 61 FR 5507, Feb. 13, 1996]

1910.1047 Ethylene oxide.

(a) Scope and application.

(1) This section applies to all occupational exposures to ethylene oxide (EtO), Chemical Abstracts Service Registry No. 75-21-8, except as provided in paragraph (a)(2) of this section.

(2) This section does not apply to the processing, use, or handling of products containing EtO where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing EtO in airborne concentrations at or above the action level under the expected conditions of processing, use, or handling that will cause the greatest possible release.

(3) Where products containing EtO are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in paragraph (k)(1) of this section.

(b) Definitions: For the purpose of this section, the following definitions shall apply:

"Action level" means a concentration of airborne EtO of 0.5 ppm calculated as an eight (8)-hour time-weighted average.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (l) of this section, or any other person authorized by the Act or regulations issued under the Act.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that is likely to or does result in an unexpected significant release of EtO.

"Employee exposure" means exposure to airborne EtO which would occur if the employee were not using respiratory protective equipment.

"Ethylene oxide" or **"EtO"** means the three-membered ring organic compound with chemical formula C₂H₄O.

(c) Permissible exposure limits (PEL) - 8-hour time-weighted average (TWA). The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of one (1) part EtO per million parts of air (1 ppm) as an eight (8)-hour time-weighted average (8-hour

TWA).

(1) 8-hour time weighted average (TWA). The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of one (1) part EtO per million parts of air (1 ppm) as an 8-hour time-weighted average (8-hour TWA).

(2) Excursion limit. The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes.

(d) Exposure monitoring

(1) General.

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA of each employee.

(ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift for each job classification in each work area.

(iii) Where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer need only determine representative employee exposure for that operation during one shift.

(2) Initial monitoring.

(i) Each employer who has a workplace or work operation covered by this standard, except as provided for in paragraph (a)(2) or (d)(2)(ii) of this section, shall perform initial monitoring to determine accurately the airborne concentrations of EtO to which employees may be exposed.

(ii) Where the employer has monitored after June 15, 1983 and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

(3) Monitoring frequency (periodic monitoring).

(i) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level but at or below the 8-hour TWA, the employer shall repeat such monitoring for each such employee at least every 6 months.

(ii) If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 8-hour TWA, the employer shall repeat such monitoring for each such

employee at least every 3 months.

(iii) The employer may alter the monitoring schedule from quarterly to semiannually for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee's exposure has decreased to or below the 8-hour TWA.

(4) Termination of monitoring.

(i) If the initial monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure to be below the action level, the employer may discontinue the monitoring for those employees whose exposures are represented by the initial monitoring.

(ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(5) Additional monitoring. Notwithstanding the provisions of paragraph (d)(4) of this section, the employer shall institute the exposure monitoring required under paragraphs (d)(2)(i) and (d)(3) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to EtO or when the employer has any reason to suspect that a change may result in new or additional exposures.

(6) Accuracy of monitoring. Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of EtO at the 1 ppm TWA and to within plus or minus 35 percent for airborne concentrations of EtO at the action level of 0.5 ppm.

(7) Employee notification of monitoring results.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) The written notification required by paragraph (d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the PEL, wherever monitoring results indicated that the PEL has been exceeded.

(e) Regulated Areas.

(1) The employer shall establish a regulated area wherever occupational exposures to airborne

concentrations of EtO may exceed the TWA.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be demarcated in any manner that minimizes the number of employees within the regulated area.

(f) Methods of compliance.

(1) Engineering controls and work practices.

(i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the TWA, except to the extent that such controls are not feasible.

(ii) Wherever the feasible engineering controls and work practices that can be instituted are not sufficient to reduce employee exposure to or below the TWA, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(iii) Engineering controls are generally infeasible for the following operations: collection of quality assurance sampling from sterilized materials removal of biological indicators from sterilized materials; loading and unloading of tank cars; changing of ethylene oxide tanks on sterilizers; and vessel cleaning. For these operations, engineering controls are required only where the Assistant Secretary demonstrates that such controls are feasible.

(2) Compliance program.

(i) Where the TWA is exceeded, the employer shall establish and implement a written program to reduce employee exposure to or below the TWA by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section.

(ii) The compliance program shall include a schedule for periodic leak detection surveys and a written plan for emergency situations, as specified in paragraph (h)(i) of this section.

(iii) Written plans for a program required in paragraph (f)(2) shall be developed and furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months, and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the TWA.

(g) Respiratory protection and personal protective equipment.

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work-practice controls;

(ii) Work operations, such as maintenance and repair activities and vessel cleaning, for which engineering and work-practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce exposure to or below the TWA.

(iv) Emergencies.

(2) Respirator program. The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(3) Respirator selection. Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use half masks of any type because EtO may cause eye irritation or injury.

(ii) Equip each air-purifying, full facepiece respirator with a front-or back-mounted canister approved for protection against ethylene oxide.

(iii) For escape, provide employees with any respirator permitted for use under paragraphs (g)(3)(i) and (ii) of this standard.

(4) Protective clothing and equipment. When employees could have eye or skin contact with EtO or EtO solutions, the employer must select and provide, at no cost to the employee, appropriate protective clothing or other equipment in accordance with 29 CFR 1901.132 and 1910.133 to protect any area of the employee's body that may come in contact with liquid EtO or EtO solution, and must ensure that the employee wears the protective clothing and equipment provided.

(h) Emergency situations.

(1) Written plan.

(i) A written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with respiratory protection as required by paragraph (g) of this section until the emergency is abated.

(iii) The plan shall include the elements prescribed in 29 CFR 1910.38 and 29 CFR 1910.39, "Employee action plans" and " Fire prevention plans.," respectively.

(2) Alerting employees. Where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly. Affected employees shall be immediately evacuated from the area in the event that an emergency occurs.

(i) Medical Surveillance-General

(i) Employees covered.

(A) The employer shall institute a medical surveillance program for all employees who are or may be exposed to EtO at or above the action level, without regard to the use of respirators, for at least 30 days a year.

(B) The employer shall make available medical examinations and consultations to all employees who have been exposed to EtO in an emergency situation.

(ii) Examination by a physician. The employer shall ensure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and are provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(2) Medical examinations and consultations.

(i) Frequency. The employer shall make available medical examinations and consultations to each employee covered under paragraph (i)(1)(i) of this section on the following schedules:

(A) Prior to assignment of the employee to an area where exposure may be at or above the action level for at least 30 days a year.

(B) At least annually each employee exposed at or above the action level for at least 30 days in the past year.

(C) At termination of employment or reassignment to an area where exposure to EtO is not at or above the action level for at least 30 days a year.

(D) As medically appropriate for any employee exposed during an emergency.

(E) As soon as possible, upon notification by an employee either

(1) that the employee has developed signs or symptoms indicating possible overexposure to EtO, or

(2) that the employee desires medical advice concerning the effects of current or past exposure to EtO on the employee's ability to produce a healthy child.

(F) If the examining physician determines that any of the examinations should be provided more frequently than specified, the employer shall provide such examinations to affected employees at the frequencies recommended by the physician.

(ii) Content.

(A) Medical examinations made available pursuant to paragraphs (i)(2)(i)(A) - (D) of this section shall include:

(1) A medical and work history with special emphasis directed to symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

(2) A physical examination with particular emphasis given to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

(3) A complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

(4) Any laboratory or other test which the examining physician deems necessary by sound medical practice.

(B) The content of medical examinations or consultation made available pursuant to paragraph (i)(2)(i)(E) of this section shall be determined by the examining physician, and shall include pregnancy testing or laboratory evaluation of fertility, if requested by the employee and deemed appropriate by the physician.

(3) Information provided to the physician. The employer shall provide the following information to the examining physician:

- (i) A copy of this standard and Appendices A, B, and C.
- (ii) A description of the affected employee's duties as they relate to the employee's exposure.
- (iii) The employee's representative exposure level or anticipated exposure level.
- (iv) A description of any personal protective and respiratory equipment used or to be used.
- (v) Information from previous medical examinations of the affected employee that is not otherwise available to the examining physician.

(4) Physician's written opinion.

(i) The employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination and shall include:

(A) The physician's opinion as to whether the employee has any detected medical conditions that would place the employee at an increased risk of material health impairment from exposure to EtO;

(B) Any recommended limitations on the employee or upon the use of personal protective equipment such as clothing or respirators; and

(C) A statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions resulting from EtO exposure that require further explanation or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion given to the employer specific findings or diagnoses unrelated to occupational exposure to EtO.

(iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days from its receipt.

(j) ~~Communication of EtO hazards to employees~~ Communication of hazards

(1) ~~Signs and labels~~ Hazard communication—general.

(i) ~~The employer shall post and maintain legible signs demarcating regulated areas and entrances or accessways to regulated areas that bear the following legend:~~ Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the

Hazard Communication Standard (HCS) (§ 1910.1200) for EtO.

~~DANGER
ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED
TO BE WORN IN THIS AREA~~

(ii) ~~The employer shall ensure that precautionary labels are affixed to all containers of EtO whose contents are capable of causing employee exposure at or above the action level, and that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this paragraph, reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers. The labels shall comply with the requirements of 29 CFR 1910.1200(f) of OSHA's Hazard Communication standard, and shall include the following legend: In classifying the hazards of EtO at least the following hazards are to be addressed: Cancer; reproductive effects; mutagenicity; central nervous system; skin sensitization; skin, eye and respiratory tract irritation; acute toxicity effects; and flammability.~~

~~(A)~~

~~DANGER
CONTAINS ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD;~~

~~—and~~

~~—(B) A warning statement against breathing airborne concentrations of EtO.~~

(iii) ~~The labeling requirements under this section do not apply where EtO is used as a pesticide, as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when it is labeled pursuant to that Act and regulations issued under that Act by the Environmental Protection Agency. Employers shall include EtO in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of EtO and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j)(3) of this section.~~

~~(2) **Material safety data sheets.** Employers who are manufacturers or importers of EtO shall comply with the requirements regarding development of material safety data sheets as specified in 29 CFR 1910.1200(g) of OSHA's Hazard Communication standard.~~

Signs and labels

(i) Signs

(A) The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:

DANGER
ETHYLENE OXIDE
MAY CAUSE CANCER
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE
REQUIRED IN
THIS AREA
AUTHORIZED PERSONNEL ONLY

(B) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(2)(i)(A) of this section:

DANGER
ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE
WORN IN
THIS AREA

(ii) Labels.

(A) The employer shall ensure that labels are affixed to all containers of EtO whose contents are capable of causing employee exposure at or above the action level or whose contents may reasonably be foreseen to cause employee exposure above the excursion limit, and that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this paragraph (j)(2)(ii), reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers.

(B) Prior to June 1, 2015, employers may include the following information on containers of EtO in lieu of the labeling requirements in paragraph (j)(1)(i) of this section:

(1) DANGER
CONTAINS ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD;

(2) A warning statement against breathing airborne concentrations of EtO.

(C) The labeling requirements under this section do not apply where EtO is used as a pesticide, as such term is defined in the Federal Insecticide, Fungicide, and

Rodenticide Act (7 U.S.C. 136 et seq.), when it is labeled pursuant to that Act and regulations issued under that Act by the Environmental Protection Agency.

(3) Information and training.

(i) The employer shall provide employees who are potentially exposed to EtO at or above the action level with information and training on EtO at the time of initial assignment and at least annually thereafter.

(ii) Employees shall be informed of the following:

(A) The requirements of this section with an explanation of its contents, including Appendices A and B;

(B) Any operations in their work area where EtO is present;

(C) The location and availability of the written EtO final rule; and

(D) The medical surveillance program required by paragraph (i) of this section with an explanation of the information in Appendix C.

(iii) Employee training shall include at least:

(A) Methods and observations that may be used to detect the presence or release of EtO in the work area (such as monitoring conducted by the employer, continuous monitoring devices, etc.);

(B) The physical and health hazards of EtO;

(C) The measures employees can take to protect themselves from hazards associated with EtO exposure, including specific procedures the employer has implemented to protect employees from exposure to EtO, such as work practices, emergency procedures, and personal protective equipment to be used; and

(D) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and how employees can obtain and use the appropriate hazard information.

(k) Recordkeeping

(1) Objective data for exempted operations.

(i) Where the processing, use, or handling of products made from or containing EtO are

exempted from other requirements of this section under paragraph (a)(2) of this section, or where objective data have been relied on in lieu of initial monitoring under paragraph (d)(2)(ii) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of EtO;

(D) A description of the operation exempted and how the data support the exemption;
and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) Exposure measurements.

(i) The employer shall keep an accurate record of all measurements taken to monitor employee exposure to EtO as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement;

(B) The operation involving exposure to EtO which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of protective devices worn, if any; and

(F) Name, social security number and exposure of the employees whose exposures are represented.

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.1020.

(3) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (i)(1)(i) of this section, in accordance with 29 CFR 1910.1020.

(ii) The record shall include at least the following information:

(A) The name and social security number of the employee;

(B) Physicians' written opinions;

(C) Any employee medical complaints related to exposure to EtO; and

(D) A copy of the information provided to the physician as required by paragraph (i)(3) of this section.

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

(4) Availability.

(i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying.

(ii) The employer, upon request, shall make any exemption and exposure records required by paragraphs (k) (1) and (2) of this section available for examination and copying to affected employees, former employees, designated representatives and the Assistant Secretary, in accordance with 29 CFR 1910.1020 (a) through (e) and (g) through (i).

(iii) The employer, upon request, shall make employee medical records required by paragraph (k)(3) of this section available for examination and copying to the subject employee, anyone having the specific written consent of the subject employee, and the Assistant Secretary, in accordance with 29 CFR 1910.1020.

(5) Transfer of records. The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

(1) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to EtO conducted in accordance with paragraph (d) of this section.

(2) Observation procedures. When observation of the monitoring of employee exposure to EtO requires entry into an area where the use of protective clothing or equipment is required, the observer shall be provided with and be required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

(m) [Reserved]

(n) Appendices. The information contained in the appendices is not intended by itself to create any additional obligations not otherwise imposed or to detract from any existing obligation.

1910.1047 App A Substance safety data sheet for ethylene oxide (non-mandatory)

APPENDIX A to 1910.1047 - SUBSTANCE SAFETY DATA SHEET FOR ETHYLENE OXIDE
(NON-MANDATORY)

I. SUBSTANCE IDENTIFICATION

A. Substance: Ethylene oxide (C(2)H(4)O).

B. Synonyms: dihydrooxirene, dimethylene oxide, EO, 1,2-epoxyethane, EtO, ETO, oxacyclopropane, oxane, oxidoethane, alpha/beta-oxidoethane, oxiran, oxirane.

C. Ethylene oxide can be found as a liquid or vapor.

D. EtO is used in the manufacture of ethylene glycol, surfactants, ethanolamines, glycol ethers, and other organic chemicals. EtO is also used as a sterilant and fumigant.

E. Appearance and odor: Colorless liquid below 10.7 deg. C (51.3 deg. F) or colorless gas with ether-like odor detected at approximately 700 parts EtO per million parts of air (700 ppm).

F. Permissible Exposure: Exposure may not exceed 1 part EtO per million parts of air averaged over the 8-hour workday.

II. HEALTH HAZARD DATA

A. Ethylene oxide can cause bodily harm if you inhale the vapor, if it comes into contact with

your eyes or skin, or if you swallow it.

B. Effects of overexposure:

1. Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, and severe irritation and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Acute effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, shortness of breath, and cyanosis (blue or purple coloring of skin). Exposure has also been associated with the occurrence of cancer, reproductive effects, mutagenic changes, neurotoxicity, and sensitization.

1. EtO has been shown to cause cancer in laboratory animals and has been associated with higher incidences of cancer in humans. Adverse reproductive effects and chromosome damage may also occur from EtO exposure.

a. Reporting signs and symptoms: You should inform your employer if you develop any signs or symptoms and suspect that they are caused by exposure to EtO.

III. EMERGENCY FIRST AID PROCEDURES

A. Eye exposure: If EtO gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper eyelids. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.

B. Skin exposure: If EtO gets on your skin, immediately wash the contaminated skin with water. If EtO soaks through your clothing, especially your shoes, remove the clothing immediately and wash the skin with water using an emergency deluge shower. Get medical attention immediately. Thoroughly wash contaminated clothing before reusing. Contaminated leather shoes or other leather articles should not be reused and should be discarded.

C. Inhalation: If large amounts of EtO are inhaled, the exposed person must be moved to fresh air at once. If breathing has stopped, perform cardiopulmonary resuscitation. Keep the affected person warm and at rest. Get medical attention immediately.

D. Swallowing: When EtO has been swallowed, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him or her touch the back of the throat with his or her finger. Do not make an unconscious person vomit. Get medical attention immediately.

E. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, attempt rescue only after notifying at least one other person of the emergency and putting into effect established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the emergency

equipment before the need arises.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

A. Respirators: You may be required to wear a respirator for nonroutine activities, in emergencies, while your employer is in the process of reducing EtO exposures through engineering controls, and in areas where engineering controls are not feasible. As of the effective date of this standard, only air supplied, positive-pressure, full-facepiece respirators are approved for protection against EtO. If air-purifying respirators are worn in the future, they must have a label issued by the National Institute for Occupational Safety and Health under the provisions of 42 CFR part 84 stating that the respirators have been approved for use with ethylene oxide. For effective protection, respirators must fit your face and head snugly. Respirators must not be loosened or removed in work situations where their use is required.

EtO does not have a detectable odor except at levels well above the permissible exposure limits. If you can smell EtO while wearing a respirator, proceed immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. Protective clothing: You may be required to wear impermeable clothing, gloves, a face shield, or other appropriate protective clothing to prevent skin contact with liquid EtO or EtO-containing solutions. Where protective clothing is required, your employer must provide clean garments to you as necessary to assure that the clothing protects you adequately.

Replace or repair protective clothing that has become torn or otherwise damaged.

EtO must never be allowed to remain on the skin. Clothing and shoes which are not impermeable to EtO should not be allowed to become contaminated with EtO, and if they do, the clothing should be promptly removed and decontaminated. Contaminated leather shoes should be discarded. Once EtO penetrates shoes or other leather articles, they should not be worn again.

C. Eye protection: You must wear splashproof safety goggles in areas where liquid EtO or EtO-containing solutions may contact your eyes. In addition, contact lenses should not be worn in areas where eye contact with EtO can occur.

V. PRECAUTIONS FOR SAFE USE, HANDLING, AND STORAGE

A. EtO is a flammable liquid, and its vapors can easily form explosive mixtures in air.

B. EtO must be stored in tightly closed containers in a cool, well-ventilated area, away from heat, sparks, flames, strong oxidizers, alkalines, and acids, strong bases, acetylide-forming metals such as copper, silver, mercury and their alloys.

C. Sources of ignition such as smoking material, open flames and some electrical devices are

prohibited wherever EtO is handled, used, or stored in a manner that could create a potential fire or explosion hazard.

D. You should use non-sparking tools when opening or closing metal containers of EtO, and containers must be bonded and grounded in the rare instances in which liquid EtO is poured or transferred.

E. Impermeable clothing wet with liquid EtO or EtO-containing solutions may be easily ignited. If you are wearing impermeable clothing and are splashed with liquid EtO or EtO-containing solution, you should immediately remove the clothing while under an emergency deluge shower.

F. If your skin comes into contact with liquid EtO or EtO-containing solutions, you should immediately remove the EtO using an emergency deluge shower.

G. You should not keep food, beverages, or smoking materials in regulated areas where employee exposures are above the permissible exposure limits.

H. Fire extinguishers and emergency deluge showers for quick drenching should be readily available, and you should know where they are and how to operate them.

I. Ask your supervisor where EtO is used in your work area and for any additional plant safety and health rules.

VI. ACCESS TO INFORMATION

A. Each year, your employer is required to inform you of the information contained in this standard and appendices for EtO. In addition, your employer must instruct you in the proper work practices for using EtO emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to EtO. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determine that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits.

C. Your employer is required to keep records of your exposures and medical examinations. These exposure records must be kept by the employer for at least thirty (30) years. Medical records must be kept for the period of your employment plus thirty (30) years.

D. Your employer is required to release your exposure and medical records to your physician or designated representative upon your written request.

VII. STERILANT USE OF ETO IN HOSPITALS AND HEALTH CARE FACILITIES

This section of Appendix A, for informational purposes, sets forth EPA's recommendations for modifications in workplace design and practice in hospitals and health care facilities for which the Environmental Protection Agency has registered EtO for uses as a sterilant or fumigant under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq. These new recommendations, published in the Federal Register by EPA at 49 FR 15268, as modified in today's Register, are intended to help reduce the exposure of hospital and health care workers to EtO to 1 ppm. EPA's recommended workplace design and workplace practice are as follows:

1. Workplace Design

a. Installation of gas line hand valves. Hand valves must be installed on the gas supply line at the connection to the supply cylinders to minimize leakage during cylinder change.

b. Installation of capture boxes. Sterilizer operations result in a gas/water discharge at the completion of the process. This discharge is routinely piped to a floor drain which is generally located in an equipment or an adjacent room. When the floor drain is not in the same room as the sterilizer and workers are not normally present, all that is necessary is that the room be well ventilated.

The installation of a "capture box" will be required for those work place layouts where the floor drain is located in the same room as the sterilizer or in a room where workers are normally present. A "capture box" is a piece of equipment that totally encloses the floor drain where the discharge from the sterilizer is pumped. The "capture box" is to be vented directly to a non-recirculating or dedicated ventilation system. Sufficient air intake should be allowed at the bottom of the box to handle the volume of air that is ventilated from the top of the box. The "capture box" can be made of metal, plastic, wood or other equivalent material. The box is intended to reduce levels of EtO discharged into the work room atmosphere. The use of a "capture box" is not required if: (1) The vacuum pump discharge floor drain is located in a well ventilated equipment or other room where workers are not normally present or (2) the water sealed vacuum pump discharges directly to a closed sealed sewer line (check local plumbing codes).

If it is impractical to install a vented "capture box" and a well ventilated equipment or other room is not feasible, a box that can be sealed over the floor drain may be used if: (1) The floor drain is located in a room where workers are not normally present and EtO cannot leak into an occupied area, and (2) the sterilizer in use is less than 12 cubic feet in capacity (check local plumbing codes).

c. Ventilation of aeration units i. Existing aeration units. Existing units must be vented to a non-recirculating or dedicated system or vented to an equipment or other room where workers are not normally present and which is well ventilated. Aerator units must be positioned as close as possible to the sterilizer to minimize the exposure from the off-gassing of sterilized

items.

ii. Installation of new aerator units (where none exist). New aerator units must be vented as described above for existing aerators. Aerator units must be in place by July 1, 1986.

d. Ventilation during cylinder change. Workers may be exposed to short but relatively high levels of EtO during the change of gas cylinders. To reduce exposure from this route, users must select one of three alternatives designed to draw off gas that may be released when the line from the sterilizer to the cylinder is disconnected:

i. Location of cylinders in a well ventilated equipment room or other room where workers are not normally present.

ii. Installation of a flexible hose (at least 4" in diameter) to a non-recirculating or dedicated ventilation system and located in the area of cylinder change in such a way that the hose can be positioned at the point where the sterilizer gas line is disconnected from the cylinder.

iii. Installation of a hood that is part of a non-recirculating or dedicated system and positioned no more than one foot above the point where the change of cylinders takes place.

e. Ventilation of sterilizer door area. One of the major sources of exposure to EtO occurs when the sterilizer door is opened following the completion of the sterilization process. In order to reduce this avenue of exposure, a hood or metal canopy closed on each end must be installed over the sterilizer door. The hood or metal canopy must be connected to a non-recirculating or dedicated ventilation system or one that exhausts gases to a well ventilated equipment or other room where workers are not normally present. A hood or canopy over the sterilizer door is required for use even with those sterilizers that have a purge cycle and must be in place by July 1, 1986.

f. Ventilation of sterilizer relief valve. Sterilizers are typically equipped with a safety relief device to release gas in case of increased pressure in the sterilizer. Generally, such relief devices are used on pressure vessels. Although these pressure relief devices are rarely opened for hospital and health care sterilizers, it is suggested that they be designed to exhaust vapor from the sterilizer by one of the following methods:

i. Through a pipe connected to the outlet of the relief valve ventilated directly outdoors at a point high enough to be away from passers by, and not near any windows that open, or near any air conditioning or ventilation air intakes.

ii. Through a connection to an existing or new non-recirculating or dedicated ventilation system.

iii. Through a connection to a well ventilated equipment or other room where workers are not normally present.

g. Ventilation systems. Each hospital and health care facility affected by this notice that uses EtO for the sterilization of equipment and supplies must have a ventilation system which enables compliance with the requirements of section (b) through (f) in the manner described in these sections and within the timeframes allowed. Thus, each affected hospital and health care facility must have or install a non-recirculating or dedicated ventilation equipment or other room where workers are not normally present in which to vent EtO.

h. Installation of alarm systems. An audible and visual indicator alarm system must be installed to alert personnel of ventilation system failures, i.e., when the ventilation fan motor is not working.

2. Workplace Practices

All the workplace practices discussed in this unit must be permanently posted near the door of each sterilizer prior to use by any operator.

a. Changing of supply line filters. Filters in the sterilizer liquid line must be changed when necessary, by the following procedure:

- i. Close the cylinder valve and the hose valve.
- ii. Disconnect the cylinder hose (piping) from the cylinder.
- iii. Open the hose valve and bleed slowly into a proper ventilating system at or near the in-use supply cylinders.
- iv. Vacate the area until the line is empty.
- v. Change the filter.
- vi. Reconnect the lines and reverse the valve position.
- vii. Check hoses, filters, and valves for leaks with a fluorocarbon leak detector (for those sterilizers using the 88 percent chlorofluorocarbon, 12 percent ethylene oxide mixture (12/88)).

b. Restricted access area. i. Areas involving use of EtO must be designated as restricted access areas. They must be identified with signs or floor marks near the sterilizer door, aerator, vacuum pump floor drain discharge, and in-use cylinder storage.

ii. All personnel must be excluded from the restricted area when certain operations are in progress, such as discharging a vacuum pump, emptying a sterilizer liquid line, or venting a non-purge sterilizer with the door ajar or other operations where EtO might be released directly into the face of workers.

c. Door opening procedures. i. Sterilizers with purge cycles. A load treated in a sterilizer equipped with a purge cycle should be removed immediately upon completion of the cycle (provided no time is lost opening the door after cycle is completed). If this is not done, the purge cycle should be repeated before opening door.

ii. Sterilizers without purge cycles. For a load treated in a sterilizer not equipped with a purge cycle, the sterilizer door must be ajar 6" for 15 minutes, and then fully opened for at least another 15 minutes before removing the treated load. The length of time of the second period should be established by peak monitoring for one hour after the two 15-minute periods suggested. If the level is above 10 ppm time-weighted average for 8 hours, more time should be added to the second waiting period (door wide open). However, in no case may the second period be shortened to less than 15 minutes.

d. Chamber unloading procedures. i. Procedures for unloading the chamber must include the use of baskets or rolling carts, or baskets and rolling tables to transfer treated loads quickly, thus avoiding excessive contact with treated articles, and reducing the duration of exposures.

ii. If rolling carts are used, they should be pulled not pushed by the sterilizer operators to avoid offgassing exposure.

e. Maintenance. A written log should be instituted and maintained documenting the date of each leak detection and any maintenance procedures undertaken. This is a suggested use practice and is not required.

i. Leak detection. Sterilizer door gaskets, cylinder and vacuum piping, hoses, filters, and valves must be checked for leaks under full pressure with a Fluorocarbon leak detector (for 12/88 systems only) every two weeks by maintenance personnel. Also, the cylinder piping connections must be checked after changing cylinders. Particular attention in leak detection should be given to the automatic solenoid valves that control the flow of EtO to the sterilizer. Specifically, a check should be made at the EtO gasline entrance port to the sterilizer, while the sterilizer door is open and the solenoid valves are in a closed position.

ii. Maintenance procedures. Sterilizer/areator door gaskets, valves, and fittings must be replaced when necessary as determined by maintenance personnel in their bi-weekly checks; in addition, visual inspection of the door gaskets for cracks, debris, and other foreign substances should be conducted daily by the operator.

1910.1047 App B Substance technical guidelines for ethylene oxide (Non-mandatory)

APPENDIX B to 1910.1047 - SUBSTANCE TECHNICAL GUIDELINES FOR ETHYLENE OXIDE (NON-MANDATORY)

I. PHYSICAL AND CHEMICAL DATA

A. Substance identification:

1. Synonyms: dihydrooxirene, dimethylene oxide, EO, 1,2-epoxyethane, EtO ETO oxacyclopropane, oxane, oxidoethane, alpha/beta-oxidoethane, oxiran, oxirane.

2. Formula: (C₂H₄O).

3. Molecular weight: 44.06

B. Physical data:

1. Boiling point (760 mm Hg): 10.70 deg. C (51.3 deg. F);

2. Specific gravity (water = 1): 0.87 (at 20 deg. C or 68 deg. F)

3. Vapor density (air = 1): 1.49;

4. Vapor pressure (at 20 deg. C); 1,095 mm Hg;

5. Solubility in water: complete;

6. Appearance and odor: colorless liquid; gas at temperature above 10.7 deg. F or 51.3 deg. C with ether-like odor above 700 ppm.

II. FIRE, EXPLOSION, AND REACTIVITY HAZARD DATA

A. Fire:

1. Flash point: less than 0 deg. F (open cup);

2. Stability: decomposes violently at temperatures above 800 deg. F;

3. Flammable limits in air, percent by volume: Lower: 3, Upper: 100;

4. Extinguishing media: Carbon dioxide for small fires, polymer or alcohol foams for large fires;

5. Special fire fighting procedures: Dilution of ethylene oxide with 23 volumes of water renders it non-flammable;

6. Unusual fire and explosion hazards: Vapors of EtO will burn without the presence of air or other oxidizers. EtO vapors are heavier than air and may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which EtO is being used.

7. For purposes of compliance with the requirements of 29 CFR 1910.106, EtO is classified as a flammable gas. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.

8. For purposes of compliance with 29 CFR 1910.155, EtO is classified as a Class B fire hazard.

9. For purpose of compliance with 29 CFR 1919.307, locations classified as hazardous due to the presence of EtO shall be Class I.

B. Reactivity:

1. Conditions contributing to instability: EtO will polymerize violently if contaminated with aqueous alkalis, amines, mineral acids, metal chlorides, or metal oxides. Violent decomposition will also occur at temperatures above 800 deg. F;

2. Incompatibilities: Alkalines and acids;

3. Hazardous decomposition products: Carbon monoxide and carbon dioxide.

III. SPILL, LEAK, AND DISPOSAL PROCEDURES

A. If EtO is spilled or leaked, the following s should be taken:

1. Remove all ignition sources.

2. The area should be evacuated at once and re-entered only after the area has been thoroughly ventilated and washed down with water.

B. Persons not wearing appropriate protective equipment should be restricted from areas of spills or leaks until cleanup has been completed.

C. Waste disposal methods: Waste material should be disposed of in a manner that is not hazardous to employees or to the general population. In selecting the method of waste disposal, applicable local, State, and Federal regulations should be consulted.

IV. MONITORING AND MEASUREMENT PROCEDURES

A. Exposure above the Permissible Exposure Limit:

1. Eight-hour exposure evaluation: Measurements taken for the purpose of determining employee exposure under this section are best taken with consecutive samples covering the full shift. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee.)

2. Monitoring techniques: The sampling and analysis under this section may be performed by collection of the EtO vapor on charcoal adsorption tubes or other composition adsorption tubes, with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monitoring systems, portable direct reading instruments, or passive dosimeters as long as measurements taken using these methods accurately evaluate the concentration of EtO in employees' breathing zones.

Appendix D describes the validated method of sampling and analysis which has been tested by OSHA for use with EtO. Other available methods are also described in Appendix D. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring should be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of EtO at 1 ppm, and to plus or minus 35 percent for concentrations at 0.5 ppm. In addition to the method described in Appendix D, there are numerous other methods available for monitoring for EtO in the workplace. Details on these other methods have been submitted by various companies to the rulemaking record, and are available at the OSHA Docket Office.

B. Since many of the duties relating to employee exposure are dependent on the results of measurement procedures, employers should assure that the evaluation of employee exposures is performed by a technically qualified person.

V. PROTECTIVE CLOTHING AND EQUIPMENT

Employees should be provided with and be required to wear appropriate protective clothing wherever there is significant potential for skin contact with liquid EtO or EtO-containing solutions. Protective clothing shall include impermeable coveralls or similar full-body work clothing, gloves, and head coverings, as appropriate to protect areas of the body which may come in contact with liquid EtO or EtO-containing solutions.

Employers should ascertain that the protective garments are impermeable to EtO. Permeable clothing, including items made of rubber, and leather shoes should not be allowed to become contaminated with liquid EtO. If permeable clothing does become contaminated, it should be immediately removed, while the employer is under an emergency deluge shower. If leather footwear or other leather garments become wet from EtO they should be discarded and not be worn again, because leather absorbs EtO and holds it against the skin.

Any protective clothing that has been damaged or is otherwise found to be defective should be repaired or replaced. Clean protective clothing should be provided to the employee as necessary to assure employee protection. Whenever impermeable clothing becomes wet with liquid EtO, it should be washed down with water before being removed by the employee. Employees are also required to wear splash-proof safety goggles where there is any possibility of EtO contacting the eyes.

VI. MISCELLANEOUS PRECAUTIONS

A. Store EtO in tightly closed containers in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.

B. Non-sparking tools must be used to open and close metal containers. These containers must be effectively grounded and bonded.

C. Do not incinerate EtO cartridges, tanks or other containers.

D. Employers should advise employees of all areas and operations where exposure to EtO occur.

VII. COMMON OPERATIONS

Common operations in which exposure to EtO is likely to occur include the following: Manufacture of EtO, surfactants, ethanolamines, glycol ethers, and specialty chemicals, and use as a sterilant in the hospital, health product and spice industries.

1910.1047 App C Medical surveillance guidelines for ethylene oxide (Non-mandatory)

APPENDIX C to 1910.1047 - MEDICAL SURVEILLANCE GUIDELINES FOR ETHYLENE OXIDE (NON-MANDATORY)

I. ROUTE OF ENTRY

Inhalation.

II. TOXICOLOGY

Clinical evidence of adverse effects associated with the exposure to EtO is present in the form of increased incidence of cancer in laboratory animals (leukemia, stomach, brain), mutation in offspring in animals, and resorptions and spontaneous abortions in animals and human populations respectively. Findings in humans and experimental animals exposed to airborne concentrations of EtO also indicate damage to the genetic material (DNA). These include hemoglobin alkylation, uncheduled DNA synthesis, sister chromatid exchange chromosomal aberration, and functional sperm abnormalities.

Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, severe irritation, and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Other effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, dyspnea and cyanosis.

III. SIGNS AND SYMPTOMS OF ACUTE OVEREXPOSURE

The early effects of acute overexposure to EtO are nausea and vomiting, headache, and irritation of the eyes and respiratory passages. The patient may notice a "peculiar taste" in the mouth. Delayed effects can include pulmonary edema, drowsiness, weakness, and incoordination. Studies suggest that blood cell changes, an increase in chromosomal aberrations, and spontaneous abortion may also be causally related to acute overexposure to EtO.

Skin contact with liquid or gaseous EtO causes characteristic burns and possibly even an allergic-type sensitization. The edema and erythema occurring from skin contact with EtO progress to vesiculation with a tendency to coalesce into blebs with desquamation. Healing occurs within three weeks, but there may be a residual brown pigmentation. A 40-80% solution is extremely dangerous, causing extensive blistering after only brief contact. Pure liquid EtO causes frostbite because of rapid evaporation. In contrast, the eye is relatively insensitive to EtO, but there may be some irritation of the cornea.

Most reported acute effects of occupational exposure to EtO are due to contact with EtO in liquid phase. The liquid readily penetrates rubber and leather, and will produce blistering if clothing or footwear contaminated with EtO are not removed.

IV. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

As noted above, exposure to EtO has been linked to an increased risk of cancer and reproductive effects including decreased male fertility, fetotoxicity, and spontaneous abortion. EtO workers are more likely to have chromosomal damage than similar groups not exposed to EtO. At the present, limited studies of chronic effects in humans resulting from exposure to EtO suggest a causal association with leukemia. Animal studies indicate leukemia and cancers at other sites (brain, stomach) as well. The physician should be aware of the findings of these studies in evaluating the health of employees exposed to EtO.

Adequate screening tests to determine an employee's potential for developing serious chronic diseases, such as cancer, from exposure to EtO do not presently exist. Laboratory tests may, however, give evidence to suggest that an employee is potentially overexposed to EtO. It is important for the physician to become familiar with the operating conditions in which exposure to EtO is likely to occur. The physician also must become familiar with the signs and symptoms that indicate a worker is receiving otherwise unrecognized and unacceptable exposure to EtO. These elements are especially important in evaluating the medical and work histories and in conducting the physical exam. When an unacceptable exposure in an active employee is identified by the physician, measures taken by the employer to lower exposure should also lower the risk of serious long-term consequences.

The employer is required to institute a medical surveillance program for all employees who are or will be exposed to EtO at or above the action level (0.5 ppm) for at least 30 days per year, without regard to respirator use. All examinations and procedures must be performed by or under the supervision of a licensed physician at a reasonable time and place for the employee and at no cost to the employee.

Although broad latitude in prescribing specific tests to be included in the medical surveillance program is extended to the examining physician, OSHA requires inclusion of the following elements in the routine examination:

(i) Medical and work histories with special emphasis directed to symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

(ii) Physical examination with particular emphasis given to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

(iii) Complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

(iv) Any laboratory or other test which the examining physician deems necessary by sound medical practice.

If requested by the employee, the medical examinations shall include pregnancy testing or laboratory evaluation of fertility as deemed appropriate by the physician.

In certain cases, to provide sound medical advice to the employer and the employee, the physician must evaluate situations not directly related to EtO. For example, employees with skin diseases may be unable to tolerate wearing protective clothing. In addition those with chronic respiratory diseases may not tolerate the wearing of negative pressure (air purifying) respirators. Additional tests and procedures that will help the physician determine which employees are medically unable to wear such respirators should include: An evaluation of cardiovascular

function, a baseline chest x-ray to be repeated at five year intervals, and a pulmonary function test to be repeated every three years. The pulmonary function test should include measurement of the employee's forced vital capacity (FVC), forced expiratory volume at one second (FEV1), as well as calculation of the ratios of FEV1 to FVC, and measured FVC and measured FEV1 to expected values corrected for variation due to age, sex, race, and height.

The employer is required to make the prescribed tests available at least annually to employees who are or will be exposed at or above the action level, for 30 or more days per year; more often than specified if recommended by the examining physician; and upon the employee's termination of employment or reassignment to another work area. While little is known about the long term consequences of high short-term exposures, it appears prudent to monitor such affected employees closely in light of existing health data. The employer shall provide physician recommended examinations to any employee exposed to EtO in emergency conditions. Likewise, the employer shall make available medical consultations including physician recommended exams to employees who believe they are suffering signs or symptoms of exposure to EtO.

The employer is required to provide the physician with the following information: a copy of this standard and its appendices; a description of the affected employee's duties as they relate to the employee exposure level; and information from the employee's previous medical examinations which is not readily available to the examining physician. Making this information available to the physician will aid in the evaluation of the employee's health in relation to assigned duties and fitness to wear personal protective equipment, when required.

The employer is required to obtain a written opinion from the examining physician containing the results of the medical examinations; the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of his or her health from exposure to EtO; any recommended restrictions upon the employee's exposure to EtO, or upon the use of protective clothing or equipment such as respirators; and a statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure to EtO, and a copy of the opinion must be provided to the affected employee.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to aid in the determination of initial placement of employees and to assess the employee's ability to use protective clothing and equipment.

1910.1047 App D Sampling and analytical methods for ethylene oxide (Non-mandatory)

APPENDIX D - SAMPLING AND ANALYTICAL METHODS FOR ETHYLENE OXIDE (NON-MANDATORY)

A number of methods are available for monitoring employee exposures to EtO. Most of these involve the use of charcoal tubes and sampling pumps, followed by analysis of the samples by gas chromatograph. The essential differences between the charcoal tube methods include, among others, the use of different desorbing solvents, the use of different lots of charcoal, and the use of different equipment for analysis of the samples.

Besides charcoal, methods using passive dosimeters, gas sampling bags, impingers, and detector tubes have been utilized for determination of EtO exposure. In addition, there are several commercially available portable gas analyzers and monitoring units.

This appendix contains details for the method which has been tested at the OSHA Analytical Laboratory in Salt Lake City. Inclusion of this method in the appendix does not mean that this method is the only one which will be satisfactory. Copies of descriptions of other methods available are available in the rulemaking record, and may be obtained from the OSHA Docket Office. These include the Union Carbide, Dow Chemical, 3M, and DuPont methods, as well as NIOSH Method S-286. These methods are briefly described at the end of this appendix.

Employers who note problems with sample breakthrough using the OSHA or other charcoal methods should try larger charcoal tubes. Tubes of larger capacity are available. In addition, lower flow rates and shorter sampling times should be beneficial in minimizing breakthrough problems. Whatever method the employer chooses, he must assure himself of the method's accuracy and precision under the unique conditions present in his workplace.

ETHYLENE OXIDE

Method No.: 30.

Matrix: Air.

Target Concentration: 1.0 ppm (1.8 mg/m³).

Procedure: Samples are collected on two charcoal tubes in series and desorbed with 1% CS₂ in benzene. The samples are derivatized with HBr and treated with sodium carbonate. Analysis is done by gas chromatography with an electron capture detector.

Recommended Air Volume and Sampling Rate: 1 liter and 0.05 Lpm.

Detection Limit of the Overall Procedure: 13.3 ppb (0.024 mg/m³) (Based on 1.0 liter air sample).

Reliable Quantitation Limit: 52.2 ppb (0.094 mg/m³) (Based on 1.0 liter air sample).

Standard Error of Estimate: 6.59% (See Backup Section 4.6).

Special Requirements: Samples must be analyzed within 15 days of sampling date.

Status of Method: The sampling and analytical method has been subjected to the established evaluation procedures of the Organic Method Evaluations Branch.

Date: August 1981.

Chemist: Wayne D. Potter.

ORGANIC SOLVENTS BRANCH, OSHA ANALYTICAL LABORATORY, SALT LAKE CITY, UTAH

1. General Discussion.

1.1 Background.

1.1.1 History of Procedure.

Ethylene oxide samples analyzed at the OSHA Laboratory have normally been collected on activated charcoal and desorbed with carbon disulfide. The analysis is performed with a gas chromatograph equipped with a FID (Flame ionization detector) as described in NIOSH Method S286 (Ref. 5.1). This method is based on a PEL of 50 ppm and has a detection limit of about 1 ppm.

Recent studies have prompted the need for a method to analyze and detect ethylene oxide at very low concentrations.

Several attempts were made to form an ultraviolet (UV) sensitive derivative with ethylene oxide for analysis with HPLC. Among those tested that gave no detectable product were: p-anisidine, methylimidazole, aniline, and 2,3,6-trichlorobenzoic acid. Each was tested with catalysts such as triethylamine, aluminum chloride, methylene chloride and sulfuric acid but no detectable derivative was produced.

The next derivatization attempt was to react ethylene oxide with HBr to form 2-bromoethanol. This reaction was successful. An ECD (electron capture detector) gave a very good response for 2-bromoethanol due to the presence of bromine. The use of carbon disulfide as the desorbing solvent gave too large a response and masked the 2-bromoethanol. Several other solvents were tested for both their response on the ECD and their ability to desorb ethylene oxide from the charcoal. Among those tested were toluene, xylene, ethyl benzene, hexane, cyclohexane and benzene. Benzene was the only solvent tested that gave a suitable response on the ECD and a high desorption. It was found that the desorption efficiency was improved by using 1% CS₂ with the benzene. The carbon disulfide did not significantly improve the recovery with the other

solvents. SKC Lot 120 was used in all tests done with activated charcoal.

1.1.2 Physical Properties (Ref. 5.2-5.4).

Synonyms: Oxirane; dimethylene oxide, 1,2-epoxy-ethane; oxane; C(2)H(4)O; ETO;

Molecular Weight: 44.06

Boiling Point: 10.7 deg. C (51.3 deg.)

Melting Point: 111 deg. C

Description: Colorless, flammable gas

Vapor Pressure: 1095 mm. at 20 deg. C

Odor: Ether-like odor

Lower Explosive Limits: 3.0% (by volume)

Flash Point (TOC): Below 0 deg. F

Molecular Structure: CH(2)-CH(2)

1.2 Limit Defining Parameters.

1.2.1 Detection Limit of the Analytical Procedure.

The detection limit of the analytical procedure is 12.0 picograms of ethylene oxide per injection. This is the amount of analyte which will give a peak whose height is five times the height of the baseline noise. (See Backup Data Section 4.1).

1.2.2 Detection Limit of the Overall Procedure.

The detection limit of the overall procedure is 24.0 ng of ethylene oxide per sample.

This is the amount of analyte spiked on the sampling device which allows recovery of an amount of analyte equivalent to the detection limit of the analytical procedure. (See Backup Data Section 4.2).

1.2.3 Reliable Quantitation Limit.

The reliable quantitation limit is 94.0 nanograms of ethylene oxide per sample. This is the smallest amount of analyte which can be quantitated within the requirements of 75% recovery and 95% confidence limits. (See Backup Data Section 4.2).

It must be recognized that the reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operating parameters. In this case, the limits reported on analysis reports will be based on the operating parameters used during the analysis of the samples.

1.2.4 Sensitivity.

The sensitivity of the analytical procedure over a concentration range representing 0.5 to 2 times the target concentration based on the recommended air volume is 34105 area units per ug/mL. The sensitivity is determined by the slope of the calibration curve (See Backup Data Section 4.3).

The sensitivity will vary somewhat with the particular instrument used in the analysis.

1.2.5 Recovery.

The recovery of analyte from the collection medium must be 75% or greater. The average recovery from spiked samples over the range of 0.5 to 2 times the target concentration is 88.0% (See Backup Section 4.4). At lower concentrations the recovery appears to be non-linear.

1.2.6 Precision (Analytical Method Only).

The pooled coefficient of variation obtained from replicate determination of analytical standards at 0.5X, 1X and 2X the target concentration is 0.036 (See Backup Data Section 4.5).

1.2.7 Precision (Overall Procedure).

The overall procedure must provide results at the target concentration that are 25% of better at the 95% confidence level. The precision at the 95% confidence level for the 15 day storage test is plus or minus 12.9% (See Backup Data Section 4.6).

This includes an additional plus or minus 5% for sampling error.

1.3 Advantages.

1.3.1 The sampling procedure is convenient.

1.3.2 The analytical procedure is very sensitive and reproducible.

1.3.3 Reanalysis of samples is possible.

1.3.4 Samples are stable for at least 15 days at room temperature.

1.3.5 Interferences are reduced by the longer GC retention time of the new derivative.

1.4 Disadvantages.

1.4.1 Two tubes in series must be used because of possible breakthrough and migration.

1.4.2 The precision of the sampling rate may be limited by the reproducibility of the pressure drop across the tubes. The pumps are usually calibrated for one tube only.

1.4.3 The use of benzene as the desorption solvent increases the hazards of analysis because of the potential carcinogenic effects of benzene.

1.4.4 After repeated injections there can be a buildup of residue formed on the electron capture detector which decreases sensitivity.

1.4.5 Recovery from the charcoal tubes appears to be nonlinear at low concentrations.

2. Sampling Procedure.

2.1 Apparatus.

2.1.1 A calibrated personal sampling pump whose flow can be determined within plus or minus 5% of the recommended flow.

2.1.2 SKC Lot 120 Charcoal tubes: glass tube with both ends flame sealed, 7 cm long with a 6 mm O.D. and a 4 - mm I.D., containing 2 sections of coconut shell charcoal separated by a 2 - mm portion of urethane foam. The adsorbing section contains 100 mg of charcoal, the backup section 50 mg. A 3 - mm portion of urethane foam is placed between the outlet end of the tube and the backup section. A plug of silylated glass wool is placed in front of the adsorbing section.

2.2 Reagents.

2.2.1 None required.

2.3 Sampling Technique.

2.3.1 Immediately before sampling, break the ends of the charcoal tubes. All tubes must be from the same lot.

2.3.2 Connect two tubes in series to the sampling pump with a short section of flexible tubing. A minimum amount of tubing is used to connect the two sampling tubes together. The tube closer to the pump is used as a backup. This tube should be identified as the backup tube.

2.3.3 The tubes should be placed in a vertical position during sampling to minimize channeling.

2.3.4 Air being sampled should not pass through any hose or tubing before entering the charcoal tubes.

2.3.5 Seal the charcoal tubes with plastic caps immediately after sampling. Also, seal each sample with OSHA seals lengthwise.

2.3.6 With each batch of samples, submit at least one blank tube from the same lot used for samples. This tube should be subjected to exactly the same handling as the samples (break, seal, transport) except that no air is drawn through it.

2.3.7 Transport the samples (and corresponding paperwork) to the lab for analysis.

2.3.8 If bulk samples are submitted for analysis, they should be transported in glass containers with Teflon-lined caps. These samples must be mailed separately from the container used for the charcoal tubes.

2.4 Breakthrough.

2.4.1 The breakthrough (5% breakthrough) volume for a 3.0 mg/m ethylene oxide sample stream at approximately 85% relative humidity, 22 deg. C and 633 mm is 2.6 liters sampled at 0.05 liters per minute. This is equivalent to 7.8 mg of ethylene oxide. Upon saturation of the tube it appeared that the water may be displacing ethylene oxide during sampling.

2.5 Desorption Efficiency.

2.5.1 The desorption efficiency, from liquid injection onto charcoal tubes, averaged 88.0% from 0.5 to 2.0 x the target concentration for a 1.0 liter air sample. At lower ranges it appears that the desorption efficiency is non-linear (See Backup Data Section 4.2).

2.5.2 The desorption efficiency may vary from one laboratory to another and also from one lot of charcoal to another. Thus, it is necessary to determine the desorption efficiency for a particular lot of charcoal.

2.6 Recommended Air Volume and Sampling Rate.

2.6.1 The recommended air volume is 1.0 liter.

2.6.2 The recommended maximum sampling rate is 0.05 Lpm.

2.7 Interferences.

2.7.1 Ethylene glycol and Freon 12 at target concentration levels did not interfere with the collection of ethylene oxide.

2.7.2 Suspected interferences should be listed on the sample data sheets.

2.7.3 The relative humidity may affect the sampling procedure.

2.8 Safety Precautions.

2.8.1 Attach the sampling equipment to the employee so that it does not interfere with work performance.

2.8.2 Wear safety glasses when breaking the ends of the sampling tubes.

2.8.3 If possible, place the sampling tubes in a holder so the sharp end is not exposed while sampling.

3. Analytical Method.

3.1 Apparatus.

3.1.1 Gas chromatograph equipped with a linearized electron capture detector.

3.1.2 GC column capable of separating the derivative of ethylene oxide (2-bromoethanol) from any interferences and the 1% CS₂ in benzene solvent. The column used for validation studies was: 10 ft x 1/8 inch stainless steel 20% SP-2100, .1% Carbowax 1500 on 100/120 Supelcoport.

3.1.3 An electronic integrator or some other suitable method of measuring peak areas.

3.1.4 Two milliliter vials with Teflon-lined caps.

3.1.5 Gas tight syringe - 500 mL or other convenient sizes for preparing standards.

3.1.6 Microliter syringes - 10 mL or other convenient sizes for diluting standards and 1 mL for sample injections.

3.1.7 Pipets for dispensing the 1% CS₂ in benzene solvent. The Glenco 1 mL dispenser is adequate and convenient.

3.1.8 Volumetric flasks - 5 mL and other convenient sizes for preparing standards.

3.1.9 Disposable Pasteur pipets.

3.2 Reagents.

3.2.1 Benzene, reagent grade.

3.2.2 Carbon Disulfide, reagent grade.

3.2.3 Ethylene oxide, 99.7% pure.

3.2.4 Hydrobromic Acid, 48% reagent grade.

3.2.5 Sodium Carbonate, anhydrous, reagent grade.

3.2.6 Desorbing reagent, 99% Benzene/1% CS₂.

3.3 Sample Preparation.

3.3.1 The front and back sections of each sample are transferred to separate 2-mL vials.

3.3.2 Each sample is desorbed with 1.0 mL of desorbing reagent.

3.3.3 The vials are sealed immediately and allowed to desorb for one hour with occasional shaking.

3.3.4 Desorbing reagent is drawn off the charcoal with a disposable pipet and put into clean 2-mL vials.

3.3.5 One drop of HBr is added to each vial. Vials are resealed and HBr is mixed well with the desorbing reagent.

3.3.6 About 0.15 gram of sodium carbonate is carefully added to each vial. Vials are again resealed and mixed well.

3.4 Standard Preparation.

3.4.1 Standards are prepared by injecting the pure ethylene oxide gas into the desorbing reagent.

3.4.2 A range of standards are prepared to make a calibration curve. A concentration of 1.0 mL of ethylene oxide gas per 1 mL desorbing reagent is equivalent to 1.0 ppm air concentration (all gas volumes at 25 deg. C and 760 mm) for the recommended 1 liter air sample. This amount is uncorrected for desorption efficiency (See Backup Data Section 4.2. for desorption efficiency corrections).

3.4.3 One drop of HBr per mL of standard is added and mixed well.

3.4.4 About 0.15 grams of sodium carbonate is carefully added for each drop of HBr (A small reaction will occur).

3.5 Analysis.

3.5.1 GC Conditions. Nitrogen flow rate - 10mL/min. Injector Temperature - 250 deg. C
Detector Temperature - 300 deg. C Column Temperature - 100 deg. C Injection size - 0.8 mL
Elution time - 3.9 minutes

3.5.2 Peak areas are measured by an integrator or other suitable means.

3.5.3 The integrator results are in area units and a calibration curve is set up with concentration vs. area units.

3.6 Interferences.

3.6.1 Any compound having the same retention time of 2-bromoethanol is a potential interference. Possible interferences should be listed on the sample data sheets.

3.6.2 GC parameters may be changed to circumvent interferences.

3.6.3 There are usually trace contaminants in benzene. These contaminants, however, posed no problem of interference.

3.6.4 Retention time data on a single column is not considered proof of chemical identity. Samples over the 1.0 ppm target level should be confirmed by GC/Mass Spec or other suitable means.

3.7 Calculations

3.7.1 The concentration in ug/mL for a sample is determined by comparing the area of a particular sample to the calibration curve, which has been prepared from analytical standards.

3.7.2 The amount of analyte in each sample is corrected for desorption efficiency by use of a desorption curve.

3.7.3 Analytical results (A) from the two tubes that compose a particular air sample are added together.

3.7.4 The concentration for a sample is calculated by the following equation:

AXB ETO, mg/ ---

$$m(3) = C$$

where: A = ug/mL B = desorption volume in milliliters C = air volume in liters.

3.7.5 To convert mg/m(3) to parts per million (ppm) the following relationship is used:

$$\frac{\text{mg/m}(3) \times 24.45}{44.05} = \text{ETO, ppm}$$

where: mg/m(3) = results from 3.7.4 24.45 = molar volume at 25 deg. C and 760mm Hg 44.05 = molecular weight of ETO.

3.8 Safety Precautions

3.8.1 Ethylene oxide and benzene are potential carcinogens and care must be exercised when working with these compounds.

3.8.2 All work done with the solvents (preparation of standards, desorption of samples, etc.) should be done in a hood.

3.8.3 Avoid any skin contact with all of the solvents.

3.8.4 Wear safety glasses at all times.

3.8.5 Avoid skin contact with HBr because it is highly toxic and a strong irritant to eyes and skin.

4. Backup Data.

4.1 Detection Limit Data.

The detection limit was determined by injecting 0.8 uL of a 0.015 ug/mL standard of ethylene oxide into 1% CS(2) in benzene. The detection limit of the analytical procedure is taken to be 1.20×10^5 ug per injection. This is equivalent to 8.3 ppb (0.015 mg/m(3)) for the recommended air volume.

4.2 Desorption Efficiency.

Ethylene oxide was spiked onto charcoal tubes and the following recovery data was obtained.

| Amount spiked (ug) | Amount recovered (ug) | Percent recovery |
|--------------------|-----------------------|------------------|
| 4.5 | 4.32 | 96.0 |
| 3.0 | 2.61 | 87.0 |
| 2.25 | 2.025 | 90.0 |
| 1.5 | 1.365 | 91.0 |
| 1.5 | 1.38 | 92.0 |
| .75 | .6525 | 87.0 |
| .375 | .315 | 84.0 |
| .375 | .312 | 83.2 |
| .1875 | .151 | 80.5 |
| .094 | .070 | 74.5 |

At lower amounts the recovery appears to be non-linear.

4.3 Sensitivity Data.

The following data was used to determine the calibration curve.

| Injection | 0.5 X .75 ug/mL | 1 X 1.5 ug/mL | 2 X 3.0 ug/mL |
|-----------|-----------------|---------------|---------------|
| 1..... | 30904 | 59567 | 111778 |
| 2..... | 30987 | 62914 | 106016 |
| 3..... | 32555 | 58578 | 106122 |
| 4..... | 32242 | 57173 | 109716 |
| X..... | 31672 | 59558 | 108408 |

Slope = 34.105.

4.4 Recovery.

The recovery was determined by spiking ethylene oxide onto lot 120 charcoal tubes and desorbing with 1% CS(2) in Benzene. Recoveries were done at 0.5, 1.0, and 2.0 X the target concentration (1 ppm) for the recommended air volume.

PERCENT RECOVERY

| Sample | 0.5x | 1.0x | 2.0x |
|--------|------|------|------|
| 1..... | 88.7 | 95.0 | 91.7 |

| | | | |
|--------|------|------|------|
| 2..... | 83.8 | 95.0 | 87.3 |
| 3..... | 84.2 | 91.0 | 86.0 |
| 4..... | 88.0 | 91.0 | 83.0 |
| 5..... | 88.0 | 86.0 | 85.0 |
| X..... | 86.5 | 90.5 | 87.0 |

Weighted Average = 88.2.

4.5 Precision of the Analytical Procedure.

The following data was used to determine the precision of the analytical method:

| Concentration | 0.5x.75 ug/mL | 1x1.5 ug/mL | 2X3.0 ug/mL |
|----------------------|------------------|----------------|----------------|
| Injection..... | .7421 | 1.4899 | 3.1184 |
| | .7441 | 1.5826 | 3.0447 |
| | .7831 | 1.4628 | 2.9149 |
| | .7753 | 1.4244 | 2.9185 |
| Average..... | .7612 | 1.4899 | 2.9991 |
| Standard Deviation.. | .0211 | .0674 | .0998 |
| CV..... | .0277 | .0452 | .0333 |

$$CV = \frac{3(.0277)(2) + 3(.0452)(2) + 3(.0333)(2)}{3 + 3 + 3}$$

CV + 0.036

4.6 Storage Data.

Samples were generated at 1.5 mg/m(3) ethylene oxide at 85% relative humidity, 22 deg. C and 633 mm. All samples were taken for 20 minutes at 0.05 Lpm. Six samples were analyzed as soon as possible and fifteen samples were stored at refrigerated temperature (5 deg. C) and fifteen samples were stored at ambient temperature (23 deg. C). These stored samples were analyzed over a period of nineteen days.

PERCENT RECOVERY

| Day analyzed | Refrigerated | Ambient |
|--------------|--------------|---------|
| 1..... | 87.0 | 87.0 |
| 1..... | 93.0 | 93.0 |
| 1..... | 94.0 | 94.0 |
| 1..... | 92.0 | 92.0 |
| 4..... | 92.0 | 91.0 |

| | | |
|---------|-------|-------|
| 4..... | 93.0 | 88.0 |
| 4..... | 91.0 | 89.0 |
| 6..... | 92.0 | |
| 6..... | 92.0 | |
| 8..... | | 92.0 |
| 8..... | | 86.0 |
| 10..... | 91.7 | |
| 10..... | 95.5 | |
| 10..... | 95.7 | |
| 11..... | | 90.0 |
| 11..... | | 82.0 |
| 13..... | 78.0 | |
| 13..... | 81.4 | |
| 13..... | 82.4 | |
| 14..... | | 78.5 |
| 14..... | | 72.1 |
| 18..... | 66.0 | |
| 18..... | 68.0 | |
| 19..... | | 64.0 |
| 19..... | | 77.0 |

4.7 Breakthrough Data.

Breakthrough studies were done at 2 ppm (3.6 mg/m³) at approximately 85% relative humidity at 22 deg.C (ambient temperature). Two charcoal tubes were used in series. The backup tube was changed every 10 minutes and analyzed for breakthrough. The flow rate was 0.050 Lpm.

| Tube No. | Time (minutes) | Percent break-through |
|----------|----------------|-----------------------|
| 1..... | 10 | (1) |
| 2..... | 20 | (1) |
| 3..... | 30 | (1) |
| 4..... | 40 | 1.23 |
| 5..... | 50 | 3.46 |
| 6..... | 60 | 18.71 |
| 7..... | 70 | 39.2 |
| 8..... | 80 | 53.3 |
| 9..... | 90 | 72.0 |
| 10..... | 100 | 96.0 |
| 11..... | 110 | 113.0 |
| 12..... | 120 | 133.9 |

Footnote(1) None.

The 5% breakthrough volume was reached when 2.6 liters of test atmosphere were drawn through the charcoal tubes.

5. References.

5.1 "NIOSH Manual of Analytical Methods," 2nd ed. NIOSH: Cincinnati, 1977; Method S286.

5.2 "IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man," International Agency for Research on Cancer: Lyon, 1976; Vol. II, p. 157.

5.3 Sax., N.I. "Dangerous Properties of Industrial Materials," 4th ed.; Van Nostrand Reinhold Company. New York, 1975; p. 741.

5.4 "The Condensed Chemical Dictionary", 9th ed.; Hawley, G.G., ed.; Van Nostrand Reinhold Company, New York, 1977; p. 361.

Summary of Other Sampling Procedures

OSHA believes that served other types of monitoring equipment and techniques exist for monitoring time-weighted averages. Considerable research and method development is currently being performed, which will lead to improvements and a wider variety of monitoring techniques. A combination of monitoring procedures can be used. There probably is no one best method for monitoring personal exposure to ethylene oxide in all cases. There are advantages, disadvantages, and limitations to each method. The method of choice will depend on the need and requirements. Some commonly used methods include the use of charcoal tubes, passive dosimeters, Tedler gas sampling bags, detector tubes, photoionization detection units, infrared detection units and gas chromatographs. A number of these methods are described below.

A. Charcoal Tube Sampling Procedures

Qazi-Ketcham method (Ex. 11-133) - This method consists of collecting EtO on Columbia JXC activated carbon, desorbing the EtO with carbon disulfide and analyzing by gas chromatography with flame ionization detection. Union Carbide has recently updated and revalidated this monitoring procedures. This method is capable of determining both eight-hour time-weighted average exposures and short-term exposures. The method was validated to 0.5 ppm. Like other charcoal collecting procedures, the method requires considerable analytical expertise.

ASTM-proposed method - The Ethylene Oxide Industry Council (EOIC) has contracted with Clayton Environmental Consultants, Inc. to conduct a collaborative study for the proposed method. The ASTM-Proposed method is similar to the method published by Qazi and Ketcham in the November 1977 American Industrial Hygiene Association Journal, and to the method of Pilney and Coyne, presented at the 1979 American Industrial Hygiene Conference. After the air to be sampled is drawn through an activated charcoal tube, the ethylene oxide is desorbed from the tube using carbon disulfide and is quantitated by gas chromatography utilizing a flame ionization detector. The ASTM-proposed method specifies a large two-section charcoal tube,

shipment in dry ice, storage at less than 5 deg.C, and analysis within three weeks to prevent migration and sample loss. Two types of charcoal tubes are being tested-Pittsburgh Coconut-Based (PCB) and Columbia JXC charcoal. This collaborative study will give an indication of the inter- and intralaboratory precision and accuracy of the ASTM-proposed method. Several laboratories have considerable expertise using the Qazi-Ketcham and Dow methods.

B. Passive Monitors - Ethylene oxide diffuses into the monitor and is collected in the sampling media. The DuPont Pro-Tek badge collects EtO in an absorbing solution, which is analyzed colorimetrically to determine the amount of EtO present. The 3M 350 badge collects the EtO on chemically treated charcoal. Other passive monitors are currently being developed and tested. Both 3M and DuPont have submitted data indicating their dosimeters meet the precision and accuracy requirements of the proposed ethylene oxide standard. Both presented laboratory validation data to 0.2 ppm (Exs. 11-65, 4-20, 108, 109, 130).

C. Tedlar Gas Sampling Bags - Samples are collected by drawing a known volume of air into a Tedlar gas sampling bag. The ethylene oxide concentration is often determined on-site using a portable gas chromatograph or portable infrared spectrometer.

D. Detector tubes - A known volume of air is drawn through a detector tube using a small hand pump. The concentration of EtO is related to the length of stain developed in the tube. Detector tubes are economical, easy to use, and give an immediate readout. Unfortunately, partly because they are nonspecific, their accuracy is often questionable. Since the sample is taken over a short period of time, they may be useful for determining the source of leaks.

E. Direct Reading Instruments - There are numerous types of direct reading instruments, each having its own strengths and weaknesses (Exs. 135B, 135C, 107, 11-78, 11-153). Many are relatively new, offering greater sensitivity and specificity. Popular ethylene oxide direct reading instruments include infrared detection units, photoionization detection units, and gas chromatographs.

Portable infrared analyzers provide an immediate, continuous indication of a concentration value; making them particularly useful for locating high concentration pockets, in leak detection and in ambient air monitoring. In infrared detection units, the amount of infrared light absorbed by the gas being analyzed at selected infrared wavelengths is related to the concentration of a particular component. Various models have either fixed or variable infrared filters, differing cell pathlengths, and microcomputer controls for greater sensitivity, automation, and interference elimination.

A fairly recent detection system is photoionization detection. The molecules are ionized by high energy ultraviolet light. The resulting current is measured. Since different substances have different ionization potentials, other organic compounds may be ionized. The lower the lamp energy, the better the selectivity. As a continuous monitor, photoionization detection can be useful for locating high concentration pockets, in leak detection, and continuous ambient air

monitoring. Both portable and stationary gas chromatographs are available with various types of detectors, including photoionization detectors. A gas chromatograph with a photoionization detector retains the photoionization sensitivity, but minimizes or eliminates interferences. For several GC/PID units, the sensitivity is in the 0.1-0.2 ppm EtO range. The GC/PID with microprocessors can sample up to 20 sample points sequentially, calculate and record data, and activate alarms or ventilation systems. Many are quite flexible and can be configured to meet the specific analysis needs for the workplace.

DuPont presented their laboratory validation data of the accuracy of the Qazi-Ketcham charcoal tube, the PCB charcoal tube, Miran 103 IR analyzer, 3M #3550 monitor and the Du Pont C-70 badge. Quoting Elbert V. Kring:

We also believe that OSHA's proposed accuracy in this standard is appropriate. At plus or minus 25 percent at one part per million, and plus or minus 35 percent below that. And, our data indicates there's only one monitoring method, right now, that we've tested thoroughly, that meets that accuracy requirements. That is the Du Pont Pro-Tek badge. . . . We also believe that this kind of data should be confirmed by another independent laboratory, using the same type dynamic chamber testing (Tr. 1470) Additional data by an independent laboratory following their exact protocol was not submitted. However, information was submitted on comparisons and precision and accuracy of those monitoring procedures which indicate far better precision and accuracy of those monitoring procedures than that obtained by Du Pont (Ex. 4-20, 130, 11-68, 11-133, 130, 135A).

The accuracy of any method depends to a large degree upon the skills and experience of those who not only collect the samples but also those who analyze the samples. Even for methods that are collaboratively tested, some laboratories are closer to the true values than others. Some laboratories may meet the precision and accuracy requirements of the method; others may consistently far exceed them for the same method.

[49 FR 25796, June 22, 1984, as amended at 50 FR 9801, Mar. 12, 1985; 50 FR 41494, Oct. 11, 1985; 51 FR 25053, July 10, 1986; 53 FR 11436, 11437, Apr. 6, 1988; 53 FR 27960, July 26, 1988; 54 FR 24334, June 7, 1989]

Editorial Note: At 53 FR 11436 and 11437, Apr. 6, 1988, 1910.1047 was amended, paragraphs (a)(2),(d),(f)(2), (g)(3) and (j) contain information collection requirements which will not become effective until approval has been obtained from the Office of Management and Budget. The Occupational Safety and Health Administration will publish a notice in the Federal Register once approval has been obtained.

1910.1048 Formaldehyde.

(a) Scope and application. This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde.

(b) Definitions. For purposes of this standard, the following definitions shall apply:

"Action level" means a concentration of 0.5 part formaldehyde per million parts of air (0.5 ppm) calculated as an eight (8)-hour time-weighted average (TWA) concentration.

"Assistant Secretary" means the Assistant Secretary of Labor for the Occupational Safety and Health Administration, U.S. Department of Labor, or designee.

"Authorized Person" means any person required by work duties to be present in regulated areas, or authorized to do so by the employer, by this section, or by the OSH Act of 1970.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Emergency" is any occurrence, such as but not limited to equipment failure, rupture of containers, or failure of control equipment that results in an uncontrolled release of a significant amount of formaldehyde.

"Employee exposure" means the exposure to airborne formaldehyde which would occur without corrections for protection provided by any respirator that is in use.

"Formaldehyde" means the chemical substance, HCHO, Chemical Abstracts Service Registry No. 50-00-0.

(c) Permissible Exposure Limit (PEL)

(1) TWA: The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds 0.75 parts formaldehyde per million parts of air (0.75 ppm) as an 8-hour TWA

(2) Short Term Exposure Limit (STEL): The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds two parts formaldehyde per million parts of air (2 ppm) as a 15-minute STEL.

(d) Exposure monitoring

(1) General.

(i) Each employer who has a workplace covered by this standard shall monitor employees to determine their exposure to formaldehyde.

(ii) Exception. Where the employer documents, using objective data, that the presence of

formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, the employer will not be required to measure employee exposure to formaldehyde.

(A) The employer need not initiate exposure monitoring unless there is a formaldehyde hazard as defined in paragraph m of this standard or there are employee health complaints possibly associated with formaldehyde exposure.

(B) Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, the employer will not be required to measure employee exposure to formaldehyde.

(iii) When an employee's exposure is determined from representative sampling, the measurements used shall be representative of the employee's full shift or short-term exposure to formaldehyde, as appropriate.

(iv) Representative samples for each job classification in each work area shall be taken for each shift unless the employer can document with objective data that exposure levels for a given job classification are equivalent for different work shifts.

(2) Initial monitoring. The employer shall identify all employees who may be exposed to or above the action level or at or above the STEL and accurately determine the exposure of each employee so identified.

(i) Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job classification for each workshift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

(ii) The initial monitoring process shall be repeated each time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

(iii) If the employer receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the employer shall promptly monitor the affected employee's exposure.

(3) Periodic monitoring.

(i) The employer shall periodically measure and accurately determine exposure to

formaldehyde for employees shown by the initial monitoring to be exposed at or above the action level or at or above the STEL.

(ii) If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.

(iii) If the last monitoring results reveal employee exposure at or above the STEL, the employer shall repeat monitoring of the employees at least once a year under worst conditions.

(4) Termination of monitoring. The employer may discontinue periodic monitoring for employees if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level and the STEL. The results must be statistically representative and consistent with the employer's knowledge of the job and work operation.

(5) Accuracy of monitoring. Monitoring shall be accurate, at the 95 percent confidence level, to within plus or minus 25 percent for airborne concentrations of formaldehyde at the TWA and the STEL and to within plus or minus 35 percent for airborne concentrations of formaldehyde at the action level.

(6) Employee notification of monitoring results. The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees. If employee exposure is above the PEL, affected employees shall be provided with a description of the corrective actions being taken by the employer to decrease exposure.

(7) Observation of monitoring.

(i) The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to formaldehyde required by this standard.

(ii) When observation of the monitoring of employee exposure to formaldehyde requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the clothing and equipment to the observer, require the observer to use such clothing and equipment, and assure that the observer complies with all other applicable safety and health procedures.

(e) Regulated areas.

(1) Signs

~~(i) The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and accessways with signs bearing the following information:~~ The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and access ways with signs bearing the following legend:

~~DANGER
FORMALDEHYDE
IRRITANT AND POTENTIAL CANCER HAZARD
AUTHORIZED PERSONNEL ONLY~~
DANGER
FORMALDEHYDE
MAY CAUSE CANCER
CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION
AUTHORIZED PERSONNEL ONLY

(ii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(1)(i) of this section:

DANGER
FORMALDEHYDE
IRRITANT AND POTENTIAL CANCER HAZARD
AUTHORIZED PERSONNEL ONLY

(2) The employer shall limit access to regulated areas to authorized persons who have been trained to recognize the hazards of formaldehyde.

(3) An employer at a multiemployer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite.

(f) Methods of compliance

(1) **Engineering controls and work practices.** The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to formaldehyde at or below the TWA and the STEL.

(2) **Exception.** Whenever the employer has established that feasible engineering and work practice controls cannot reduce employee exposure to or below either of the PELs, the employer shall apply these controls to reduce employee exposures to the extent feasible and shall supplement them with respirators which satisfy this standard.

(g) Respiratory protection

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work practice controls.

(ii) Work operations, such as maintenance and repair activities or vessel cleaning, for which the employer establishes that engineering and work-practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the PELs.

(iv) Emergencies.

(2) Respirator program.

(i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) When employees use air-purifying respirators with chemical cartridges or canisters that do not contain end-of-service-life indicators approved by the National Institute for Occupational Safety and Health, employers must replace these cartridges or canisters as specified by paragraphs (d)(3)(iii)(B)(1) and (B)(2) of 29 CFR 1910.134, or at the end of the workshift, whichever condition occurs first.

(A) Replace the cartridge after three (3) hours of use or at the end of the workshift, whichever occurs first, unless the cartridge contains a NIOSH-approved end-of-service-life indicator (ESLI) to show when breakthrough occurs.

(B) Unless the canister contains a NIOSH-approved ESLI to show when breakthrough occurs, replace canisters used in atmospheres up to 7.5 ppm (10xPEL) every four (4) hours and industrial-sized canisters used in atmospheres up to 75 ppm (100xPEL) every two (2) hours, or at the end of the workshift, whichever occurs first.

(3) Respirator selection.

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified

in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Equip each air-purifying, full facepiece respirator with a canister or cartridge approved for protection against formaldehyde.

(C) For escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the demand or pressure-demand mode; or a full facepiece respirator having a chin-style, or a front-or back-mounted industrial-size, canister or cartridge approved for protection against formaldehyde.

(ii) Employers may substitute an air-purifying, half mask respirator for an air-purifying, full facepiece respirator when they equip the half mask respirator with a cartridge approved for protection against formaldehyde and provide the affected employee with effective gas-proof goggles.

(iii) Employers must provide employees who have difficulty using negative pressure respirators with powered air-purifying respirators permitted for use under paragraph (g)(3)(i)(A) of this standard and that affords adequate protection against formaldehyde exposures.

(h) Protective equipment and clothing. Employers shall comply with the provisions of 29 CFR 1910.132 and 29 CFR 1910.133. When protective equipment or clothing is provided under these provisions, the employer shall provide these protective devices at no cost to the employee and assure that the employee wears them.

(1) Selection. The employer shall select protective clothing and equipment based upon the form of formaldehyde to be encountered, the conditions of use, and the hazard to be prevented.

(i) All contact of the eyes and skin with liquids containing 1 percent or more formaldehyde shall be prevented by the use of chemical protective clothing made of material impervious to formaldehyde and the use of other personal protective equipment, such as goggles and face shields, as appropriate to the operation.

(ii) Contact with irritating or sensitizing materials shall be prevented to the extent necessary to eliminate the hazard.

(iii) Where a face shield is worn, chemical safety goggles are also required if there is a danger of formaldehyde reaching the area of the eye.

(iv) Full body protection shall be worn for entry into areas where concentrations exceed 100 ppm and for emergency reentry into areas of unknown concentration.

(2) Maintenance of protective equipment and clothing.

(i) The employer shall assure that protective equipment and clothing that has become contaminated with formaldehyde is cleaned or laundered before its reuse.

~~(ii) When ventilating formaldehyde-contaminated clothing and equipment, the employer shall establish a storage area so that employee exposure is minimized. Containers for contaminated clothing and equipment and storage areas shall have labels and signs containing the following information: When formaldehyde-contaminated clothing and equipment is ventilated, the employer shall establish storage areas so that employee exposure is minimized.~~

~~DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
AVOID INHALATION AND SKIN CONTACT~~

(A) Signs. Storage areas for contaminated clothing and equipment shall have signs bearing the following legend:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
MAY CAUSE CANCER
CAUSES SKIN, EYE AND RESPIRATORY IRRITATION
DO NOT BREATHE VAPOR
DO NOT GET ON SKIN

(B) Labels. The employer shall ensure containers for contaminated clothing and equipment are labeled consistent with the Hazard Communication Standard, Sec. 1910.1200, and shall, as a minimum, include the following:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
MAY CAUSE CANCER
CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION
DO NOT BREATHE VAPOR
DO NOT GET ON SKIN

(C) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (h)(2)(ii)(A) of this section:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
AVOID INHALATION AND SKIN CONTACT

(D) Prior to June 1, 2015, employers may include the following information on

containers of protective clothing and equipment in lieu of the labeling requirements in paragraphs (h)(2)(i)(B) of this section:

DANGER

FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT

AVOID INHALATION AND SKIN CONTACT

(iii) The employer shall assure that only persons trained to recognize the hazards of formaldehyde remove the contaminated material from the storage area for purposes of cleaning, laundering, or disposal.

(iv) The employer shall assure that no employee takes home equipment or clothing that is contaminated with formaldehyde.

(v) The employer shall repair or replace all required protective clothing and equipment for each affected employee as necessary to assure its effectiveness.

(vi) The employer shall inform any person who launders, cleans, or repairs such clothing or equipment of formaldehyde's potentially harmful effects and of procedures to safely handle the clothing and equipment.

(i) Hygiene protection.

(1) The employer shall provide change rooms, as described in 29 CFR 1910.141 for employees who are required to change from work clothing into protective clothing to prevent skin contact with formaldehyde.

(2) If employees' skin may become splashed with solutions containing 1 percent or greater formaldehyde, for example because of equipment failure or improper work practices, the employer shall provide conveniently located quick drench showers and assure that affected employees use these facilities immediately.

(3) If there is any possibility that an employee's eyes may be splashed with solutions containing 0.1 percent or greater formaldehyde, the employer shall provide acceptable eyewash facilities within the immediate work area for emergency use.

(j) Housekeeping. For operations involving formaldehyde liquids or gas, the employer shall conduct a program to detect leaks and spills, including regular visual inspections.

(1) Preventative maintenance of equipment, including surveys for leaks, shall be undertaken at regular intervals.

(2) In work areas where spillage may occur, the employer shall make provisions to contain

the spill, to decontaminate the work area, and to dispose of the waste.

(3) The employer shall assure that all leaks are repaired and spills are cleaned promptly by employees wearing suitable protective equipment and trained in proper methods for cleanup and decontamination.

~~(4) Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde.~~ Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde. The employer shall ensure that the labels are in accordance with paragraph (m) of this section.

(k) **Emergencies.** For each workplace where there is the possibility of an emergency involving formaldehyde, the employer shall assure appropriate procedures are adopted to minimize injury and loss of life. Appropriate procedures shall be implemented in the event of an emergency.

(l) **Medical surveillance**

(1) **Employees covered.**

(i) The employer shall institute medical surveillance programs for all employees exposed to formaldehyde at concentrations at or exceeding the action level or exceeding the STEL.

(ii) The employer shall make medical surveillance available for employees who develop signs and symptoms of overexposure to formaldehyde and for all employees exposed to formaldehyde in emergencies. When determining whether an employee may be experiencing signs and symptoms of possible overexposure to formaldehyde, the employer may rely on the evidence that signs and symptoms associated with formaldehyde exposure will occur only in exceptional circumstances when airborne exposure is less than 0.1 ppm and when formaldehyde is present in materials in concentrations less than 0.1 percent.

(2) **Examination by a physician.** All medical procedures, including administration of medical disease questionnaires, shall be performed by or under the supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(3) **Medical disease questionnaire.** The employer shall make the following medical surveillance available to employees prior to assignment to a job where formaldehyde exposure is at or above the action level or above the STEL and annually thereafter. The employer shall also make the following medical surveillance available promptly upon determining that an employee is experiencing signs and symptoms indicative of possible overexposure to formaldehyde.

(i) Administration of a medical disease questionnaire, such as in Appendix D, which is designed to elicit information on work history, smoking history, any evidence of eye, nose, or throat irritation; chronic airway problems or hyperreactive airway disease; allergic skin conditions or dermatitis; and upper or lower respiratory problems.

(ii) A determination by the physician, based on evaluation of the medical disease questionnaire, of whether a medical examination is necessary for employees not required to wear respirators to reduce exposure to formaldehyde.

(4) Medical examinations. Medical examinations shall be given to any employee who the physician feels, based on information in the medical disease questionnaire, may be at increased risk from exposure to formaldehyde and at the time of initial assignment and at least annually thereafter to all employees required to wear a respirator to reduce exposure to formaldehyde. The medical examination shall include:

(i) A physical examination with emphasis on evidence of irritation or sensitization of the skin and respiratory system, shortness of breath, or irritation of the eyes.

(ii) Laboratory examinations for respirator wearers consisting of baseline and annual pulmonary function tests. As a minimum, these tests shall consist of forced vital capacity (FVC), forced expiratory volume in one second (FEV1), and forced expiratory flow (FEF).

(iii) Any other test which the examining physician deems necessary to complete the written opinion.

(iv) Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde on the increased risk of impairment of their health.

(5) Examinations for employees exposed in an emergency. The employer shall make medical examinations available as soon as possible to all employees who have been exposed to formaldehyde in an emergency.

(i) The examination shall include a medical and work history with emphasis on any evidence of upper or lower respiratory problems, allergic conditions, skin reaction or hypersensitivity, and any evidence of eye, nose, or throat irritation.

(ii) Other examinations shall consist of those elements considered appropriate by the examining physician.

(6) Information provided to the physician. The employer shall provide the following information to the examining physician:

- (i) A copy of this standard and Appendices A, C, D, and E;
- (ii) A description of the affected employee's job duties as they relate to the employee's exposure to formaldehyde;
- (iii) The representative exposure level for the employee's job assignment;
- (iv) Information concerning any personal protective equipment and respiratory protection used or to be used by the employee; and
- (v) Information from previous medical examinations of the affected employee within the control of the employer.
- (vi) In the event of a nonroutine examination because of an emergency, the employer shall provide to the physician as soon as possible: a description of how the emergency occurred and the exposure the victim may have received.

(7) Physician's written opinion.

- (i) For each examination required under this standard, the employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination except that it shall not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde. The written opinion shall include:
 - (A) The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk of material impairment of health from exposure to formaldehyde;
 - (B) Any recommended limitations on the employee's exposure or changes in the use of personal protective equipment, including respirators;
 - (C) A statement that the employee has been informed by the physician of any medical conditions which would be aggravated by exposure to formaldehyde, whether these conditions may have resulted from past formaldehyde exposure or from exposure in an emergency, and whether there is a need for further examination or treatment.
- (ii) The employer shall provide for retention of the results of the medical examination and tests conducted by the physician.
- (iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days of its receipt.

(8) Medical removal.

(i) The provisions of paragraph (1)(8) apply when an employee reports significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization attributed to workplace formaldehyde exposure. Medical removal provisions do not apply in the case of dermal irritation or dermal sensitization when the product suspected of causing the dermal condition contains less than 0.05% formaldehyde.

(ii) An employee's report of signs or symptoms of possible overexposure to formaldehyde shall be evaluated by a physician selected by the employer pursuant to paragraph (1)(3). If the physician determines that a medical examination is not necessary under paragraph (1)(3)(ii), there shall be a two-week evaluation and remediation period to permit the employer to ascertain whether the signs or symptoms subside untreated or with the use of creams, gloves, first aid treatment or personal protective equipment. Industrial hygiene measures that limit the employee's exposure to formaldehyde may also be implemented during this period. The employee shall be referred immediately to a physician prior to expiration of the two-week period if the signs or symptoms worsen. Earnings, seniority and benefits may not be altered during the two-week period by virtue of the report.

(iii) If the signs or symptoms have not subsided or been remedied by the end of the two-week period, or earlier if signs or symptoms warrant, the employee shall be examined by a physician selected by the employer. The physician shall presume, absent contrary evidence, that observed dermal irritation or dermal sensitization are not attributable to formaldehyde when products to which the affected employee is exposed contain less than 0.1% formaldehyde.

(iv) Medical examinations shall be conducted in compliance with the requirements of paragraph (1)(5)(i) and (ii). Additional guidelines for conducting medical exams are contained in appendix C.

(v) If the physician finds that significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization result from workplace formaldehyde exposure and recommends restrictions or removal, the employer shall promptly comply with the restrictions or recommendation of removal. In the event of a recommendation of removal, the employer shall remove the affected employee from the current formaldehyde exposure and if possible, transfer the employee to work having no or significantly less exposure to formaldehyde.

(vi) When an employee is removed pursuant to paragraph (1)(8)(v), the employer shall transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the formaldehyde exposures are as low as possible, but not higher than the action level. The employer shall maintain the employee's current earnings, seniority, and other benefits. If there is no such work available, the employer shall maintain the employee's current earnings, seniority and other benefits until such work becomes available, until the employee is determined to be unable to return to workplace formaldehyde exposure, until the

employee is determined to be able to return to the original job status, or for six months, whichever comes first.

(vii) The employer shall arrange for a follow-up medical examination to take place within six months after the employee is removed pursuant to this paragraph. This examination shall determine if the employee can return to the original job status, or if the removal is to be permanent. The physician shall make a decision within six months of the date the employee was removed as to whether the employee can be returned to the original job status, or if the removal is to be permanent.

(viii) An employer's obligation to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program or from employment with another employer made possible by virtue of the employee's removal.

(ix) In making determinations of the formaldehyde content of materials under this paragraph the employer may rely on objective data.

(9) Multiple physician review.

(i) After the employer selects the initial physician who conducts any medical examination or consultation to determine whether medical removal or restriction is appropriate, the employee may designate a second physician to review any findings, determinations or recommendations of the initial physician and to conduct such examinations, consultations, and laboratory tests as the second physician deems necessary and appropriate to evaluate the effects of formaldehyde exposure and to facilitate this review.

(ii) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical or consultation for the purpose of medical removal or restriction.

(iii) The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the notification of the right to seek a medical opinion, or receipt of the initial physician's written opinion, whichever is later;

(A) The employee informs the employer of the intention to seek a second medical opinion, and

(B) The employee initiates s to make an appointment with a second physician.

(iv) If the findings, determinations or recommendations of the second physician differ

from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve the disagreement. If the two physicians are unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician who shall be a specialist in the field at issue:

(A) To review the findings, determinations or recommendations of the prior physicians; and

(B) To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(v) In the alternative, the employer and the employee or authorized employee representative may jointly designate such third physician.

(vi) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(m) ~~Hazard communication~~ Communication of hazards.

(1) Hazard communication- General. Communication of the hazards associated with formaldehyde in the workplace shall be governed by the requirements of paragraph (m). The definitions of 29 CFR 1910.1200(c) shall apply under this paragraph.

(i) ~~The following shall be subject to the hazard communication requirements of this paragraph: formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air, under reasonably foreseeable conditions of use, at concentrations reaching or exceeding 0.1 ppm. Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for formaldehyde.~~

(ii) ~~As a minimum, specific health hazards that the employer shall address are: cancer, irritation and sensitization of the skin and respiratory system, eye and throat irritation, and acute toxicity. In classifying the hazards of formaldehyde at least the following hazards are to be addressed: Cancer; skin and respiratory sensitization; eye, skin and respiratory tract irritation; acute toxicity effects; and flammability.~~

(iii) Employers shall include formaldehyde in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of formaldehyde and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (n) of this section.

(iv) Paragraphs (m)(1)(i), (m)(1)(ii), and (m)(1)(iii) of this section apply to chemicals associated with formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air at concentrations reaching or exceeding 0.1 ppm.

(v) In making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use.

~~(2)(i) Manufacturers and importers who produce or import formaldehyde or formaldehyde-containing products shall provide downstream employers using or handling these products with an objective determination through the required labels and MSDSs if these items may constitute a health hazard within the meaning of 29 CFR 1910.1200(d) under normal conditions of use. In addition to the requirements in paragraphs (m)(1) through (m)(1)(iv) of this section, for materials listed in paragraph (m)(1)(iv) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in paragraph (d) of § 1910.1200 and Appendices A and B to § 1910.1200, including cancer and respiratory sensitization, and shall contain the hazard statement "May Cause Cancer."~~

(ii) As a minimum, for all materials listed in paragraph (m)(1)(i) and (iv) of this section capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address of the responsible party; and state that physical and health hazard information is readily available from the employer and from safety data sheets.

(iii) Prior to June 1, 2015, employers may include the phrase "Potential Cancer Hazard" in lieu of "May Cause Cancer" as specified in paragraph (m)(2)(i) of this section.

(3) Labels.

(i) The employer shall assure that hazard warning labels complying with the requirements of 29 CFR 1910.1200(f) are affixed to all containers of materials listed in paragraph (m)(1)(i), except to the extent that 29 CFR 1910.1200(f) is inconsistent with this paragraph.

(ii) Information on labels. As a minimum, for all materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address of the responsible party; and state that physical and health hazard information is readily available from the employer and from material safety data sheets.

(iii) For materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in 29 CFR 1910.1200(d) and 29 CFR 1910.1200 appendices A and B, including respiratory sensitization,

and shall contain the words ``Potential Cancer Hazard."

(iv) In making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use.

(v) Substitute warning labels. The employer may use warning labels required by other statutes, regulations, or ordinances which impart the same information as the warning statements required by this paragraph.

(4) Material safety data sheets.

(i) Any employer who uses formaldehyde-containing materials listed in paragraph (m)(1)(i) shall comply with the requirements of 29 CFR 1910.1200(g) with regard to the development and updating of material safety data sheets.

(ii) Manufacturers, importers, and distributors of formaldehyde-containing materials listed in paragraph (m)(1)(i) shall assure that material safety data sheets and updated information are provided to all employers purchasing such materials at the time of the initial shipment and at the time of the first shipment after a material safety data sheet is updated.

(5) Written hazard communication program. The employer shall develop, implement, and maintain at the workplace, a written hazard communication program for formaldehyde exposures in the workplace, which at a minimum describes how the requirements specified in this paragraph for labels and other forms of warning and material safety data sheets, and paragraph (n) for employee information and training, will be met. Employers in multi-employer workplaces shall comply with the requirements of 29 CFR 1910.1200(e)(2).

(n) Employee information and training

(1) Participation. The employer shall assure that all employees who are assigned to workplaces where there is exposure to formaldehyde participate in a training program, except that where the employer can show, using objective data, that employees are not exposed to formaldehyde at or above 0.1 ppm, the employer is not required to provide training.

(2) Frequency. Employers shall provide such information and training to employees at the time of initial assignment, and whenever a new exposure to formaldehyde is introduced into the work area. The training shall be repeated at least annually.

(i) Employers shall provide employees with information and training on formaldehyde at the time of their initial assignment and whenever a new hazard from formaldehyde is introduced into their work area.

(ii) Employers shall provide such information and training at least annually for all employees exposed to formaldehyde concentrations at or above the action level or the STEL.

(3) Training program. The training program shall be conducted in a manner which the employee is able to understand and shall include:

(i) A discussion of the contents of this regulation and the contents of the Material Safety Data Sheet.

(ii) The purpose for and a description of the medical surveillance program required by this standard, including:

(A) A description of the potential health hazards associated with exposure to formaldehyde and a description of the signs and symptoms of exposure to formaldehyde.

(B) Instructions to immediately report to the employer the development of any adverse signs or symptoms that the employee suspects is attributable to formaldehyde exposure.

(iii) Description of operations in the work area where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure to formaldehyde in each job;

(iv) The purpose for, proper use of, and limitations of personal protective clothing and equipment;

(v) Instructions for the handling of spills, emergencies, and clean-up procedures;

(vi) An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls; and

(vii) A review of emergency procedures including the specific duties or assignments of each employee in the event of an emergency.

(4) Access to training materials.

(i) The employer shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost, to the affected employees.

(ii) The employer shall provide, upon request, all training materials relating to the employee training program to the Assistant Secretary and the Director.

(o) Recordkeeping

(1) Exposure measurements. The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to formaldehyde. This record shall include:

- (i) The date of measurement;
- (ii) The operation being monitored;
- (iii) The methods of sampling and analysis and evidence of their accuracy and precision;
- (iv) The number, durations, time, and results of samples taken;
- (v) The types of protective devices worn; and

(vi) The names, job classifications, social security numbers, and exposure estimates of the employees whose exposures are represented by the actual monitoring results.

(2) Exposure determinations. Where the employer has determined that no monitoring is required under this standard, the employer shall maintain a record of the objective data relied upon to support the determination that no employee is exposed to formaldehyde at or above the action level.

(3) Medical surveillance. The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under this standard. This record shall include:

- (i) The name and social security number of the employee;
- (ii) The physician's written opinion;
- (iii) A list of any employee health complaints that may be related to exposure to formaldehyde.
- (iv) A copy of the medical examination results, including medical disease questionnaires and results of any medical tests required by the standard or mandated by the examining physician.

(4) Respirator fit testing.

(i) The employer shall establish and maintain accurate records for employees subject to negative pressure respirator fit testing required by this standard.

- (ii) This record shall include:

(A) A copy of the protocol selected for respirator fit testing.

(B) A copy of the results of any fit testing performed.

(C) The size and manufacturer of the types of respirators available for selection.

(D) The date of the most recent fit testing, the name and social security number of each tested employee, and the respirator type and facepiece selected.

(5) Record retention. The employer shall retain records required by this standard for at least the following periods:

(i) Exposure records and determinations shall be kept for at least 30 years.

(ii) Medical records shall be kept for the duration of employment plus 30 years.

(iii) Respirator fit testing records shall be kept until replaced by a more recent record.

(6) Availability of records.

(i) Upon request, the employer shall make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary and the Director.

(ii) The employer shall make employee exposure records, including estimates made from representative monitoring and available upon request for examination, and copying to the subject employee, or former employee, and employee representatives in accordance with 29 CFR 1910.1020(a) - (e) and (g) - (i).

(iii) Employee medical records required by this standard shall be provided upon request for examination and copying, to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee in accordance with 29 CFR 1910.1020 (a) - (e) and (g) - (j).

(Approved by the Office of Management and Budget under control number 1218-0145)

1910.1048 App A Substance technical guidelines for formalin

APPENDIX A TO 1910.1048 - SUBSTANCE TECHNICAL GUIDELINES FOR FORMALIN

The following Substance Technical Guideline for Formalin provides information on uninhibited formalin solution (37% formaldehyde, no methanol stabilizer). It is designed to inform employees at the production level of their rights and duties under the formaldehyde standard whether their job title defines them as workers or supervisors. Much of the information provided is general; however, some information is specific for formalin. When employee exposure to

formaldehyde is from resins capable of releasing formaldehyde, the resin itself and other impurities or decomposition products may also be toxic, and employers should include this information as well when informing employees of the hazards associated with the materials they handle. The precise hazards associated with exposure to formaldehyde depend both on the form (solid, liquid, or gas) of the material and the concentration of formaldehyde present. For example, 37-50 percent solutions of formaldehyde present a much greater hazard to the skin and eyes from spills or splashes than solutions containing less than 1 percent formaldehyde. Individual Substance Technical Guidelines used by the employer for training employees should be modified to properly give information on the material actually being used.

Substance Identification

Chemical Name: Formaldehyde

Chemical Family: Aldehyde

Chemical Formula: HCHO

Molecular Weight: 30.03

Chemical Abstracts Service Number (CAS Number): 50-00-0

Synonyms: Formalin; Formic Aldehyde; Paraform; Formol; Formalin (Methanol-free); Fyde; Formalith; Methanal; Methyl Aldehyde; Methylene Glycol; Methylene Oxide; Tetraoxymethalene; Oxomethane; Oxymethylene

Components and Contaminants

Percent: 37.0 Formaldehyde

Percent: 63.0 Water

(Note.-Inhibited solutions contain methanol.)

Other Contaminants: Formic acid (alcohol free)

Exposure Limits:

OSHA TWA-1 ppm

OSHA STEL-2 ppm

Physical Data

Description: Colorless liquid, pungent odor

Boiling point: 214 deg. F (101 deg. C)

Specific Gravity: 1.08 (H₂O=1 @ 20 deg. C)

pH: 2.8-4.0

Solubility in Water: Miscible

Solvent Solubility: Soluble in alcohol and acetone

Vapor Density: 1.04 (Air=1 @ 20 deg. C)

Odor Threshold: 0.8-1 ppm

Fire and Explosion Hazard

Moderate fire and explosion hazard when exposed to heat or flame.

The flash point of 37% formaldehyde solutions is above normal room temperature, but the explosion range is very wide, from 7 to 73% by volume in air.

Reaction of formaldehyde with nitrogen dioxide, nitromethane, perchloric acid and aniline, or peroxyformic acid yields explosive compounds. Flash Point: 185 deg. F (85 deg. C) closed cup

Lower Explosion Limit: 7%

Upper Explosion Limit: 73%

Autoignition Temperature: 806 deg. F (430 deg. C)

Flammability Class (OSHA): III A

Extinguishing Media: Use dry chemical, "alcohol foam", carbon dioxide, or water in flooding amounts as fog. Solid streams may not be effective. Cool fire-exposed containers with water from side until well after fire is out.

Use of water spray to flush spills can also dilute the spill to produce nonflammable mixtures. Water runoff, however, should be contained for treatment.

National Fire Protection Association Section 325M Designation:

Health: 2-Materials hazardous to health, but areas may be entered with full-faced mask self-contained breathing apparatus which provides eye protection.

Flammability: 2-Materials which must be moderately heated before ignition will occur. Water spray may be used to extinguish the fire because the material can be cooled below its flash point.

Reactivity: D-Materials which (in themselves) are normally stable even under fire exposure conditions and which are not reactive with water. Normal fire fighting procedures may be used.

Reactivity

Stability: Formaldehyde solutions may self-polymerize to form paraformaldehyde which precipitates.

Incompatibility (Materials to Avoid): Strong oxidizing agents, caustics, strong alkalis, isocyanates, anhydrides, oxides, and inorganic acids. Formaldehyde reacts with hydrochloric acid to form the potent carcinogen, bis-chloromethyl ether. Formaldehyde reacts with nitrogen dioxide, nitromethane, perchloric acid and aniline, or peroxyformic acid to yield explosive

compounds. A violent reaction occurs when formaldehyde is mixed with strong oxidizers.

Hazardous Combustion or Decomposition Products: Oxygen from the air can oxidize formaldehyde to formic acid, especially when heated. Formic acid is corrosive.

Health Hazard Data

Acute Effects of Exposure

Ingestion (Swallowing): Liquids containing 10 to 40% formaldehyde cause severe irritation and inflammation of the mouth, throat, and stomach. Severe stomach pains will follow ingestion with possible loss of consciousness and death. Ingestion of dilute formaldehyde solutions (0.03-0.04%) may cause discomfort in the stomach and pharynx.

Inhalation (Breathing): Formaldehyde is highly irritating to the upper respiratory tract and eyes. Concentrations of 0.5 to 2.0 ppm may irritate the eyes, nose, and throat of some individuals. Concentrations of 3 to 5 ppm also cause tearing of the eyes and are intolerable to some persons. Concentrations of 10 to 20 ppm cause difficulty in breathing, burning of the nose and throat, cough, and heavy tearing of the eyes, and 25 to 30 ppm causes severe respiratory tract injury leading to pulmonary edema and pneumonitis. A concentration of 100 ppm is immediately dangerous to life and health. Deaths from accidental exposure to high concentrations of formaldehyde have been reported.

Skin (Dermal): Formalin is a severe skin irritant and a sensitizer. Contact with formalin causes white discoloration, smarting, drying, cracking, and scaling. Prolonged and repeated contact can cause numbness and a hardening or tanning of the skin. Previously exposed persons may react to future exposure with an allergic eczematous dermatitis or hives.

Eye Contact: Formaldehyde solutions splashed in the eye can cause injuries ranging from transient discomfort to severe, permanent corneal clouding and loss of vision. The severity of the effect depends on the concentration of formaldehyde in the solution and whether or not the eyes are flushed with water immediately after the accident.

Note.-The perception of formaldehyde by odor and eye irritation becomes less sensitive with time as one adapts to formaldehyde. This can lead to overexposure if a worker is relying on formaldehyde's warning properties to alert him or her to the potential for exposure.

Acute Animal Toxicity:

Oral, rats: LD50=800 mg/kg

Oral, mouse: LD50=42 mg/kg

Inhalation, rats: LCLo=250 mg/kg

Inhalation, mouse: LCLo=900 mg/kg

Inhalation, rats: LC50=590 mg/kg

Chronic Effects of Exposure

Carcinogenicity: Formaldehyde has the potential to cause cancer in humans. Repeated and prolonged exposure increases the risk. Various animal experiments have conclusively shown formaldehyde to be a carcinogen in rats. In humans, formaldehyde exposure has been associated with cancers of the lung, nasopharynx and oropharynx, and nasal passages.

Mutagenicity: Formaldehyde is genotoxic in several in vitro test systems showing properties of both an initiator and a promoter.

Toxicity: Prolonged or repeated exposure to formaldehyde may result in respiratory impairment. Rats exposed to formaldehyde at 2 ppm developed benign nasal tumors and changes of the cell structure in the nose as well as inflamed mucous membranes of the nose. Structural changes in the epithelial cells in the human nose have also been observed. Some persons have developed asthma or bronchitis following exposure to formaldehyde, most often as the result of an accidental spill involving a single exposure to a high concentration of formaldehyde.

Emergency and First Aid Procedures

Ingestion (Swallowing): If the victim is conscious, dilute, inactivate, or absorb the ingested formaldehyde by giving milk, activated charcoal, or water. Any organic material will inactivate formaldehyde. Keep affected person warm and at rest. Get medical attention immediately. If vomiting occurs, keep head lower than hips.

Inhalation (Breathing): Remove the victim from the exposure area to fresh air immediately. Where the formaldehyde concentration may be very high, each rescuer must put on a self-contained breathing apparatus before attempting to remove the victim, and medical personnel should be informed of the formaldehyde exposure immediately. If breathing has stopped, give artificial respiration. Keep the affected person warm and at rest. Qualified first-aid or medical personnel should administer oxygen, if available, and maintain the patient's airways and blood pressure until the victim can be transported to a medical facility. If exposure results in a highly irritated upper respiratory tract and coughing continues for more than 10 minutes, the worker should be hospitalized for observation and treatment.

Skin Contact: Remove contaminated clothing (including shoes) immediately. Wash the affected area of your body with soap or mild detergent and large amounts of water until no evidence of the chemical remains (at least 15 to 20 minutes). If there are chemical burns, get first aid to cover the area with sterile, dry dressing, and bandages. Get medical attention if you experience appreciable eye or respiratory irritation.

Eye Contact: Wash the eyes immediately with large amounts of water occasionally lifting lower and upper lids, until no evidence of chemical remains (at least 15 to 20 minutes). In case of

burns, apply sterile bandages loosely without medication. Get medical attention immediately. If you have experienced appreciable eye irritation from a splash or excessive exposure, you should be referred promptly to an ophthalmologist for evaluation.

Emergency Procedures

Emergencies: If you work in an area where a large amount of formaldehyde could be released in an accident or from equipment failure, your employer must develop procedures to be followed in event of an emergency. You should be trained in your specific duties in the event of an emergency, and it is important that you clearly understand these duties. Emergency equipment must be accessible and you should be trained to use any equipment that you might need. Formaldehyde contaminated equipment must be cleaned before reuse.

If a spill of appreciable quantity occurs, leave the area quickly unless you have specific emergency duties. Do not touch spilled material. Designated persons may stop the leak and shut off ignition sources if these procedures can be done without risk. Designated persons should isolate the hazard area and deny entry except for necessary people protected by suitable protective clothing and respirators adequate for the exposure. Use water spray to reduce vapors. Do not smoke, and prohibit all flames or flares in the hazard area.

Special Firefighting Procedures: Learn procedures and responsibilities in the event of a fire in your workplace. Become familiar with the appropriate equipment and supplies and their location. In firefighting, withdraw immediately in case of rising sound from venting safety device or any discoloration of storage tank due to fire.

Spill, Leak, and Disposal Procedures

Occupational Spill: For small containers, place the leaking container in a well ventilated area. Take up small spills with absorbent material and place the waste into properly labeled containers for later disposal. For larger spills, dike the spill to minimize contamination and facilitate salvage or disposal. You may be able to neutralize the spill with sodium hydroxide or sodium sulfite. Your employer must comply with EPA rules regarding the clean-up of toxic waste and notify state and local authorities, if required. If the spill is greater than 1,000 lb/day, it is reportable under EPA's Superfund legislation.

Waste Disposal: Your employer must dispose of waste containing formaldehyde in accordance with applicable local, state, and Federal law and in a manner that minimizes exposure of employees at the site and of the clean-up crew.

Monitoring and Measurement Procedures

Monitoring Requirements: If your exposure to formaldehyde exceeds the 0.5 ppm action level or the 2 ppm STEL, your employer must monitor your exposure. Your employer need not

measure every exposure if a "high exposure" employee can be identified. This person usually spends the greatest amount of time nearest the process equipment. If you are a "representative employee", you will be asked to wear a sampling device to collect formaldehyde. This device may be a passive badge, a sorbent tube attached to a pump, or an impinger containing liquid. You should perform your work as usual, but inform the person who is conducting the monitoring of any difficulties you are having wearing the device.

Evaluation of 8-hour Exposure: Measurements taken for the purpose of determining time-weighted average (TWA) exposures are best taken with samples covering the full shift. Samples collected must be taken from the employee's breathing zone air.

Short-term Exposure Evaluation: If there are tasks that involve brief but intense exposure to formaldehyde, employee exposure must be measured to assure compliance with the STEL. Sample collections are for brief periods, only 15 minutes, but several samples may be needed to identify the peak exposure.

Monitoring Techniques: OSHA's only requirement for selecting a method for sampling and analysis is that the methods used accurately evaluate the concentration of formaldehyde in employees' breathing zones. Sampling and analysis may be performed by collection of formaldehyde on liquid or solid sorbents with subsequent chemical analysis. Sampling and analysis may also be performed by passive diffusion monitors and short-term exposure may be measured by instruments such as real-time continuous monitoring systems and portable direct reading instruments.

Notification of Results: Your employer must inform you of the results of exposure monitoring representative of your job. You may be informed in writing, but posting the results where you have ready access to them constitutes compliance with the standard.

Protective Equipment and Clothing

[Material impervious to formaldehyde is needed if the employee handles formaldehyde solutions of 1% or more. Other employees may also require protective clothing or equipment to prevent dermatitis.]

Respiratory Protection: Use NIOSH-approved full facepiece negative pressure respirators equipped with approved cartridges or canisters within the use limitations of these devices. (Present restrictions on cartridges and canisters do not permit them to be used for a full workshift.) In all other situations, use positive pressure respirators such as the positive-pressure air purifying respirator or the self-contained breathing apparatus (SCBA). If you use a negative pressure respirator, your employer must provide you with fit testing of the respirator at least once a year.

Protective Gloves: Wear protective (impervious) gloves provided by your employer, at no cost,

to prevent contact with formalin. Your employer should select these gloves based on the results of permeation testing and in accordance with the ACGIH Guidelines for Selection of Chemical Protective Clothing.

Eye Protection: If you might be splashed in the eyes with formalin, it is essential that you wear goggles or some other type of complete protection for the eye. You may also need a face shield if your face is likely to be splashed with formalin, but you must not substitute face shields for eye protection. (This section pertains to formaldehyde solutions of 1% or more.)

Other Protective Equipment: You must wear protective (impervious) clothing and equipment provided by your employer at no cost to prevent repeated or prolonged contact with formaldehyde liquids. If you are required to change into whole-body chemical protective clothing, your employer must provide a change room for your privacy and for storage of your normal clothing.

If you are splashed with formaldehyde, use the emergency showers and eyewash fountains provided by your employer immediately to prevent serious injury. Report the incident to your supervisor and obtain necessary medical support.

Entry Into an IDLH Atmosphere

Enter areas where the formaldehyde concentration might be 100 ppm or more only with complete body protection including a self-contained breathing apparatus with a full facepiece operated in a positive pressure mode or a supplied air respirator with full facepiece and operated in a positive pressure mode. This equipment is essential to protect your life and health under such extreme conditions.

Engineering Controls

Ventilation is the most widely applied engineering control method for reducing the concentration of airborne substances in the breathing zones of workers. There are two distinct types of ventilation.

Local Exhaust: Local exhaust ventilation is designed to capture airborne contaminants as near to the point of generation as possible. To protect you, the direction of contaminant flow must always be toward the local exhaust system inlet and away from you.

General (Mechanical): General dilution ventilation involves continuous introduction of fresh air into the workroom to mix with the contaminated air and lower your breathing zone concentration of formaldehyde. Effectiveness depends on the number of air changes per hour. Where devices emitting formaldehyde are spread out over a large area, general dilution ventilation may be the only practical method of control.

Work Practices: Work practices and administrative procedures are an important part of a control system. If you are asked to perform a task in a certain manner to limit your exposure to formaldehyde, it is extremely important that you follow these procedures.

Medical Surveillance

Medical surveillance helps to protect employees' health. You are encouraged strongly to participate in the medical surveillance program.

Your employer must make a medical surveillance program available at no expense to you and at a reasonable time and place if you are exposed to formaldehyde at concentrations above 0.5 ppm as an 8-hour average or 2 ppm over any 15-minute period. You will be offered medical surveillance at the time of your initial assignment and once a year afterward as long as your exposure is at least 0.5 ppm (TWA) or 2 ppm (STEL). Even if your exposure is below these levels, you should inform your employer if you have signs and symptoms that you suspect, through your training, are related to your formaldehyde exposure because you may need medical surveillance to determine if your health is being impaired by your exposure.

The surveillance plan includes:

- (a) A medical disease questionnaire.
- (b) A physical examination if the physician determines this is necessary.

If you are required to wear a respirator, your employer must offer you a physical examination and a pulmonary function test every year.

The physician must collect all information needed to determine if you are at increased risk from your exposure to formaldehyde. At the physician's discretion, the medical examination may include other tests, such as a chest x-ray, to make this determination.

After a medical examination the physician will provide your employer with a written opinion which includes any special protective measures recommended and any restrictions on your exposure. The physician must inform you of any medical conditions you have which would be aggravated by exposure to formaldehyde.

All records from your medical examinations, including disease surveys, must be retained at your employer's expense.

Emergencies

If you are exposed to formaldehyde in an emergency and develop signs or symptoms associated with acute toxicity from formaldehyde exposure, your employer must provide you with a medical

examination as soon as possible. This medical examination will include all s necessary to stabilize your health. You may be kept in the hospital for observation if your symptoms are severe to ensure that any delayed effects are recognized and treated.

1910.1048 App B Sampling strategy and analytical methods for formaldehyde

APPENDIX B TO 1910.1048 - SAMPLING STRATEGY AND ANALYTICAL METHODS FOR FORMALDEHYDE

To protect the health of employees, exposure measurements must be unbiased and representative of employee exposure. The proper measurement of employee exposure requires more than a token commitment on the part of the employer. OSHA's mandatory requirements establish a baseline; under the best of circumstances all questions regarding employee exposure will be answered. Many employers, however, will wish to conduct more extensive monitoring before undertaking expensive commitments, such as engineering controls, to assure that the modifications are truly necessary. The following sampling strategy, which was developed at NIOSH by Nelson A. Leidel, Kenneth A. Busch, and Jeremiah R. Lynch and described in NIOSH publication No. 77-173 (Occupational Exposure Sampling Strategy Manual) will assist the employer in developing a strategy for determining the exposure of his or her employees.

There is no one correct way to determine employee exposure. Obviously, measuring the exposure of every employee exposed to formaldehyde will provide the most information on any given day. Where few employees are exposed, this may be a practical solution. For most employers, however, use of the following strategy will give just as much information at less cost.

Exposure data collected on a single day will not automatically guarantee the employer that his or her workplace is always in compliance with the formaldehyde standard. This does not imply, however, that it is impossible for an employer to be sure that his or her worksite is in compliance with the standard. Indeed, a properly designed sampling strategy showing that all employees are exposed below the PELs, at least with a 95 percent certainty, is compelling evidence that the exposure limits are being achieved provided that measurements are conducted using valid sampling strategy and approved analytical methods.

There are two PELs, the TWA concentration and the STEL. Most employers will find that one of these two limits is more critical in the control of their operations, and OSHA expects that the employer will concentrate monitoring efforts on the critical component. If the more difficult exposure is controlled, this information, along with calculations to support the assumptions, should be adequate to show that the other exposure limit is also being achieved.

Sampling Strategy

Determination of the Need for Exposure Measurements

The employer must determine whether employees may be exposed to concentrations in excess of the action level. This determination becomes the first in an employee exposure monitoring program that minimizes employer sampling burdens while providing adequate employee protection. If employees may be exposed above the action level, the employer must measure exposure. Otherwise, an objective determination that employee exposure is low provides adequate evidence that exposure potential has been examined.

The employer should examine all available relevant information, eg. insurance company and trade association data and information from suppliers or exposure data collected from similar operations. The employer may also use previously-conducted sampling including area monitoring. The employer must make a determination relevant to each operation although this need not be on a separate piece of paper. If the employer can demonstrate conclusively that no employee is exposed above the action level or the STEL through the use of objective data, the employer need proceed no further on employee exposure monitoring until such time that conditions have changed and the determination is no longer valid.

If the employer cannot determine that employee exposure is less than the action level and the STEL, employee exposure monitoring will have to be conducted.

Workplace Material Survey

The primary purpose of a survey of raw material is to determine if formaldehyde is being used in the work environment and if so, the conditions under which formaldehyde is being used.

The first is to tabulate all situations where formaldehyde is used in a manner such that it may be released into the workplace atmosphere or contaminate the skin. This information should be available through analysis of company records and information on the MSDSs available through provisions of this standard and the Hazard Communication standard.

If there is an indication from materials handling records and accompanying MSDSs that formaldehyde is being used in the following types of processes or work operations, there may be a potential for releasing formaldehyde into the workplace atmosphere:

- (1) Any operation that involves grinding, sanding, sawing, cutting, crushing, screening, sieving, or any other manipulation of material that generates formaldehyde-bearing dust
- (2) Any processes where there have been employee complaints or symptoms indicative of exposure to formaldehyde
- (3) Any liquid or spray process involving formaldehyde
- (4) Any process that uses formaldehyde in preserved tissue

(5) Any process that involves the heating of a formaldehyde-bearing resin. Processes and work operations that use formaldehyde in these manners will probably require further investigation at the worksite to determine the extent of employee monitoring that should be conducted.

Workplace Observations

To this point, the only intention has been to provide an indication as to the existence of potentially exposed employees. With this information, a visit to the workplace is needed to observe work operations, to identify potential health hazards, and to determine whether any employees may be exposed to hazardous concentrations of formaldehyde.

In many circumstances, sources of formaldehyde can be identified through the sense of smell. However, this method of detection should be used with caution because of olfactory fatigue.

Employee location in relation to source of formaldehyde is important in determining if an employee may be significantly exposed to formaldehyde. In most instances, the closer a worker is to the source, the higher the probability that a significant exposure will occur.

Other characteristics should be considered. Certain high temperature operations give rise to higher evaporation rates. Locations of open doors and windows provide natural ventilation that tend to dilute formaldehyde emissions. General room ventilation also provides a measure of control.

Calculation of Potential Exposure Concentrations

By knowing the ventilation rate in a workplace and the quantity of formaldehyde generated, the employer may be able to determine by calculation if the PELs might be exceeded. To account for poor mixing of formaldehyde into the entire room, locations of fans and proximity of employees to the work operation, the employer must include a safety factor. If an employee is relatively close to a source, particularly if he or she is located downwind, a safety factor of 100 may be necessary. For other situations, a factor of 10 may be acceptable. If the employer can demonstrate through such calculations that employee exposure does not exceed the action level or the STEL, the employer may use this information as objective data to demonstrate compliance with the standard.

Sampling Strategy

Once the employer determines that there is a possibility of substantial employee exposure to formaldehyde, the employer is obligated to measure employee exposure.

The next is selection of a maximum risk employee. When there are different processes where employees may be exposed to formaldehyde, a maximum risk employee should be selected for

each work operation.

Selection of the maximum risk employee requires professional judgment. The best procedure for selecting the maximum risk employee is to observe employees and select the person closest to the source of formaldehyde. Employee mobility may affect this selection; eg. if the closest employee is mobile in his tasks, he may not be the maximum risk employee. Air movement patterns and differences in work habits will also affect selection of the maximum risk employee.

When many employees perform essentially the same task, a maximum risk employee cannot be selected. In this circumstance, it is necessary to resort to random sampling of the group of workers. The objective is to select a subgroup of adequate size so that there is a high probability that the random sample will contain at least one worker with high exposure if one exists. The number of persons in the group influences the number that need to be sampled to ensure that at least one individual from the highest 10 percent exposure group is contained in the sample. For example, to have 90 percent confidence in the results, if the group size is 10, nine should be sampled; for 50, only 18 need to be sampled.

If measurement shows exposure to formaldehyde at or above the action level or the STEL, the employer needs to identify all other employees who may be exposed at or above the action level or STEL and measure or otherwise accurately characterize the exposure of these employees.

Whether representative monitoring or random sampling are conducted, the purpose remains the same-to determine if the exposure of any employee is above the action level. If the exposure of the most exposed employee is less than the action level and the STEL, regardless of how the employee is identified, then it is reasonable to assume that measurements of exposure of the other employees in that operation would be below the action level and the STEL.

Exposure Measurements

There is no "best" measurement strategy for all situations. Some elements to consider in developing a strategy are:

- (1) Availability and cost of sampling equipment
- (2) Availability and cost of analytic facilities
- (3) Availability and cost of personnel to take samples
- (4) Location of employees and work operations
- (5) Intraday and interday variations in the process
- (6) Precision and accuracy of sampling and analytic methods, and

(7) Number of samples needed.

Samples taken for determining compliance with the STEL differ from those that measure the TWA concentration in important ways. STEL samples are best taken in a nonrandom fashion using all available knowledge relating to the area, the individual, and the process to obtain samples during periods of maximum expected concentrations. At least three measurements on a shift are generally needed to spot gross errors or mistakes; however, only the highest value represents the STEL.

If an operation remains constant throughout the workshift, a much greater number of samples would need to be taken over the 32 discrete nonoverlapping periods in an 8-hour workshift to verify compliance with a STEL. If employee exposure is truly uniform throughout the workshift, however, an employer in compliance with the 1 ppm TWA would be in compliance with the 2 ppm STEL, and this determination can probably be made using objective data.

Need to Repeat the Monitoring Strategy

Interday and intraday fluctuations in employee exposure are mostly influenced by the physical processes that generate formaldehyde and the work habits of the employee. Hence, in-plant process variations influence the employer's determination of whether or not additional controls need to be imposed. Measurements that employee exposure is low on a day that is not representative of worst conditions may not provide sufficient information to determine whether or not additional engineering controls should be installed to achieve the PELs.

The person responsible for conducting sampling must be aware of systematic changes which will negate the validity of the sampling results. Systematic changes in formaldehyde exposure concentration for an employee can occur due to:

- (1) The employee changing patterns of movement in the workplace
- (2) Closing of plant doors and windows
- (3) Changes in ventilation from season to season
- (4) Decreases in ventilation efficiency or abrupt failure of engineering control equipment
- (5) Changes in the production process or work habits of the employee. Any of these changes, if they may result in additional exposure that reaches the next level of action (i.e. 0.5 or 1.0 ppm as an 8-hr average or 2 ppm over 15 minutes) require the employer to perform additional monitoring to reassess employee exposure.

A number of methods are suitable for measuring employee exposure to formaldehyde or for

characterizing emissions within the worksite. The preamble to this standard describes some methods that have been widely used or subjected to validation testing. A detailed analytical procedure derived from the OSHA Method 52 for acrolein and formaldehyde is presented below for informational purposes.

Inclusion of OSHA's method in this appendix in no way implies that it is the only acceptable way to measure employee exposure to formaldehyde. Other methods that are free from significant interferences and that can determine formaldehyde at the permissible exposure limits within + or - 25 percent of the "true" value at the 95 percent confidence level are also acceptable. Where applicable, the method should also be capable of measuring formaldehyde at the action level to + or - 35 percent of the "true" value with a 95 percent confidence level. OSHA encourages employers to choose methods that will be best for their individual needs. The employer must exercise caution, however, in choosing an appropriate method since some techniques suffer from interferences that are likely to be present in workplaces of certain industry sectors where formaldehyde is used.

OSHA's Analytical Laboratory Method

Method No: 52

Matrix: Air

Target Concentration: 1 ppm (1.2 mg/m³)

Procedures: Air samples are collected by drawing known volumes of air through sampling tubes containing XAD-2 adsorbent which have been coated with 2-(hydroxymethyl) piperidine. The samples are desorbed with toluene and then analyzed by gas chromatography using a nitrogen selective detector.

Recommended Sampling Rate and Air Volumes: 0.1 L/min and 24 L

Reliable Quantitation Limit: 16 ppb (20 ug/m³)

Standard Error of Estimate at the Target Concentration: 7.3%

Status of the Method: A sampling and analytical method that has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch.

Date: March 1985

1. General Discussion

1.1 Background: The current OSHA method for collecting acrolein vapor recommends the use of activated 13X molecular sieves. The samples must be stored in an ice bath during and after sampling and also they must be analyzed within 48 hours of collection. The current OSHA method for collecting formaldehyde vapor recommends the use of bubblers containing 10% methanol in water as the trapping solution.

This work was undertaken to resolve the sample stability problems associated with acrolein and also to eliminate the need to use bubblers to sample formaldehyde. A goal of this work was to

develop and/or to evaluate a common sampling and analytical procedure for acrolein and formaldehyde.

NIOSH has developed independent methodologies for acrolein and formaldehyde which recommend the use of reagent-coated adsorbent tubes to collect the aldehydes as stable derivatives. The formaldehyde sampling tubes contain Chromosorb 102 adsorbent coated with N-benzylethanolamine (BEA) which reacts with formaldehyde vapor to form a stable oxazolidine compound. The acrolein sampling tubes contain XAD-2 adsorbent coated with 2-(hydroxymethyl)piperidine (2-HMP) which reacts with acrolein vapor to form a different, stable oxazolidine derivative. Acrolein does not appear to react with BEA to give a suitable reaction product. Therefore, the formaldehyde procedure cannot provide a common method for both aldehydes. However, formaldehyde does react with 2-HMP to form a very suitable reaction product. It is the quantitative reaction of acrolein and formaldehyde with 2-HMP that provides the basis for this evaluation.

This sampling and analytical procedure is very similar to the method recommended by NIOSH for acrolein. Some changes in the NIOSH methodology were necessary to permit the simultaneous determination of both aldehydes and also to accommodate OSHA laboratory equipment and analytical techniques.

1.2 Limit-defining parameters: The analyte air concentrations reported in this method are based on the recommended air volume for each analyte collected separately and a desorption volume of 1 mL. The amounts are presented as acrolein and/or formaldehyde, even though the derivatives are the actual species analyzed.

1.2.1 Detection limits of the analytical procedure: The detection limit of the analytical procedure was 386 pg per injection for formaldehyde. This was the amount of analyte which gave a peak whose height was about five times the height of the peak given by the residual formaldehyde derivative in a typical blank front section of the recommended sampling tube.

1.2.2 Detection limits of the overall procedure: The detection limits of the overall procedure were 482 ng per sample (16 ppb or 20 ug/m³) for formaldehyde. This was the amount of analyte spiked on the sampling device which allowed recoveries approximately equal to the detection limit of the analytical procedure.

1.2.3 Reliable quantitation limits: The reliable quantitation limit was 482 ng per sample (16 ppb or 20 ug/m³) for formaldehyde. These were the smallest amounts of analyte which could be quantitated within the limits of a recovery of at least 75% and a precision ((+ or -)(1.96 SD) of + or - 25% or better.

The reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at

the routine operating parameters.

1.2.4 Sensitivity: The sensitivity of the analytical procedure over concentration ranges representing 0.4 to 2 times the target concentration, based on the recommended air volumes, was 7,589 area units per ug/mL for formaldehyde. This value was determined from the slope of the calibration curve. The sensitivity may vary with the particular instrument used in the analysis.

1.2.5 Recovery: The recovery of formaldehyde from samples used in an 18-day storage test remained above 92% when the samples were stored at ambient temperature. These values were determined from regression lines which were calculated from the storage data. The recovery of the analyte from the collection device must be at least 75% following storage.

1.2.6 Precision (analytical method only): The pooled coefficient of variation obtained from replicate determinations of analytical standards over the range of 0.4 to 2 times the target concentration was 0.0052 for formaldehyde (Section 4.3).

1.2.7 Precision (overall procedure): The precision at the 95% confidence level for the ambient temperature storage tests was (+ or -) 14.3% for formaldehyde. These values each include an additional (+ or -) 5% for sampling error. The overall procedure must provide results at the target concentrations that are (+ or -) 25% at the 95% confidence level.

1.2.8 Reproducibility: Samples collected from controlled test atmospheres and a draft copy of this procedure were given to a chemist unassociated with this evaluation. The formaldehyde samples were analyzed following 15 days storage. The average recovery was 96.3% and the standard deviation was 1.7%.

1.3 Advantages:

1.3.1 The sampling and analytical procedures permit the simultaneous determination of acrolein and formaldehyde.

1.3.2 Samples are stable following storage at ambient temperature for at least 18 days.

1.4 Disadvantages: None. 2. Sampling Procedure

2.1 Apparatus:

2.1.1 Samples are collected by use of a personal sampling pump that can be calibrated to within (+ or -) 5% of the recommended 0.1 L/min sampling rate with the sampling tube in line.

2.1.2 Samples are collected with laboratory prepared sampling tubes. The sampling tube is constructed of silane treated glass and is about 8-cm long. The ID is 4 mm and the OD is 6 mm. One end of the tube is tapered so that a glass wool end plug will hold the contents of the tube in place during sampling. The other end of the sampling tube is open to its full 4-mm ID to

facilitate packing of the tube. Both ends of the tube are fire-polished for safety. The tube is packed with a 75-mg backup section, located nearest the tapered end and a 150-mg sampling section of pretreated XAD-2 adsorbent which has been coated with 2-HMP. The two sections of coated adsorbent are separated and retained with small plugs of silanized glass wool. Following packing, the sampling tubes are sealed with two 7/32 inch OD plastic end caps. Instructions for the pretreatment and the coating of XAD-2 adsorbent are presented in Section 4 of this method.

2.1.3 Sampling tubes, similar to those recommended in this method, are marketed by Supelco, Inc. These tubes were not available when this work was initiated; therefore, they were not evaluated.

2.2 Reagents: None required.

2.3 Technique:

2.3.1 Properly label the sampling tube before sampling and then remove the plastic end caps.

2.3.2 Attach the sampling tube to the pump using a section of flexible plastic tubing such that the large, front section of the sampling tube is exposed directly to the atmosphere. Do not place any tubing ahead of the sampling tube. The sampling tube should be attached in the worker's breathing zone in a vertical manner such that it does not impede work performance.

2.3.3 After sampling for the appropriate time, remove the sampling tube from the pump and then seal the tube with plastic end caps.

2.3.4 Include at least one blank for each sampling set. The blank should be handled in the same manner as the samples with the exception that air is not drawn through it.

2.3.5 List any potential interferences on the sample data sheet.

2.4 Breakthrough:

2.4.1 Breakthrough was defined as the relative amount of analyte found on a backup sample in relation to the total amount of analyte collected on the sampling train.

2.4.2 For formaldehyde collected from test atmospheres containing 6 times the PEL, the average 5% breakthrough air volume was 41 L. The sampling rate was 0.1 L/min and the average mass of formaldehyde collected was 250 ug.

2.5 Desorption Efficiency: No desorption efficiency corrections are necessary to compute air sample results because analytical standards are prepared using coated adsorbent. Desorption efficiencies were determined, however, to investigate the recoveries of the analytes from the

sampling device. The average recovery over the range of 0.4 to 2 times the target concentration, based on the recommended air volumes, was 96.2% for formaldehyde. Desorption efficiencies were essentially constant over the ranges studied.

2.6 Recommended Air Volume and Sampling Rate:

2.6.1. The recommended air volume for formaldehyde is 24 L.

2.6.2. The recommended sampling rate is 0.1 L/min.

2.7 Interferences:

2.7.1 Any collected substance that is capable of reacting 2-HMP and thereby depleting the derivatizing agent is a potential interference. Chemicals which contain a carbonyl group, such as acetone, may be capable or reacting with 2-HMP.

2.7.2 There are no other known interferences to the sampling method.

2.8 Safety Precautions:

2.8.1 Attach the sampling equipment to the worker in such a manner that it well not interfere with work performance or safety.

2.8.2 Follow all safety practices that apply to the work area being sampled. 3. Analytical Procedure

3.1 Apparatus:

3.1.1 A gas chromatograph (GC), equipped with a nitrogen selective detector. A Hewlett-Packard Model 5840A GC fitted with a nitrogen-phosphorus flame ionization detector (NPD) was used for this evaluation. Injections were performed using a Hewlett-Packard Model 7671A automatic sampler.

3.1.2 A GC column capable of resolving the analytes from any interference. A 6 ft x 1/4 in OD (2mm ID) glass GC column containing 10% UCON 50-HB-5100 + 2% KOH on 80/100 mesh Chromosorb W-AW was used for the evaluation. Injections were performed on-column.

3.1.3 Vials, glass 2-mL with Teflon-lined caps.

3.1.4 Volumetric flasks, pipets, and syringes for preparing standards, making dilutions, and performing injections.

3.2 Reagents:

3.2.1 Toluene and dimethylformamide. Burdick and Jackson solvents were used in this evaluation.

3.2.2 Helium, hydrogen, and air, GC grade.

3.2.3 Formaldehyde, 37%, by weight, in water. Aldrich Chemical, ACS Reagent Grade formaldehyde was used in this evaluation.

3.2.4 Amberlite XAD-2 adsorbent coated with 2-(hydroxymethyl-piperidine (2-HMP), 10% by weight (Section 4).

3.2.5 Desorbing solution with internal standard. This solution was prepared by adding 20 uL of dimethylformamide to 100 mL of toluene.

3.3 Standard preparation:

3.3.1 Formaldehyde: Prepare stock standards by diluting known volumes of 37% formaldehyde solution with methanol. A procedure to determine the formaldehyde content of these standards is presented in Section 4. A standard containing 7.7 mg/mL formaldehyde was prepared by diluting 1 mL of the 37% reagent to 50 mL with methanol.

3.3.2 It is recommended that analytical standards be prepared about 16 hours before the air samples are to be analyzed in order to ensure the complete reaction of the analytes with 2-HMP. However, rate studies have shown the reaction to be greater than 95% complete after 4 hours. Therefore, one or two standards can be analyzed after this reduced time if sample results are outside the concentration range of the prepared standards.

3.3.3 Place 150-mg portions of coated XAD-2 adsorbent, from the same lot number as used to collect the air samples, into each of several glass 2-mL vials. Seal each vial with a Teflon-lined cap.

3.3.4 Prepare fresh analytical standards each day by injecting appropriate amounts of the diluted analyte directly onto 150-mg portions of coated adsorbent. It is permissible to inject both acrolein and formaldehyde on the same adsorbent portion. Allow the standards to stand at room temperature. A standard, approximately the target levels, was prepared by injecting 11 uL of the acrolein and 12 uL of the formaldehyde stock standards onto a single coated XAD-2 adsorbent portion.

3.3.5 Prepare a sufficient number of standards to generate the calibration curves. Analytical standard concentrations should bracket sample concentrations. Thus, if samples are not in the concentration range of the prepared standards, additional standards must be prepared to determine detector response.

3.3.7 Desorb the standards in the same manner as the samples following the 16-hour reaction time.

3.4 Sample preparation:

3.4.1 Transfer the 150-mg section of the sampling tube to a 2-mL vial. Place the 75-mg section in a separate vial. If the glass wool plugs contain a significant number of adsorbent beads, place them with the appropriate sampling tube section. Discard the glass wool plugs if they do not contain a significant number of adsorbent beads.

3.4.2 Add 1 mL of desorbing solution to each vial.

3.4.3 Seal the vials with Teflon-lined caps and then allow them to desorb for one hour. Shake the vials by hand with vigorous force several times during the desorption time.

3.4.4 Save the used sampling tubes to be cleaned and recycled.

3.5 Analysis:

3.5.1 GC Conditions

Column Temperature: Bi-level temperature program-First level: 100 to 140 deg. C at 4 deg. C/min following completion of the first level. Second level: 140 to 180 deg. C at 20 deg. C/min following completion of the first level. Isothermal period: Hold column at 180 deg. C until the recorder pen returns to baseline (usually about 25 min after injection). Injector temperature: 180 deg. C Helium flow rate: 30 mL/min (detector response will be reduced if nitrogen is substituted for helium carrier gas). Injection volume: 0.8 uL GC column: Six-ft x 1/4 -in OD (2 mm ID) glass GC column containing 10% UCON 50-HB-5100+2% KOH on 80/100 Chromosorb W-AW.

NPD conditions:

Hydrogen flow rate: 3 mL/min

Air flow rate: 50 mL/min

Detector temperature: 275 deg. C

3.5.2 Chromatogram: For an example of a typical chromatogram, see Figure 4.11 in OSHA Method 52.

3.5.3 Use a suitable method, such as electronic integration, to measure detector response.

3.5.4 Use an internal standard method to prepare the calibration curve with several standard solutions of different concentrations. Prepare the calibration curve daily. Program the integrator to report results in ug/mL.

3.5.5 Bracket sample concentrations with standards.

3.6 Interferences (Analytical)

3.6.1 Any compound with the same general retention time as the analytes and which also gives a detector response is a potential interference. Possible interferences should be reported to the laboratory with submitted samples by the industrial hygienist.

3.6.2 GC parameters (temperature, column, etc.) may be changed to circumvent interferences.

3.6.3 A useful means of structure designation is GC/MS. It is recommended this procedure be used to confirm samples whenever possible.

3.6.4 The coated adsorbent usually contains a very small amount of residual formaldehyde derivative (Section 4.8).

3.7 Calculations:

3.7.1 Results are obtained by use of calibration curves. Calibration curves are prepared by plotting detector response against concentration for each standard. The best line through the data points is determined by curve fitting.

3.7.2 The concentration, in ug/mL, for a particular sample is determined by comparing its detector response to the calibration curve. If either of the analytes is found on the backup section, it is added to the amount found on the front section. Blank corrections should be performed before adding the results together.

3.7.3 The acrolein and/or formaldehyde air concentration can be expressed using the following equation:

$\text{mg/m}^3 = (A)(B)/C$ where A=ug/mL from 3.7.2, B=desorption volume, and C=L of air sampled.

No desorption efficiency corrections are required.

3.7.4 The following equation can be used to convert results in mg/m³ to ppm.

$\text{ppm} = (\text{mg/m}^3)(24.45)/\text{MW}$ where mg/m³=result from 3.7.3, 24.45=molar volume of an ideal gas at 760 mm Hg and 25 deg. C, MW=molecular weight (30.0).

4. Backup Data

4.1 Backup data on detection limits, reliable quantitation limits, sensitivity and precision of the analytical method, breakthrough, desorption efficiency, storage, reproducibility, and generation of test atmospheres are available in OSHA Method 52, developed by the Organics Methods Evaluation Branch, OSHA Analytical Laboratory, Salt Lake City, Utah.

4.2 Procedure to Coat XAD-2 Adsorbent with 2-HMP:

4.2.1 Apparatus: Soxhlet extraction apparatus, rotary evaporation apparatus, vacuum dessicator, 1-L vacuum flask, 1-L round-bottomed evaporative flask, 1-L Erlenmeyer flask, 250-mL Buchner funnel with a coarse fritted disc, etc.

4.2.2 Reagents:

4.2.2.1 Methanol, isooctane, and toluene.

4.2.2.2 2-(Hydroxymethyl)piperidine.

4.2.2.3 Amberlite XAD-2 non-ionic polymeric adsorbent, 20 to 60 mesh, Aldrich Chemical XAD-2 was used in this evaluation.

4.2.3 Procedure: Weigh 125 g of crude XAD-2 adsorbent into a 1-L Erlenmeyer flask. Add about 200 mL of water to the flask and then swirl the mixture to wash the adsorbent. Discard any adsorbent that floats to the top of the water and then filter the mixture using a fritted Buchner funnel. Air dry the adsorbent for 2 minutes. Transfer the adsorbent back to the Erlenmeyer flask and then add about 200 mL of methanol to the flask. Swirl and then filter the mixture as before. Transfer the washed adsorbent back to the Erlenmeyer flask and then add about 200 mL of methanol to the flask. Swirl and then filter the mixture as before. Transfer the washed adsorbent to a 1-L round-bottomed evaporative flask, add 13 g of 2-HMP and then 200 mL of methanol, swirl the mixture and then allow it to stand for one hour. Remove the methanol at about 40 deg. C and reduced pressure using a rotary evaporation apparatus. Transfer the coated adsorbent to a suitable container and store it in a vacuum desiccator at room temperature overnight. Transfer the coated adsorbent to a Soxhlet extractor and then extract the material with toluene for about 24 hours. Discard the contaminated toluene, add methanol in its place and then continue the Soxhlet extraction for an additional 4 hours. Transfer the adsorbent to a weighted 1-L round-bottom evaporative flask and remove the methanol using the rotary evaporation apparatus. Determine the weight of the adsorbent and then add an amount of 2-HMP, which is 10% by weight of the adsorbent. Add 200 mL of methanol and then swirl the mixture. Allow the mixture to stand for one hour. Remove the methanol by rotary evaporation. Transfer the coated adsorbent to a suitable container and store it in a vacuum desiccator until all traces of solvents are gone. Typically, this will take 2-3 days. The coated adsorbent should be protected from

contamination. XAD-2 adsorbent treated in this manner will probably not contain residual acrolein derivative. However, this adsorbent will often contain residual formaldehyde derivative levels of about 0.1 ug per 150 mg of adsorbent. If the blank values for a batch of coated adsorbent are too high, then the batch should be returned to the Soxhlet extractor, extracted with toluene again and then recoated. This process can be repeated until the desired blank levels are attained.

The coated adsorbent is now ready to be packed into sampling tubes. The sampling tubes should be stored in a sealed container to prevent contamination. Sampling tubes should be stored in the dark at room temperature. The sampling tubes should be segregated by coated adsorbent lot number. A sufficient amount of each lot number of coated adsorbent should be retained to prepare analytical standards for use with air samples from that lot number.

4.3 A Procedure to Determine Formaldehyde by Acid Titration: Standardize the 0.1 N HCl solution using sodium carbonate and methyl orange indicator.

Place 50 mL of 0.1 M sodium sulfite and three drops of thymophthalein indicator into a 250-mL Erlenmeyer flask. Titrate the contents of the flask to a colorless endpoint with 0.1 N HCl (usually one or two drops is sufficient). Transfer 10 mL of the formaldehyde/methanol solution (prepared in 3.3.1) into the same flask and titrate the mixture with 0.1 N HCl, again, to a colorless endpoint. The formaldehyde concentration of the standard may be calculated by the following equation:

$$\frac{\text{acid titer} \times \text{acid normality} \times 30.0}{\text{mL of sample}} = \text{Formaldehyde, mg/mL}$$

This method is based on the quantitative liberation of sodium hydroxide when formaldehyde reacts with sodium sulfite to form the formaldehyde-bisulfite addition product. The volume of sample may be varied depending on the formaldehyde content but the solution to be titrated must contain excess sodium sulfite. Formaldehyde solutions containing substantial amounts of acid or base must be neutralized before analysis.

1910.1048 App C Medical surveillance - Formaldehyde

APPENDIX C TO 1910.1048 - MEDICAL SURVEILLANCE - FORMALDEHYDE

I. Health Hazards

The occupational health hazards of formaldehyde are primarily due to its toxic effects after inhalation, after direct contact with the skin or eyes by formaldehyde in liquid or vapor form, and after ingestion.

II. Toxicology

A. Acute Effects of Exposure

1. Inhalation (breathing): Formaldehyde is highly irritating to the upper airways. The concentration of formaldehyde that is immediately dangerous to life and health is 100 ppm. Concentrations above 50 ppm can cause severe pulmonary reactions within minutes. These include pulmonary edema, pneumonia, and bronchial irritation which can result in death. Concentrations above 5 ppm readily cause lower airway irritation characterized by cough, chest tightness and wheezing. There is some controversy regarding whether formaldehyde gas is a pulmonary sensitizer which can cause occupational asthma in a previously normal individual. Formaldehyde can produce symptoms of bronchial asthma in humans. The mechanism may be either sensitization of the individual by exposure to formaldehyde or direct irritation by formaldehyde in persons with pre-existing asthma. Upper airway irritation is the most common respiratory effect reported by workers and can occur over a wide range of concentrations, most frequently above 1 ppm. However, airway irritation has occurred in some workers with exposures to formaldehyde as low as 0.1 ppm. Symptoms of upper airway irritation include dry or sore throat, itching and burning sensations of the nose, and nasal congestion. Tolerance to this level of exposure may develop within 1-2 hours. This tolerance can permit workers remaining in an environment of gradually increasing formaldehyde concentrations to be unaware of their increasingly hazardous exposure.

2. Eye contact: Concentrations of formaldehyde between 0.05 ppm and 0.5 ppm produce a sensation of irritation in the eyes with burning, itching, redness, and tearing. Increased rate of blinking and eye closure generally protects the eye from damage at these low levels, but these protective mechanisms may interfere with some workers' work abilities. Tolerance can occur in workers continuously exposed to concentrations of formaldehyde in this range. Accidental splash injuries of human eyes to aqueous solutions of formaldehyde (formalin) have resulted in a wide range of ocular injuries including corneal opacities and blindness. The severity of the reactions have been directly dependent on the concentration of formaldehyde in solution and the amount of time lapsed before emergency and medical intervention.

3. Skin contact: Exposure to formaldehyde solutions can cause irritation of the skin and allergic contact dermatitis. These skin diseases and disorders can occur at levels well below those encountered by many formaldehyde workers. Symptoms include erythema, edema, and vesiculation or hives. Exposure to liquid formalin or formaldehyde vapor can provoke skin reactions in sensitized individuals even when airborne concentrations of formaldehyde are well below 1 ppm.

4. Ingestion: Ingestion of as little as 30 ml of a 37 percent solution of formaldehyde (formalin) can result in death. Gastrointestinal toxicity after ingestion is most severe in the stomach and results in symptoms which can include nausea, vomiting, and severe abdominal pain. Diverse damage to other organ systems including the liver, kidney, spleen, pancreas, brain,

and central nervous systems can occur from the acute response to ingestion of formaldehyde.

B. Chronic Effects of Exposure

Long term exposure to formaldehyde has been shown to be associated with an increased risk of cancer of the nose and accessory sinuses, nasopharyngeal and oropharyngeal cancer, and lung cancer in humans. Animal experiments provide conclusive evidence of a causal relationship between nasal cancer in rats and formaldehyde exposure. Concordant evidence of carcinogenicity includes DNA binding, genotoxicity in short-term tests, and cytotoxic changes in the cells of the target organ suggesting both preneoplastic changes and a dose-rate effect. Formaldehyde is a complete carcinogen and appears to exert an effect on at least two stages of the carcinogenic process.

III. Surveillance considerations

A. History

1. Medical and occupational history: Along with its acute irritative effects, formaldehyde can cause allergic sensitization and cancer. One of the goals of the work history should be to elicit information on any prior or additional exposure to formaldehyde in either the occupational or the non-occupational setting.

2. Respiratory history: As noted above, formaldehyde has recognized properties as an airway irritant and has been reported by some authors as a cause of occupational asthma. In addition, formaldehyde has been associated with cancer of the entire respiratory system of humans. For these reasons, it is appropriate to include a comprehensive review of the respiratory system in the medical history. Components of this history might include questions regarding dyspnea on exertion, shortness of breath, chronic airway complaints, hyperreactive airway disease, rhinitis, bronchitis, bronchiolitis, asthma, emphysema, respiratory allergic reaction, or other preexisting pulmonary disease.

In addition, generalized airway hypersensitivity can result from exposures to a single sensitizing agent. The examiner should, therefore, elicit any prior history of exposure to pulmonary irritants, and any short- or long-term effects of that exposure.

Smoking is known to decrease mucociliary clearance of materials deposited during respiration in the nose and upper airways. This may increase a worker's exposure to inhaled materials such as formaldehyde vapor. In addition, smoking is a potential confounding factor in the investigation of any chronic respiratory disease, including cancer. For these reasons, a complete smoking history should be obtained.

3. Skin Disorders: Because of the dermal irritant and sensitizing effects of formaldehyde, a history of skin disorders should be obtained. Such a history might include the existence of skin

irritation, previously documented skin sensitivity, and other dermatologic disorders. Previous exposure to formaldehyde and other dermal sensitizers should be recorded.

4. History of atopic or allergic diseases: Since formaldehyde can cause allergic sensitization of the skin and airways, it might be useful to identify individuals with prior allergen sensitization. A history of atopic disease and allergies to formaldehyde or any other substances should also be obtained. It is not definitely known at this time whether atopic diseases and allergies to formaldehyde or any other substances should also be obtained. Also it is not definitely known at this time whether atopic individuals have a greater propensity to develop formaldehyde sensitivity than the general population, but identification of these individuals may be useful for ongoing surveillance.

5. Use of disease questionnaires: Comparison of the results from previous years with present results provides the best method for detecting a general deterioration in health when toxic signs and symptoms are measured subjectively. In this way recall bias does not affect the results of the analysis. Consequently, OSHA has determined that the findings of the medical and work histories should be kept in a standardized form for comparison of the year-to-year results.

B. Physical Examination

1. Mucosa of eyes and airways: Because of the irritant effects of formaldehyde, the examining physician should be alert to evidence of this irritation. A speculum examination of the nasal mucosa may be helpful in assessing possible irritation and cytotoxic changes, as may be indirect inspection of the posterior pharynx by mirror.

2. Pulmonary system: A conventional respiratory examination, including inspection of the thorax and auscultation and percussion of the lung fields should be performed as part of the periodic medical examination. Although routine pulmonary function testing is only required by the standard once every year for persons who are exposed over the TWA concentration limit, these tests have an obvious value in investigating possible respiratory dysfunction and should be used wherever deemed appropriate by the physician. In cases of alleged formaldehyde-induced airway disease, other possible causes of pulmonary dysfunction (including exposures to other substances) should be ruled out. A chest radiograph may be useful in these circumstances. In cases of suspected airway hypersensitivity or allergy, it may be appropriate to use bronchial challenge testing with formaldehyde or methacholine to determine the nature of the disorder. Such testing should be performed by or under the supervision of a physician experienced in the procedures involved.

3. Skin: The physician should be alert to evidence of dermal irritation of sensitization, including reddening and inflammation, urticaria, blistering, scaling, formation of skin fissures, or other symptoms. Since the integrity of the skin barrier is compromised by other dermal diseases, the presence of such disease should be noted. Skin sensitivity testing carries with it some risk of inducing sensitivity, and therefore, skin testing for formaldehyde sensitivity should not be used as

a routine screening test. Sensitivity testing may be indicated in the investigation of a suspected existing sensitivity. Guidelines for such testing have been prepared by the North American Contact Dermatitis Group.

C. Additional Examinations or Tests

The physician may deem it necessary to perform other medical examinations or tests as indicated. The standard provides a mechanism whereby these additional investigations are covered under the standard for occupational exposure to formaldehyde.

D. Emergencies

The examination of workers exposed in an emergency should be directed at the organ systems most likely to be affected. Much of the content of the examination will be similar to the periodic examination unless the patient has received a severe acute exposure requiring immediate attention to prevent serious consequences. If a severe overexposure requiring medical intervention or hospitalization has occurred, the physician must be alert to the possibility of delayed symptoms. Followup nonroutine examinations may be necessary to assure the patient's well-being.

E. Employer Obligations

The employer is required to provide the physician with the following information: A copy of this standard and appendices A, C, D, and E; a description of the affected employee's duties as they relate to his or her exposure concentration; an estimate of the employee's exposure including duration (e.g. 15 hr/wk, three 8-hour shifts, full-time); a description of any personal protective equipment, including respirators, used by the employee; and the results of any previous medical determinations for the affected employee related to formaldehyde exposure to the extent that this information is within the employer's control.

F. Physician's Obligations

The standard requires the employer to obtain a written statement from the physician. This statement must contain the physician's opinion as to whether the employee has any medical condition which would place him or her at increased risk of impaired health from exposure to formaldehyde or use of respirators, as appropriate. The physician must also state his opinion regarding any restrictions that should be placed on the employee's exposure to formaldehyde or upon the use of protective clothing or equipment such as respirators. If the employee wears a respirator as a result of his or her exposure to formaldehyde, the physician's opinion must also contain a statement regarding the suitability of the employee to wear the type of respirator assigned. Finally, the physician must inform the employer that the employee has been told the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion is not to contain any information on specific findings or diagnoses unrelated to occupational exposure to formaldehyde.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in assuring that their health is not being impaired by formaldehyde, and to assess the employee's ability to use any required protective equipment.

1910.1048 App D Nonmandatory medical disease questionnaire

APPENDIX D TO 1910.1048 - NONMANDATORY MEDICAL DISEASE QUESTIONNAIRE

A. Identification

Plant Name _____
Date _____
Employee Name _____
S.S. # _____
Job Title _____
Birthdate: _____
Age: _____
Sex: _____
Height: _____
Weight: _____

B. Medical History

1. Have you ever been in the hospital as a patient?
Yes__ No__
If yes, what kind of problem were you having? _____

2. Have you ever had any kind of operation?
Yes__ No__
If yes, what kind? _____

3. Do you take any kind of medicine regularly?
Yes__ No__
If yes, what kind? _____

4. Are you allergic to any drugs, foods, or chemicals?
Yes__ No__
If yes, what kind of allergy is it? _____

What causes the allergy? _____

5. Have you ever been told that you have asthma, hayfever, or sinusitis?
Yes__ No__
6. Have you ever been told that you have emphysema, bronchitis, or any other respiratory problems?
Yes__ No__
7. Have you ever been told you had hepatitis?
Yes__ No__
8. Have you ever been told that you had cirrhosis?
Yes__ No__
9. Have you ever been told that you had cancer?
Yes__ No__
10. Have you ever had arthritis or joint pain?
Yes__ No__
11. Have you ever been told that you had high blood pressure?
Yes__ No__
12. Have you ever had a heart attack or heart trouble?
Yes__ No__

B-1. Medical History Update

1. Have you been in the hospital as a patient any time within the past year?

Yes__ No__

If so, for what condition? _____

2. Have you been under the care of a physician during the past year?

Yes__ No__

If so, for what condition? _____

3. Is there any change in your breathing since last year?

Yes__ No__

Better? _____

Worse? _____

No change? _____

If change, do you know why? _____

4. Is your general health different this year from last year?

Yes__ No__

If different, in what way? _____

5. Have you in the past year or are you now taking any medication on a regular basis?

Yes__ No__

Name Rx _____
Condition being treated _____

C. Occupational History

1. How long have you worked for your present employer?

2. What jobs have you held with this employer? Include job title and length of time in each job.

3. In each of these jobs, how many hours a day were you exposed to chemicals?

4. What chemicals have you worked with most of the time?

5. Have you ever noticed any type of skin rash you feel was related to your work?

Yes__ No__

6. Have you ever noticed that any kind of chemical makes you cough?

Yes__ No__

Wheeze?

Yes__ No__

Become short of breath or cause your chest to become tight?

Yes__ No__

7. Are you exposed to any dust or chemicals at home?

Yes__ No__

If yes, explain: _____

8. In other jobs, have you ever had exposure to:

Wood dust?

Yes__ No__

Nickel or chromium?

Yes__ No__

Silica (foundry, sand blasting)?

Yes__ No__

Arsenic or asbestos?

Yes__ No__

Organic solvents?

Yes__ No__

Urethane foams?

Yes__ No__

C-1. Occupational History Update

1. Are you working on the same job this year as you were last year?

Yes__ No__

If not, how has your job changed?_____

2. What chemicals are you exposed to on your job?

3. How many hours a day are you exposed to chemicals?

4. Have you noticed any skin rash within the past year you feel was related to your work?

Yes__ No__

If so, explain circumstances:_____

5. Have you noticed that any chemical makes you cough, be short of breath, or wheeze?

Yes__ No__

If so, can you identify it?_____

D. Miscellaneous

1. Do you smoke?

Yes__ No__

If so, how much and for how long?_____

Pipe_____

Cigars_____

Cigarettes_____

2. Do you drink alcohol in any form?

Yes__ No__

If so, how much, how long, and how often?_____

3. Do you wear glasses or contact lenses?

Yes__ No__

4. Do you get any physical exercise other than that required to do your job?

Yes__ No__

If so, explain:_____

5. Do you have any hobbies or "side jobs" that require you to use

chemicals, such as furniture stripping, sand blasting, insulation or manufacture of urethane foam, furniture, etc?

Yes__ No__

If so, please describe, giving type of business or hobby, chemicals used and length of exposures.

E. Symptoms Questionnaire

1. Do you ever have any shortnes of breath?

Yes__ No__

If yes, do you have to rest after climbing several flights of stairs?

Yes__ No__

If yes, if you walk on the level with people your own age, do you walk slower than they do?

Yes__ No__

If yes, if you walk slower than a normal pace, do you have to limit the distance that you walk?

Yes__ No__

If yes, do you have to stop and rest while bathing or dressing?

Yes__ No__

2. Do you cough as much as three months out of the year?

Yes__ No__

If yes, have you had this cough for more than two years?

Yes__ No__

If yes, do you ever cough anything up from chest?

Yes__ No__

3. Do you ever have a feeling of smothering, unable to take a deep breath, or tightness in your chest?

Yes__ No__

If yes, do you notice that this on any particular day of the week?

Yes__ No__

If yes, what day or the week?

Yes__ No__

If yes, do you notice that this occurs at any particular place?

Yes__ No__

If yes, do you notice that this is worse after you have returned to work after being off for several days?

Yes__ No__

4. Have you ever noticed any wheezing in your chest?

Yes__ No__

If yes, is this only with colds or other infections?

Yes__ No__

Is this caused by exposure to any kind of dust or other material?

Yes__ No__

If yes, what kind?_____

5. Have you noticed any burning, tearing, or redness of your eyes when you are at work?

Yes__ No__

If so, explain circumstances:_____

6. Have you noticed any sore or burning throat or itchy or burning nose when you are at work?

Yes__ No__

If so, explain circumstances:_____

7. Have you noticed any stuffiness or dryness of your nose?

Yes__ No__

8. Do you ever have swelling of the eyelids or face?

Yes__ No__

9. Have you ever been jaundiced?

Yes__ No__

If yes, was this accompanied by any pain?

Yes__ No__

10. Have you ever had a tendency to bruise easily or bleed excessively?

Yes__ No__

11. Do you have frequent headaches that are not relieved by aspirin or tylenol?

Yes__ No__

If yes, do they occur at any particular time of the day or week?

Yes__ No__

If yes, when do they occur?_____

12. Do you have frequent episodes of nervousness or irritability?

Yes__ No__

13. Do you tend to have trouble concentrating or remembering?

Yes__ No__

14. Do you ever feel dizzy, light-headed, excessively drowsy or like you have been drugged?

Yes__ No__

15. Does your vision ever become blurred?

Yes__ No__

16. Do you have numbness or tingling of the hands or feet or other parts of your body?

Yes__ No__

17. Have you ever had chronic weakness or fatigue?

Yes__ No__

18. Have you ever had any swelling of your feet or ankles to the point where you could not wear your shoes?

Yes__ No__

19. Are you bothered by heartburn or indigestion?

Yes__ No__

20. Do you ever have itching, dryness, or peeling and scaling of the hands?

Yes__ No__

21. Do you ever have a burning sensation in the hands, or reddening of the skin?

Yes__ No__

22. Do you ever have cracking or bleeding of the skin on your hands?

Yes__ No__

23. Are you under a physician's care?

Yes__ No__

If yes, for what are you being treated?_____

24. Do you have any physical complaints today?

Yes__ No__

If yes, explain?_____

25. Do you have other health conditions not covered by these questions?

Yes__ No__

If yes, explain:_____

1910.1048 App E Qualitative and quantitative fit testing procedures [Reserved]

APPENDIX E TO 1910.1048 - QUALITATIVE AND QUANTITATIVE FIT TESTING PROCEDURES [Reserved]

1910.1050 Methylenedianiline.

(a) Scope and application.

(1) This section applies to all occupational exposures to MDA, Chemical Abstracts Service Registry No. 101-77-9, except as provided in paragraphs (a)(2) through (a)(7) of this section.

(2) Except as provided in paragraphs (a)(8) and (e)(5) of this section, this section does not apply to the processing, use, and handling of products containing MDA where initial monitoring indicates that the product is not capable of releasing MDA in excess of the action level under the expected conditions of processing, use, and handling which will cause the greatest possible

release; and where no dermal exposure to MDA can occur.

(3) Except as provided in paragraph (a)(8) of this section, this section does not apply to the processing, use, and handling of products containing MDA where objective data are reasonably relied upon which demonstrate the product is not capable of releasing MDA under the expected conditions of processing, use, and handling which will cause the greatest possible release; and where no "dermal exposure to MDA" can occur.

(4) This section does not apply to the storage, transportation, distribution or sale of MDA in intact containers sealed in such a manner as to contain the MDA dusts, vapors, or liquids, except for the provisions of 29 CFR 1910.1200 and paragraph (d) of this section.

(5) This section does not apply to the construction industry as defined in 29 CFR 1910.12(b). (Exposure to MDA in the construction industry is covered by 29 CFR 1926.60).

(6) Except as provided in paragraph (a)(8) of this section, this section does not apply to materials in any form which contain less than 0.1% MDA by weight or volume.

(7) Except as provided in paragraph (a)(8) of this section, this section does not apply to unfinished articles containing MDA.

(8) Where products containing MDA are exempted under paragraphs (a)(2) through (a)(7) of this section, the employer shall maintain records of the initial monitoring results or objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in the recordkeeping provision of paragraph (n) of this section.

(b) Definitions. For the purpose of this section, the following definitions shall apply:

Action level means a concentration of airborne MDA of 5 ppb as an eight (8)-hour time-weighted average.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees, for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (o) of this section, or any other person authorized by the Act or regulations issued under the Act.

Container means any barrel, bottle, can, cylinder, drum, reaction vessel, storage tank, commercial packaging or the like, but does not include piping systems.

Dermal exposure to MDA occurs where employees are engaged in the handling, application or use of mixtures or materials containing MDA, with any of the following non-airborne forms of MDA:

(i) Liquid, powdered, granular, or flaked mixtures containing MDA in concentrations greater than 0.1% by weight or volume; and

(ii) Materials other than "finished articles" containing MDA in concentrations greater than 0.1% by weight or volume.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which results in an unexpected and potentially hazardous release of MDA.

Employee exposure means exposure to MDA which would occur if the employee were not using respirators or protective work clothing and equipment.

Finished article containing MDA is defined as a manufactured item:

(i) Which is formed to a specific shape or design during manufacture;

(ii) Which has end use function(s) dependent in whole or part upon its shape or design during end use; and

(iii) Where applicable, is an item which is fully cured by virtue of having been subjected to the conditions (temperature, time) necessary to complete the desired chemical reaction.

4,4' Methylene-dianiline or MDA means the chemical, 4,4'-diaminodiphenylmethane, Chemical Abstract Service Registry number 101-77-9, in the form of a vapor, liquid, or solid. The definition also includes the salts of MDA.

Regulated areas means areas where airborne concentrations of MDA exceed or can reasonably be expected to exceed, the permissible exposure limits, or where dermal exposure to MDA can occur.

STEL means short term exposure limit as determined by any 15 minute sample period.

(c) **Permissible exposure limits (PEL).** The employer shall assure that no employee is exposed to an airborne concentration of MDA in excess of ten parts per billion (10 ppb) as an 8-hour time-weighted average or a STEL of 100 ppb.

(d) Emergency situations

(1) Written plan.

(i) A written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with the appropriate personal protective equipment and clothing as required in paragraphs (h) and (i) of this section until the emergency is abated.

(iii) The plan shall specifically include provisions for alerting and evacuating affected employees as well as the elements prescribed in 29 CFR 1910.38 and 29 CFR 1910.39, A "Emergency action plans" and "Fire prevention plans" respectively.

(2) Alerting employees. Where there is the possibility of employee exposure to MDA due to an emergency, means shall be developed to alert promptly those employees who have the potential to be directly exposed. Affected employees not engaged in correcting emergency conditions shall be evacuated immediately in the event that an emergency occurs. Means shall also be developed and implemented for alerting other employees who may be exposed as a result of the emergency.

(e) Exposure monitoring

(1) General.

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of each employee's exposure to airborne MDA over an eight (8) hour period. Determination of employee exposure to the STEL shall be made from breathing zone air samples collected over a 15 minute sampling period.

(ii) Representative employee exposure shall be determined on the basis of one or more samples representing full shift exposure for each shift for each job classification in each work area where exposure to MDA may occur.

(iii) Where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer shall only be required to determine representative employee exposure for that operation during one shift.

(2) Initial monitoring. Each employer who has a workplace or work operation covered by this standard shall perform initial monitoring to determine accurately the airborne concentrations of MDA to which employees may be exposed.

(3) Periodic monitoring and monitoring frequency.

(i) If the monitoring required by paragraph (e)(2) of this section reveals employee exposure at or above the action level, but at or below the PELs, the employer shall repeat such representative monitoring for each such employee at least every six (6) months.

(ii) If the monitoring required by paragraph (e)(2) of this section reveals employee exposure above the PELs, the employer shall repeat such monitoring for each such employee at least every three (3) months.

(iii) The employer may alter the monitoring schedule from every three months to every six months for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee exposure has decreased to below the TWA but above the action level.

(4) Termination of monitoring.

(i) If the initial monitoring required by paragraph (e)(2) of this section reveals employee exposure to be below the action level, the employer may discontinue the monitoring for that employee, except as otherwise required by paragraph (e)(5) of this section.

(ii) If the periodic monitoring required by paragraph (e)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level the employer may discontinue the monitoring for that employee, except as otherwise required by paragraph (e)(5) of this section.

(5) Additional monitoring. The employer shall institute the exposure monitoring required under paragraphs (e)(2) and (e)(3) of this section when there has been a change in production process, chemicals present, control equipment, personnel, or work practices which may result in new or additional exposures to MDA, or when the employer has any reason to suspect a change which may result in new or additional exposures.

(6) Accuracy of monitoring. Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of MDA.

(7) Employee notification of monitoring results.

(i) The employer shall, within 15 working days after the receipt of the results of any monitoring performed under this standard, notify each employee of these results, in writing, either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) The written notification required by paragraph (e)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce the employee exposure to or below the

PELs, wherever the PELs are exceeded.

(8) Visual monitoring. The employer shall make routine inspections of employee hands, face and forearms potentially exposed to MDA. Other potential dermal exposures reported by the employee must be referred to the appropriate medical personnel for observation. If the employer determines that the employee has been exposed to MDA the employer shall:

(i) Determine the source of exposure;

(ii) Implement protective measures to correct the hazard; and

(iii) Maintain records of the corrective actions in accordance with paragraph (n) of this section.

(f) Regulated areas

(1) Establishment

(i) Airborne exposures. The employer shall establish regulated areas where airborne concentrations of MDA exceed or can reasonably be expected to exceed, the permissible exposure limits.

(ii) Dermal exposures. Where employees are subject to dermal exposure to MDA the employer shall establish those work areas as regulated areas.

(2) Demarcation. Regulated areas shall be demarcated from the rest of the workplace in a manner that minimizes the number of persons potentially exposed.

(3) Access. Access to regulated areas shall be limited to authorized persons.

(4) Personal protective equipment and clothing. Each person entering a regulated area shall be supplied with, and required to use, the appropriate personal protective clothing and equipment in accordance with paragraphs (h) and (i) of this section.

(5) Prohibited activities. The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

(g) Methods of compliance

(1) Engineering controls and work practices.

(i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to MDA at or below the PELs except to the extent that the employer

can establish that these controls are not feasible or where the provisions of paragraph (g)(1)(ii) or (h)(1) (i) through (iv) of this section apply.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the PELs, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protective devices which comply with the requirements of paragraph (h) of this section.

(2) Compliance program.

(i) The employer shall establish and implement a written program to reduce employee exposure to or below the PELs by means of engineering and work practice controls, as required by paragraph (g)(1) of this section, and by use of respiratory protection where permitted under this section. The program shall include a schedule for periodic maintenance (e.g., leak detection) and shall include the written plan for emergency situations as specified in paragraph (d) of this section.

(ii) Upon request this written program shall be furnished for examination and copying to the Assistant Secretary, the Director, affected employees, and designated employee representatives. The employer shall review and, as necessary, update such plans at least once every 12 months to make certain they reflect the current status of the program.

(3) Employee rotation. Employee rotation shall not be permitted as a means of reducing exposure.

(h) Respiratory protection

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work-practice controls;

(ii) Work operations for which the employer establishes that engineering and work-practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the PEL.

(iv) Emergencies.

(2) Respirator program. The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(3) Respirator selection.

(i) Employer must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide HEPA filters for powered and non-powered air-purifying respirators.

(C) For escape, provide employees with one of the following respirator options: Any self-contained breathing apparatus with a full facepiece or hood operated in the positive-pressure or continuous-flow mode; or a full facepiece air-purifying respirator.

(D) Provide a combination HEPA filter and organic vapor canister or cartridge with powered or non-powered air-purifying respirators when MDA is in liquid form or used as part of a process requiring heat.

(ii) Any employee who cannot use a negative-pressure respirator must be given the option of using a positive-pressure respirator, or a supplied-air respirator operated in the continuous-flow or pressure-demand mode.

(i) Protective work clothing and equipment

(1) Provision and use. Where employees are subject to dermal exposure to MDA, where liquids containing MDA can be splashed into the eyes, or where airborne concentrations of MDA are in excess of the PEL, the employer shall provide, at no cost to the employee, and ensure that the employee uses, appropriate protective work clothing and equipment which prevent contact with MDA such as, but not limited to:

(i) Aprons, coveralls or other full-body work clothing;

(ii) Gloves, head coverings, and foot coverings; and

(iii) Face shields, chemical goggles; or

(iv) Other appropriate protective equipment which comply with 1910.133.

(2) Removal and storage.

(i) The employer shall ensure that, at the end of their work shift, employees remove MDA-contaminated protective work clothing and equipment that is not routinely removed throughout the day in change rooms provided in accordance with the provisions established for change rooms.

(ii) The employer shall ensure that, during their work shift, employees remove all other MDA-contaminated protective work clothing or equipment before leaving a regulated area.

(iii) The employer shall ensure that no employee takes MDA-contaminated work clothing or equipment out of the change room, except those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(iv) MDA-contaminated work clothing or equipment shall be placed and stored in closed containers which prevent dispersion of the MDA outside the container.

(v) Containers of MDA-contaminated protective work clothing or equipment which are to be taken out of change rooms or the workplace for cleaning, maintenance, or disposal, shall bear labels warning of the hazards of MDA.

(3) Cleaning and replacement.

(i) The employer shall provide the employee with clean protective clothing and equipment. The employer shall ensure that protective work clothing or equipment required by this paragraph is cleaned, laundered, repaired, or replaced at intervals appropriate to maintain its effectiveness.

(ii) The employer shall prohibit the removal of MDA from protective work clothing or equipment by blowing, shaking, or any methods which allow MDA to re-enter the workplace.

(iii) The employer shall ensure that laundering of MDA-contaminated clothing shall be done so as to prevent the release of MDA in the workplace.

(iv) Any employer who gives MDA-contaminated clothing to another person for laundering shall inform such person of the requirement to prevent the release of MDA.

(v) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with MDA of the potentially harmful effects of exposure.

(vi) MDA-contaminated clothing shall be transported in properly labeled, sealed, impermeable bags or containers.

(j) Hygiene facilities and practices

(1) Change rooms.

(i) The employer shall provide clean change rooms for employees, who must wear protective clothing, or who must use protective equipment because of their exposure to MDA.

(ii) Change rooms must be equipped with separate storage for protective clothing and equipment and for street clothes which prevents MDA contamination of street clothes.

(2) Showers.

(i) The employer shall ensure that employees, who work in areas where there is the potential for exposure resulting from airborne MDA (e.g., particulates or vapors) above the action level, shower at the end of the work shift.

(A) Shower facilities required by this paragraph shall comply with 1910.141(d)(3).

(B) The employer shall ensure that employees who are required to shower pursuant to the provisions contained herein do not leave the workplace wearing any protective clothing or equipment worn during the work shift.

(ii) Where dermal exposure to MDA occurs, the employer shall ensure that materials spilled or deposited on the skin are removed as soon as possible by methods which do not facilitate the dermal absorption of MDA.

(3) Lunch facilities

(i) Availability and construction.

(A) Whenever food or beverages are consumed at the worksite and employees are exposed to MDA at or above the PEL or are subject to dermal exposure to MDA the employer shall provide readily accessible lunch areas.

(B) Lunch areas located within the workplace and in areas where there is the potential for airborne exposure to MDA at or above the PEL shall have a positive pressure, temperature controlled, filtered air supply.

(C) Lunch areas may not be located in areas within the workplace where the

potential for dermal exposure to MDA exists.

(ii) The employer shall ensure that employees who have been subjected to dermal exposure to MDA or who have been exposed to MDA above the PEL wash their hands and faces with soap and water prior to eating, drinking, smoking, or applying cosmetics.

(iii) The employer shall ensure that employees exposed to MDA do not enter lunch facilities with MDA-contaminated protective work clothing or equipment.

(k) ~~Communication of hazards to employees~~ Communication of hazards

(1) ~~Signs and labels~~ Hazard communication—general.

~~(i) The employer shall post and maintain legible signs demarcating regulated areas and entrances or accessways to regulated areas that bear the following legend: Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for MDA.~~

~~DANGER MDA MAY CAUSE CANCER LIVER TOXIN AUTHORIZED PERSONNEL ONLY RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA~~

~~(ii) The employer shall ensure that labels or other appropriate forms of warning are provided for containers of MDA within the workplace. The labels shall comply with the requirements of 29 CFR 1910.1200(f) and shall include the following legend: In classifying the hazards of MDA at least the following hazards are to be addressed: Cancer; liver effects; and skin sensitization.~~

~~———(A) For Pure MDA~~

~~DANGER CONTAINS MDA MAY CAUSE CANCER LIVER TOXIN~~

~~———(B) For mixtures containing MDA~~

~~DANGER CONTAINS MDA CONTAINS MATERIALS WHICH MAY CAUSE CANCER LIVER TOXIN~~

~~(iii) Employers shall include MDA in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of MDA and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (k)(4) of this section.~~

(2)(i) ~~Material safety data sheets (MSDS)~~ Signs.

(A) The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:

DANGER

MDA

MAY CAUSE CANCER

CAUSES DAMAGE TO THE LIVER

RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA

AUTHORIZED PERSONNEL ONLY

~~(i) Employers shall obtain or develop, and shall provide access to their employees, to a material safety data sheet (MSDS) for MDA. In meeting this obligation, employers shall make appropriate use of the information found in Appendices A and B.~~

(B) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (k)(2)(i)(A) of this section:

DANGER

MDA

MAY CAUSE CANCER

LIVER TOXIN

AUTHORIZED PERSONNEL ONLY

RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA

(ii) Labels. Prior to June 1, 2015, employers may include the following information workplace labels in lieu of the labeling requirements in paragraph (k)(1) of this section:

(A) For pure MDA:

DANGER

CONTAINS MDA

MAY CAUSE CANCER

LIVER TOXIN

(B) For mixtures containing MDA:

DANGER

CONTAINS MDA

CONTAINS MATERIALS WHICH MAY CAUSE CANCER

LIVER TOXIN

~~(ii) Employers who are manufacturers or importers shall:~~

~~——(A) Comply with paragraph (k) (1) (ii) of this section as appropriate, and~~

~~——(B) Comply with the requirement in OSHA's Hazard Communication standard, 29 CFR 1910.1200, that they deliver to downstream employers an MSDS for MDA.~~

(3) Safety data sheets (SDS). In meeting the obligation to provide safety data sheets, employers shall make appropriate use of the information found in Appendices A and B to § 1910.1050.

(3)(4) Information and training.

(i) The employer shall provide employees with information and training on MDA, in accordance with 29 CFR 1910.1200(h), at the time of initial assignment and at least annually thereafter.

(ii) In addition to the information required under 29 CFR 1910.1200, the employer shall:

(A) Provide an explanation of the contents of this section, including appendices A and B, and indicate to employees where a copy of the standard is available;

(B) Describe the medical surveillance program required under paragraph (m) of this section, and explain the information contained in Appendix C; and

(C) Describe the medical removal provision required under paragraph (m) of this section.

(4)(5) Access to training materials.

(i) The employer shall make readily available to all affected employees, without cost, all written materials relating to the employee training program, including a copy of this regulation.

(ii) The employer shall provide to the Assistant Secretary and the Director, upon request, all information and training materials relating to the employee information and training program.

(1) Housekeeping.

(1) All surfaces shall be maintained as free as practicable of visible accumulations of MDA.

(2) The employer shall institute a program for detecting MDA leaks, spills, and discharges, including regular visual inspections of operations involving liquid or solid MDA.

(3) All leaks shall be repaired and liquid or dust spills cleaned up promptly.

(4) Surfaces contaminated with MDA may not be cleaned by the use of compressed air.

(5) Shoveling, dry sweeping, and other methods of dry clean-up of MDA may be used where HEPA-filtered vacuuming and/or wet cleaning are not feasible or practical.

(6) Waste, scrap, debris, bags, containers, equipment, and clothing contaminated with MDA shall be collected and disposed of in a manner to prevent the re-entry of MDA into the workplace.

(m) Medical surveillance

(1) General.

(i) The employer shall make available a medical surveillance program for employees exposed to MDA:

(A) Employees exposed at or above the action level for 30 or more days per year;

(B) Employees who are subject to dermal exposure to MDA for 15 or more days per year;

(C) Employees who have been exposed in an emergency situation;

(D) Employees whom the employer, based on results from compliance with paragraph (e)(8) of this section, has reason to believe are being dermally exposed; and

(E) Employees who show signs or symptoms of MDA exposure.

(ii) The employer shall ensure that all medical examinations and procedures are performed by, or under the supervision of, a licensed physician, at a reasonable time and place, and provided without cost to the employee.

(2) Initial examinations.

(i) Within 150 days of the effective date of this standard, or before the time of initial assignment, the employer shall provide each employee covered by paragraph (m)(1)(i) of this section with a medical examination including the following elements:

(A) A detailed history which includes:

(1) Past work exposure to MDA or any other toxic substances;

(2) A history of drugs, alcohol, tobacco, and medication routinely taken (duration and quantity); and

(3) A history of dermatitis, chemical skin sensitization, or previous hepatic disease.

(B) A physical examination which includes all routine physical examination parameters, skin examination, and signs of liver disease.

(C) Laboratory tests including:

(1) Liver function tests and

(2) Urinalysis.

(D) Additional tests as necessary in the opinion of the physician.

(ii) No initial medical examination is required if adequate records show that the employee has been examined in accordance with the requirements of this section within the previous six months prior to the effective date of this standard or prior to the date of initial assignment.

(3) Periodic examinations.

(i) The employer shall provide each employee covered by this section with a medical examination at least annually following the initial examination. These periodic examinations shall include at least the following elements:

(A) A brief history regarding any new exposure to potential liver toxins, changes in drug, tobacco, and alcohol intake, and the appearance of physical signs relating to the liver, and the skin;

(B) The appropriate tests and examinations including liver function tests and skin examinations; and

(C) Appropriate additional tests or examinations as deemed necessary by the physician.

(ii) If in the physicians' opinion the results of liver function tests indicate an abnormality, the employee shall be removed from further MDA exposure in accordance with paragraph (m)(9) of this section. Repeat liver function tests shall be conducted on advice of the physician.

(4) Emergency examinations. If the employer determines that the employee has been

exposed to a potentially hazardous amount of MDA in an emergency situation as addressed in paragraph (d) of this section, the employer shall provide medical examinations in accordance with paragraphs (m)(3)(i) and (ii) of this section. If the results of liver function testing indicate an abnormality, the employee shall be removed in accordance with paragraph (m)(9) of this section. Repeat liver function tests shall be conducted on the advice of the physician. If the results of the tests are normal, tests must be repeated two to three weeks from the initial testing. If the results of the second set of tests are normal and on the advice of the physician, no additional testing is required.

(5) Additional examinations. Where the employee develops signs and symptoms associated with exposure to MDA, the employer shall provide the employee with an additional medical examination including a liver function test. Repeat liver function tests shall be conducted on the advice of the physician. If the results of the tests are normal, tests must be repeated two to three weeks from the initial testing. If the results of the second set of tests are normal and, on the advice of the physician, no additional testing is required.

(6) Multiple physician review mechanism.

(i) If the employer selects the initial physician who conducts any medical examination or consultation provided to an employee under this section, and the employee has signs or symptoms of occupational exposure to MDA (which could include an abnormal liver function test), and the employee disagrees with the opinion of the examining physician, and this opinion could affect the employee's job status, the employee may designate an appropriate, mutually acceptable second physician:

(A) To review any findings, determinations, or recommendations of the initial physician; and

(B) To conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

(ii) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation pursuant to this section. The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the foregoing notification, or receipt of the initial physician's written opinion, whichever is later:

(A) The employee informing the employer that he or she intends to seek a second medical opinion, and

(B) The employee initiating s to make an appointment with a second physician.

(iii) If the findings, determinations, or recommendations of the second physician differ

from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve any disagreement.

(iv) If the two physicians have been unable to resolve quickly their disagreement, then the employer and the employee through their respective physicians shall designate a third physician;

(A) To review any findings, determinations, or recommendations of the prior physicians; and

(B) To conduct such examinations, consultations, laboratory tests, and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(v) The employer shall act consistent with the findings, determinations, and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(7) Information provided to the examining and consulting physicians.

(i) The employer shall provide the following information to the examining physician:

(A) A copy of this regulation and its appendices;

(B) A description of the affected employee's duties as they relate to the employee's potential exposure to MDA;

(C) The employee's current actual or representative MDA exposure level;

(D) A description of any personal protective equipment used or to be used; and

(E) Information from previous employment-related medical examinations of the affected employee.

(ii) The employer shall provide the foregoing information to a second physician under this section upon request either by the second physician, or by the employee.

(8) Physician's written opinion.

(i) For each examination under this section, the employer shall obtain, and provide the employee with a copy of, the examining physician's written opinion within 15 days of its receipt. The written opinion shall include the following:

(A) The occupationally-pertinent results of the medical examination and tests;

(B) The physician's opinion concerning whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of health from exposure to MDA;

(C) The physician's recommended limitations upon the employee's exposure to MDA or upon the employee's use of protective clothing or equipment and respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from MDA exposure which require further explanation or treatment.

(ii) The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposures.

(9) Medical removal

(i) Temporary medical removal of an employee

(A) Temporary removal resulting from occupational exposure. The employee shall be removed from work environments in which exposure to MDA is at or above the action level or where dermal exposure to MDA may occur, following an initial examination (paragraph (m)(2) of this section), periodic examinations (paragraph (m)(3) of this section), an emergency situation paragraph (m)(4) of this section, or an additional examination (paragraph (m)(5) of this section) in the following circumstances:

(1) When the employee exhibits signs and/or symptoms indicative of acute exposure to MDA; or

(2) When the examining physician determines that an employee's abnormal liver function tests are not associated with MDA exposure but that the abnormalities may be exacerbated as a result of occupational exposure to MDA.

(B) Temporary removal due to a final medical determination.

(1) The employer shall remove an employee from work environments in which exposure to MDA is at or above the action level or where dermal exposure to MDA may occur, on each occasion that there is a final medical determination or opinion that the employee has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to MDA.

(2) For the purposes of this section, the phrase "final medical determination" shall mean the outcome of the physician review mechanism used pursuant to the

medical surveillance provisions of this section.

(3) Where a final medical determination results in any recommended special protective measures for an employee, or limitations on an employee's exposure to MDA, the employer shall implement and act consistent with the recommendation.

(ii) Return of the employee to former job status.

(A) The employer shall return an employee to his or her former job status:

(1) When the employee no longer shows signs or symptoms of exposure to MDA, or upon the advice of the physician.

(2) When a subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to MDA.

(B) For the purposes of this section, the requirement that an employer return an employee to his or her former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

(iii) Removal of other employee special protective measure or limitations. The employer shall remove any limitations placed on an employee, or end any special protective measures provided to an employee, pursuant to a final medical determination, when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

(iv) Employer options pending a final medical determination. Where the physician review mechanism used pursuant to the medical surveillance provisions of this section, has not yet resulted in a final medical determination with respect to an employee, the employer shall act as follows:

(A) Removal. The employer may remove the employee from exposure to MDA, provide special protective measures to the employee, or place limitations upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status.

(B) Return. The employer may return the employee to his or her former job status, and end any special protective measures provided to the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions.

(1) If the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician; or

(2) If the employee has been on removal status for the preceding six months as a result of exposure to MDA, then the employer shall await a final medical determination.

(v) Medical removal protection benefits

(A) Provisions of medical removal protection benefits. The employer shall provide to an employee up to six (6) months of medical removal protection benefits on each occasion that an employee is removed from exposure to MDA or otherwise limited pursuant to this section.

(B) Definition of medical removal protection benefits. For the purposes of this section, the requirement that an employer provide medical removal protection benefits means that the employer shall maintain the earnings, seniority, and other employment rights and benefits of an employee as though the employee had not been removed from normal exposure to MDA or otherwise limited.

(C) Follow-up medical surveillance during the period of employee removal or limitations. During the period of time that an employee is removed from normal exposure to MDA or otherwise limited, the employer may condition the provision of medical removal protection benefits upon the employee's participation in follow-up medical surveillance made available pursuant to this section.

(D) Workers' compensation claims. If a removed employee files a claim for workers' compensation payments for a MDA-related disability, then the employer shall continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation shall be reduced by such amount. The employer shall receive no credit for workers' compensation payments received by the employee for treatment-related expenses.

(E) Other credits. The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from non-MDA-related employment with any employer made possible by virtue of the employee's removal.

(F) Employees who do not recover within the 6 months of removal. The employer

shall take the following measures with respect to any employee removed from exposure to MDA:

(1) The employer shall make available to the employee a medical examination pursuant to this section to obtain a final medical determination with respect to the employee;

(2) The employer shall assure that the final medical determination obtained indicates whether or not the employee may be returned to his or her former job status, and, if not, what s should be taken to protect the employee's health;

(3) Where the final medical determination has not yet been obtained, or, once obtained indicates that the employee may not yet be returned to his or her former job status, the employer shall continue to provide medical removal protection benefits to the employee until either the employee is returned to former job status, or a final medical determination is made that the employee is incapable of ever safely returning to his or her former job status; and

(4) Where the employer acts pursuant to a final medical determination which permits the return of the employee to his or her former job status, despite what would otherwise be an abnormal liver function test, later questions concerning removing the employee again shall be decided by a final medical determination. The employer need not automatically remove such an employee pursuant to the MDA removal criteria provided by this section.

(vi) Voluntary removal or restriction of an employee. Where an employer, although not required by this section to do so, removes an employee from exposure to MDA or otherwise places limitations on an employee due to the effects of MDA exposure on the employee's medical condition, the employer shall provide medical removal protection benefits to the employee equal to that required by paragraph (m)(9)(v) of this section.

(n) Recordkeeping

(1) Monitoring data for exempted employers.

(i) Where as a result of the initial monitoring the processing, use, or handling of products made from or containing MDA are exempted from other requirements of this section under paragraph (a)(2) of this section, the employer shall establish and maintain an accurate record of monitoring relied on in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product qualifying for exemption;

(B) The source of the monitoring data (e.g., was monitoring performed by the employer or a private contractor);

(C) The testing protocol, results of testing, and/or analysis of the material for the release of MDA;

(D) A description of the operation exempted and how the data support the exemption (e.g., are the monitoring data representative of the conditions at the affected facility); and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) Objective data for exempted employers.

(i) Where the processing, use, or handling of products made from or containing MDA are exempted from other requirements of this section under paragraph (a) of this section, the employer shall establish and maintain an accurate record of objective data relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of MDA;

(D) A description of the operation exempted and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(3) Exposure measurements.

(i) The employer shall establish and maintain an accurate record of all measurements required by paragraph (e) of this section, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the procedure used to determine representative employee exposures;

(B) Identification of the sampling and analytical methods used;

(C) A description of the type of respiratory protective devices worn, if any; and

(D) The name, social security number, job classification and exposure levels of the employee monitored and all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 30 years, in accordance with 29 CFR 1910.1020.

(4) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance required by paragraph (m) of this section, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The name, social security number and description of the duties of the employee;

(B) The employer's copy of the physician's written opinion on the initial, periodic, and any special examinations, including results of medical examination and all tests, opinions, and recommendations;

(C) Results of any airborne exposure monitoring done for that employee and the representative exposure levels supplied to the physician; and

(D) Any employee medical complaints related to exposure to MDA;

(iii) The employer shall keep, or assure that the examining physician keeps, the following medical records:

(A) A copy of this standard and its appendices, except that the employer may keep one copy of the standard and its appendices for all employees provided the employer references the standard and its appendices in the medical surveillance record of each employee;

(B) A copy of the information provided to the physician as required by any paragraphs in the regulatory text;

(C) A description of the laboratory procedures and a copy of any standards or guidelines used to interpret the test results or references to the information;

(D) A copy of the employee's medical and work history related to exposure to MDA; and

(iv) The employer shall maintain this record for at least the duration of employment plus 30 years, in accordance with 29 CFR 1910.1020.

(5) Medical removals.

(i) The employer shall establish and maintain an accurate record for each employee removed from current exposure to MDA pursuant to paragraph (m) of this section.

(ii) Each record shall include:

(A) The name and social security number of the employee;

(B) The date of each occasion that the employee was removed from current exposure to MDA as well as the corresponding date on which the employee was returned to his or her former job status;

(C) A brief explanation of how each removal was or is being accomplished; and

(D) A statement with respect to each removal indicating the reason for the removal.

(iii) The employer shall maintain each medical removal record for at least the duration of an employee's employment plus 30 years.

(6) Availability.

(i) The employer shall assure that records required to be maintained by this section shall be made available, upon request, to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure monitoring records required by this section shall be provided upon request for examination and copying to employees, employee representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a)-(e) and (g)-(i).

(iii) Employee medical records required by this section shall be provided upon request for examination and copying, to the subject employee, to anyone having the specific written consent of the subject employee, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

(7) Transfer of records. The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(o) Observation of monitoring

(1) Employee observation. The employer shall provide affected employees, or their designated representatives, an opportunity to observe the measuring or monitoring of employee exposure to MDA conducted pursuant to paragraph (e) of this section.

(2) Observation procedures. When observation of the measuring or monitoring of employee exposure to MDA requires entry into areas where the use of protective clothing and equipment or respirators is required, the employer shall provide the observer with personal protective clothing and equipment or respirators required to be worn by employees working in the area, assure the use of such clothing and equipment or respirators, and require the observer to comply with all other applicable safety and health procedures.

(p) [Reserved]

(q) Appendices. The information contained in Appendices A, B, C, and D of this section is not intended, by itself, to create any additional obligations not otherwise imposed by this standard nor detract from any existing obligation.

Appendix A to Section 1910.1050.-Substance Safety Data Sheet for 4,4'-Methylenedianiline

I. Substance Identification

A. Substance: Methylenedianiline (MDA)

B. Permissible Exposure:

1. Airborne: Ten parts per billion parts of air (10 ppb), time-weighted average (TWA) for an 8-hour workday and an action level of five parts per billion parts of air (5 ppb).

2. Dermal: Eye contact and skin contact with MDA are not permitted.

C. Appearance and odor: White to tan solid; amine odor

II. Health Hazard Data

A. Ways in which MDA affects your health. MDA can affect your health if you inhale it, or if it comes in contact with your skin or eyes. MDA is also harmful if you happen to swallow it. Do not get MDA in eyes, on skin, or on clothing.

B. Effects of overexposure.

1. Short-term (acute) overexposure: Overexposure to MDA may produce fever, chills, loss of appetite, vomiting, jaundice. Contact may irritate skin, eyes and mucous membranes. Sensitization may occur.

2. Long-term (chronic) exposure. Repeated or prolonged exposure to MDA, even at relatively low concentrations, may cause cancer. In addition, damage to the liver, kidneys, blood, and spleen may occur with long term exposure.

3. Reporting signs and symptoms: You should inform your employer if you develop any signs or symptoms which you suspect are caused by exposure to MDA including yellow staining of the skin.

III. Protective Clothing and Equipment

A. Respirators. Respirators are required for those operations in which engineering controls or work-practice controls are not adequate or feasible to reduce exposure to the permissible limit. If respirators are worn, they must have a label issued by the National Institute for Occupational Safety and Health under the provisions of 42 CFR part 84 stating that the respirators have been approved for this purpose, and cartridges and canisters must be replaced in accordance with the requirements of 29 CFR 1910.134. If you experience difficulty breathing while wearing a respirator, you may request a positive- pressure respirator from your employer. You must be thoroughly trained to use the assigned respirator, and the training will be provided by your employer.

MDA does not have a detectable odor except at levels well above the permissible exposure limits. Do not depend on odor to warn you when a respirator canister is exhausted. If you can smell MDA while wearing a respirator, proceed immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. Protective Clothing. You may be required to wear coveralls, aprons, gloves, face shields, or other appropriate protective clothing to prevent skin contact with MDA. Where protective clothing is required, your employer is required to provide clean garments to you, as necessary, to assure that the clothing protects you adequately. Replace or repair impervious clothing that has developed leaks.

MDA should never be allowed to remain on the skin. Clothing and shoes which are not

impervious to MDA should not be allowed to become contaminated with MDA, and if they do, the clothing and shoes should be promptly removed and decontaminated. The clothing should be laundered to remove MDA or discarded. Once MDA penetrates shoes or other leather articles, they should not be worn again.

C. Eye protection. You must wear splashproof safety goggles in areas where liquid MDA may contact your eyes. Contact lenses should not be worn in areas where eye contact with MDA can occur. In addition, you must wear a face shield if your face could be splashed with MDA liquid.

IV. Emergency and First Aid Procedures

A. Eye and face exposure. If MDA is splashed into the eyes, wash the eyes for at least 15 minutes. See a doctor as soon as possible.

B. Skin exposure. If MDA is spilled on your clothing or skin, remove the contaminated clothing and wash the exposed skin with large amounts of soap and water immediately. Wash contaminated clothing before you wear it again.

C. Breathing. If you or any other person breathes in large amounts of MDA, get the exposed person to fresh air at once. Apply artificial respiration if breathing has stopped. Call for medical assistance or a doctor as soon as possible. Never enter any vessel or confined space where the MDA concentration might be high without proper safety equipment and at least one other person present who will stay outside. A life line should be used.

D. Swallowing. If MDA has been swallowed and the patient is conscious, do not induce vomiting. Call for medical assistance or a doctor immediately.

V. Medical Requirements

If you are exposed to MDA at a concentration at or above the action level for more than 30 days per year, or exposed to liquid mixtures more than 15 days per year, your employer is required to provide a medical examination, including a medical history and laboratory tests, within 60 days of the effective date of this standard and annually thereafter. These tests shall be provided without cost to you. In addition, if you are accidentally exposed to MDA (either by ingestion, inhalation, or skin/eye contact) under conditions known or suspected to constitute toxic exposure to MDA, your employer is required to make special examinations and tests available to you.

VI. Observation of Monitoring

Your employer is required to perform measurements that are representative of your exposure to MDA and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the s taken in the measurement procedure and to record the results

obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you and your representative must also be provided with, and must wear, the protective clothing and equipment.

VII. Access to Records

You or your representative are entitled to see the records of measurements of your exposure to MDA upon written request to your employer. Your medical examination records can be furnished to your physician or designated representative upon request by you to your employer.

VIII. Precautions for Safe Use, Handling and Storage

A. Material is combustible. Avoid strong acids and their anhydrides. Avoid strong oxidants. Consult supervisor for disposal requirements.

B. Emergency clean-up. Wear self-contained breathing apparatus and fully clothe the body in the appropriate personal protective clothing and equipment.

Appendix B to Section 1910.1050-Substance Technical Guidelines, MDA

I. Identification

A. Substance identification.

1. Synonyms: CAS No. 101-77-9. 4,4'-methylenedianiline; 4,4'-methylenebis(aniline); methylenedianiline; dianilinomethane.

2. Formula: C₁₃H₁₄N₂

II. Physical Data

1. Appearance and Odor: White to tan solid; amine odor

2. Molecular Weight: 198.26

3. Boiling Point: 398-399 degrees C at 760 mm Hg

4. Melting Point: 88-93 degrees C (190-100 degrees F)

5. Vapor Pressure: 9 mmHg at 232 degrees C

6. Evaporation Rate (n-butyl acetate = 1): Negligible

7. Vapor Density (Air=1): Not Applicable

8. Volatile Fraction by Weight: Negligible

9. Specific Gravity (Water=1): Slight

10. Heat of Combustion: -8.40 kcal/g

11. Solubility in Water: Slightly soluble in cold water, very soluble in alcohol, benzene, ether, and many organic solvents.

III. Fire, Explosion, and Reactivity Hazard Data

1. Flash Point: 190 degrees C (374 degrees F) Setflash closed cup

2. Flash Point: 226 degrees C (439 degrees F) Cleveland open cup

3. Extinguishing Media: Water spray; Dry Chemical; Carbon dioxide.

4. Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

5. Unusual Fire and Explosion Hazards: Fire or excessive heat may cause production of hazardous decomposition products.

IV. Reactivity Data

1. Stability: Stable

2. Incompatibility: Strong oxidizers

3. Hazardous Decomposition Products: As with any other organic material, combustion may produce carbon monoxide. Oxides of nitrogen may also be present.

4. Hazardous Polymerization: Will not occur.

V. Spill and Leak Procedures

1. Sweep material onto paper and place in fiber carton.

2. Package appropriately for safe feed to an incinerator or dissolve in compatible waste solvents prior to incineration.

3. Dispose of in an approved incinerator equipped with afterburner and scrubber or contract

with licensed chemical waste disposal service.

4. Discharge treatment or disposal may be subject to federal, state, or local laws.

5. Wear appropriate personal protective equipment.

VI. Special Storage and Handling Precautions

A. High exposure to MDA can occur when transferring the substance from one container to another. Such operations should be well ventilated and good work practices must be established to avoid spills.

B. Pure MDA is a solid with a low vapor pressure. Grinding or heating operations increase the potential for exposure.

C. Store away from oxidizing materials.

D. Employers shall advise employees of all areas and operations where exposure to MDA could occur.

VII. Housekeeping and Hygiene Facilities

A. The workplace should be kept clean, orderly, and in a sanitary condition.

The employer should institute a leak and spill detection program for operations involving MDA in order to detect sources of fugitive MDA emissions.

B. Adequate washing facilities with hot and cold water are to be provided and maintained in a sanitary condition. Suitable cleansing agents should also be provided to assure the effective removal of MDA from the skin.

VIII. Common Operations

Common operations in which exposure to MDA is likely to occur include the following: Manufacture of MDA; Manufacture of Methylene diisocyanate; Curing agent for epoxy resin structures; Wire coating operations; and filament winding.

Appendix C to Section 1910.1050-Medical Surveillance Guidelines for MDA

I. Route of Entry

Inhalation; skin absorption; ingestion. MDA can be inhaled, absorbed through the skin, or ingested.

II. Toxicology

MDA is a suspect carcinogen in humans. There are several reports of liver disease in humans and animals resulting from acute exposure to MDA. A well documented case of an acute cardiomyopathy secondary to exposure to MDA is on record. Numerous human cases of hepatitis secondary to MDA are known. Upon direct contact MDA may also cause damage to the eyes. Dermatitis and skin sensitization have been observed. Almost all forms of acute environmental hepatic injury in humans involve the hepatic parenchyma and produce hepatocellular jaundice. This agent produces intrahepatic cholestasis. The clinical picture consists of cholestatic jaundice, preceded or accompanied by abdominal pain, fever, and chills. Onset in about 60% of all observed cases is abrupt with severe abdominal pain. In about 30% of observed cases, the illness presented and evolved more slowly and less dramatically, with only slight abdominal pain. In about 10% of the cases only jaundice was evident. The cholestatic nature of the jaundice is evident in the prominence of itching, the histologic predominance of bile stasis, and portal inflammatory infiltration, accompanied by only slight parenchymal injury in most cases, and by the moderately elevated transaminase values. Acute, high doses, however, have been known to cause hepatocellular damage resulting in elevated SGPT, SGOT, alkaline phosphatase and bilirubin.

Absorption through the skin is rapid. MDA is metabolized and excreted over a 48-hour period. Direct contact may be irritating to the skin, causing dermatitis. Also MDA which is deposited on the skin is not thoroughly removed through washing.

MDA may cause bladder cancer in humans. Animal data supporting this assumption is not available nor is conclusive human data. However, human data collected on workers at a helicopter manufacturing facility where MDA is used suggests a higher incidence of bladder cancer among exposed workers.

III. Signs and Symptoms

Skin may become yellow from contact with MDA.

Repeated or prolonged contact with MDA may result in recurring dermatitis (red-itchy, cracked skin) and eye irritation. Inhalation, ingestion or absorption through the skin at high concentrations may result in hepatitis, causing symptoms such as fever and chills, nausea and vomiting, dark urine, anorexia, rash, right upper quadrant pain and jaundice. Corneal burns may occur when MDA is splashed in the eyes.

IV. Treatment of Acute Toxic Effects/Emergency Situation

If MDA gets into the eyes, immediately wash eyes with large amounts of water. If MDA is splashed on the skin, immediately wash contaminated skin with mild soap or detergent.

Employee should be removed from exposure and given proper medical treatment. Medical tests required under the emergency section of the medical surveillance section (M)(4) must be conducted.

If the chemical is swallowed do not induce vomiting but remove by gastric lavage.

Appendix D to Section 1910.1050-Sampling and Analytical Methods for MDA Monitoring and Measurement Procedures

Measurements taken for the purpose of determining employee exposure to MDA are best taken so that the representative average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Short-time interval samples (or grab samples) may also be used to determine average exposure level if a minimum of five measurements are taken in a random manner over the 8-hour work shift. Random sampling means that any portion of the work shift has the same chance of being sampled as any other. The arithmetic average of all such random samples taken on one work shift is an estimate of an employee's average level of exposure for that work shift. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

There are a number of methods available for monitoring employee exposures to MDA. The method OSHA currently uses is included below.

The employer, however, has the obligation of selecting any monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring must have an accuracy, to a 95 percent confidence level, of not less than plus or minus 25 percent for the select PEL.

OSHA Methodology

Sampling Procedure

Apparatus

Samples are collected by use of a personal sampling pump that can be calibrated within 5% of the recommended flow rate with the sampling filter in line.

Samples are collected on 37 mm Gelman type A/E glass fiber filters treated with sulfuric acid. The filters are prepared by soaking each filter with 0.5 mL of 0.26N H₂SO₄. (0.26 N H₂SO₄ can be prepared by diluting 1.5 mL of 36N H₂SO₄ to 200 mL with deionized water.) The filters are dried in an oven at 100 degrees C for one hour and then assembled into two-piece 37 mm polystyrene cassettes with backup pads. The cassettes are sealed with shrink bands and the ends are plugged with plastic plugs.

After sampling, the filters are carefully removed from the cassettes and individually transferred to small vials containing approximately 2 mL deionized water. The vials must be tightly sealed. The water can be added before or after the filters are transferred. The vials must be sealable and capable of holding at least 7 mL of liquid. Small glass scintillation vials with caps containing Teflon liners are recommended.

Reagents

Deionized water is needed for addition to the vials.

Sampling Technique

Immediately before sampling, remove the plastic plugs from the filter cassettes.

Attach the cassette to the sampling pump with flexible tubing and place the cassette in the employee's breathing zone.

After sampling, seal the cassettes with plastic plugs until the filters are transferred to the vials containing deionized water.

At some convenient time within 10 hours of sampling, transfer the sample filters to vials.

Seal the small vials lengthwise.

Submit at least one blank filter with each sample set. Blanks should be handled in the same manner as samples, but no air is drawn through them.

Record sample volumes (in L of air) for each sample, along with any potential interferences.

Retention Efficiency

A retention efficiency study was performed by drawing 100 L of air (80% relative humidity) at 1 L/min through sample filters that had been spiked with 0.814 μg MDA. Instead of using backup pads, blank acid-treated filters were used as backups in each cassette. Upon analysis, the top filters were found to have an average of 91.8% of the spiked amount. There was no MDA found on the bottom filters, so the amount lost was probably due to the slight instability of the MDA salt.

Extraction Efficiency

The average extraction efficiency for six filters spiked at the target concentration is 99.6%.

The stability of extracted and derivatized samples was verified by reanalyzing the above six

samples the next day using fresh standards. The average extraction efficiency for the reanalyzed samples is 98.7%.

Recommended Air Volume and Sampling Rate

The recommended air volume is 100 L.

The recommended sampling rate is 1 L/min.

Interferences (Sampling)

MDI appears to be a positive interference. It was found that when MDI was spiked onto an acid-treated filter, the MDI converted to MDA after air was drawn through it.

Suspected interferences should be reported to the laboratory with submitted samples.

Safety Precautions (Sampling)

Attach the sampling equipment to the employees so that it will not interfere with work performance or safety.

Follow all safety procedures that apply to the work area being sampled.

Analytical Procedure

Apparatus: The following are required for analysis.

A GC equipped with an electron capture detector. For this evaluation a Tracor 222 Gas Chromatograph equipped with a Nickel 63 High Temperature Electron Capture Detector and a Linearizer was used.

A GC column capable of separating the MDA derivative from the solvent and interferences. A 6 ft X 2 mm ID glass column packed with 3% OV-101 coated on 100/120 Gas Chrom Q was used in this evaluation.

A electronic integrator or some other suitable means of measuring peak areas or heights.

Small resealable vials with Teflon-lined caps capable of holding 4 mL.

A dispenser or pipet for toluene capable of delivering 2.0 mL.

Pipets (or repipets with plastic or Teflon tips) capable of delivering 1 mL for the sodium hydroxide and buffer solutions.

A repipet capable of delivering 25 μ L HFAA.

Syringes for preparation of standards and injection of standards and samples into a GC.

Volumetric flasks and pipets to dilute the pure MDA in preparation of standards.

Disposable pipets to transfer the toluene layers after the samples are extracted.

Reagents

0.5 NaOH prepared from reagent grade NaOH.

Toluene, pesticide grade. Burdick and Jackson distilled in glass toluene was used.

Heptafluorobutyric acid anhydride (HFAA). HFAA from Pierce Chemical Company was used.

pH 7.0 phosphate buffer, prepared from 136 g potassium dihydrogen phosphate and 1 L deionized water. The pH is adjusted to 7.0 with saturated sodium hydroxide solution.

4,4'-Methylenedianiline (MDA), reagent grade.

Standard Preparation

Concentrated stock standards are prepared by diluting pure MDA with toluene. Analytical standards are prepared by injecting μ L amounts of diluted stock standards into vials that contain 2.0 mL toluene.

25 μ L HFAA are added to each vial and the vials are capped and shaken for 10 seconds.

After 10 min, 1 mL of buffer is added to each vial.

The vials are recapped and shaken for 10 seconds.

After allowing the layers to separate, aliquots of the toluene (upper) layers are removed with a syringe and analyzed by GC.

Analytical standard concentrations should bracket sample concentrations. Thus, if samples fall out of the range of prepared standards, additional standards must be prepared to ascertain detector response.

Sample Preparation

The sample filters are received in vials containing deionized water.

1 mL of 0.5N NaOH and 2.0 mL toluene are added to each vial.

The vials are recapped and shaken for 10 min.

After allowing the layers to separate, approximately 1 mL aliquots of the toluene (upper) layers are transferred to separate vials with clean disposable pipets.

The toluene layers are treated and analyzed.

Analysis

GC conditions

Zone temperatures:

Column-220 degrees C

Injector-235 degrees C

Detector-335 degrees C

Gas flows, Ar/CH₄ Column-28 mL/min

(95/5) Purge-40 mL/min

Injection volume: 5.0 uL

Column: 6 ft X 1/8 in ID glass, 3% OV-101 on 100/120 Gas Chrom Q

Retention time of MDA derivative: 3.5 min

Chromatogram

Peak areas or heights are measured by an integrator or other suitable means.

A calibration curve is constructed by plotting response (peak areas or heights) of standard injections versus ug of MDA per sample. Sample concentrations must be bracketed by standards.

Interferences (Analytical)

Any compound that gives an electron capture detector response and has the same general retention time as the HFAA derivative of MDA is a potential interference. Suspected interferences reported to the laboratory with submitted samples by the industrial hygienist must

be considered before samples are derivatized.

GC parameters may be changed to possibly circumvent interferences.

Retention time on a single column is not considered proof of chemical identity. Analyte identity should be confirmed by GC/MS if possible.

Calculations

The analyte concentration for samples is obtained from the calibration curve in terms of ug MDA per sample. The extraction efficiency is 100%. If any MDA is found on the blank, that amount is subtracted from the sample amounts. The air concentrations are calculated using the following formulae.

$$\mu\text{g}/\text{m}^3 = (\mu\text{g MDA per sample}) (1000) / (\text{L of air sampled})$$

$$\text{ppb} = (\mu\text{g}/\text{m}^3) (24.46) / (198.3) = (\mu\text{g}/\text{m}^3) (0.1233) \text{ where } 24.46 \text{ is the molar volume at } 25 \text{ degrees C and } 760 \text{ mm Hg}$$

Safety Precautions (Analytical)

Avoid skin contact and inhalation of all chemicals.

Restrict the use of all chemicals to a fume hood if possible.

Wear safety glasses and a lab coat at all times while in the lab area.

1910.1050 App. E Qualitative and Quantitative Fit Testing Procedures

[Reserved]

1910.1051 1,3-Butadiene

(a) Scope and application.

(1) This section applies to all occupational exposures to 1,3-Butadiene (BD), Chemical Abstracts Service Registry No. 106-99-0, except as provided in paragraph (a)(2) of this section.

(2)

(i) Except for the recordkeeping provisions in paragraph (m)(1) of this section, this section does not apply to the processing, use, or handling of products containing BD or to other

work operations and streams in which BD is present where objective data are reasonably relied upon that demonstrate the work operation or the product or the group of products or operations to which it belongs may not reasonably be foreseen to release BD in airborne concentrations at or above the action level or in excess of the STEL under the expected conditions of processing, use, or handling that will cause the greatest possible release or in any plausible accident.

(ii) This section also does not apply to work operations, products or streams where the only exposure to BD is from liquid mixtures containing 0.1% or less of BD by volume or the vapors released from such liquids, unless objective data become available that show that airborne concentrations generated by such mixtures can exceed the action level or STEL under reasonably predictable conditions of processing, use or handling that will cause the greatest possible release.

(iii) Except for labeling requirements and requirements for emergency response, this section does not apply to the storage, transportation, distribution or sale of BD or liquid mixtures in intact containers or in transportation pipelines sealed in such a manner as to fully contain BD vapors or liquid.

(3) Where products or processes containing BD are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in paragraph (m)(1) of this section.

(b) Definitions: For the purpose of this section, the following definitions shall apply:

"Action level" means a concentration of airborne BD of 0.5 ppm calculated as an eight (8)-hour time-weighted average.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person specifically designated by the employer, whose duties require entrance into a regulated area, or a person entering such an area as a designated representative of employees to exercise the right to observe monitoring and measuring procedures under paragraph (d)(8) of this section, or a person designated under the Act or regulations issued under the Act to enter a regulated area. "1,3-Butadiene" means an organic compound with chemical formula $\text{CH}_2=\text{CH}-\text{CH}=\text{CH}_2$ that has a molecular weight of approximately 54.15 gm/mole.

"Business day" means any Monday through Friday, except those days designated as federal, state, local or company specific holidays.

"Complete Blood Count (CBC)" means laboratory tests performed on whole blood specimens and includes the following: White blood cell count (WBC), hematocrit (Hct), red blood cell count (RBC), hemoglobin (Hgb), differential count of white blood cells, red blood cell morphology, red blood cell indices, and platelet count.

"Day" means any part of a calendar day.

"Director" means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

"Emergency situation" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of BD.

"Employee exposure" means exposure of a worker to airborne concentrations of BD which would occur if the employee were not using respiratory protective equipment.

"Objective data" means monitoring data, or mathematical modelling or calculations based on composition, chemical and physical properties of a material, stream or product.

"Permissible Exposure Limits, PELs" means either the 8 hour Time Weighted Average (8-hr TWA) exposure or the Short-Term Exposure Limit (STEL).

"Physician or other licensed health care professional" is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide one or more of the specific health care services required by paragraph (k) of this section.

"Regulated area" means any area where airborne concentrations of BD exceed or can reasonably be expected to exceed the 8-hour time weighted average (8-hr TWA) exposure of 1 ppm or the short-term exposure limit (STEL) of 5 ppm for 15 minutes. "This section" means this 1,3-butadiene standard.

(c) Permissible exposure limits (PELs). --

(1) Time-weighted average (TWA) limit. The employer shall ensure that no employee is exposed to an airborne concentration of BD in excess of one (1) part BD per million parts of air (ppm) measured as an eight (8)-hour time-weighted average.

(2) Short-term exposure limit (STEL). The employer shall ensure that no employee is exposed to an airborne concentration of BD in excess of five parts of BD per million parts of air (5 ppm) as determined over a sampling period of fifteen (15) minutes.

(d) Exposure monitoring

(1) General.

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute short-term exposures of each employee.

(ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift and for each job classification in each work area.

(iii) Representative 15-minute short-term employee exposures shall be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the STEL for each shift and for each job classification in each work area.

(iv) Except for the initial monitoring required under paragraph (d)(2) of this section, where the employer can document that exposure levels are equivalent for similar operations on different work shifts, the employer need only determine representative employee exposure for that operation from the shift during which the highest exposure is expected.

(2) Initial monitoring.

(i) Each employer who has a workplace or work operation covered by this section, shall perform initial monitoring to determine accurately the airborne concentrations of BD to which employees may be exposed, or shall rely on objective data pursuant to paragraph (a)(2)(i) of this section to fulfill this requirement. The initial monitoring required under this paragraph shall be completed within 60 days of the introduction of BD into the workplace.

(ii) Where the employer has monitored within two years prior to the effective date of this section and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section, provided that the conditions under which the initial monitoring was conducted have not changed in a manner that may result in new or additional exposures.

(3) Periodic monitoring and its frequency.

(i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be at or above the action level but at or below both the 8-hour TWA limit and the STEL, the employer shall repeat the representative monitoring required by paragraph (d)(1) of this section every twelve months.

(ii) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be above the 8-hour TWA limit, the employer shall repeat the representative monitoring required by paragraph (d)(1)(ii) of this section at least every three months until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year

period, after which such monitoring must occur at least every six months.

(iii) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be above the STEL, the employer shall repeat the representative monitoring required by paragraph (d)(1)(iii) of this section at least every three months until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period, after which such monitoring must occur at least every six months.

(iv) The employer may alter the monitoring schedule from every six months to annually for any required representative monitoring for which two consecutive measurements taken at least 7 days apart indicate that employee exposure has decreased to or below the 8-hour TWA, but is at or above the action level.

(4) Termination of monitoring.

(i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be below the action level and at or below the STEL, the employer may discontinue the monitoring for employees whose exposures are represented by the initial monitoring.

(ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level and at or below the STEL, the employer may discontinue the monitoring for those employees who are represented by such monitoring.

(5) Additional monitoring.

(i) The employer shall institute the exposure monitoring required under paragraph (d) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to BD or when the employer has any reason to suspect that a change may result in new or additional exposures.

(ii) Whenever spills, leaks, ruptures or other breakdowns occur that may lead to employee exposure above the 8-hr TWA limit or above the STEL, the employer shall monitor [using leak source, such as direct reading instruments, area or personal monitoring], after the cleanup of the spill or repair of the leak, rupture or other breakdown, to ensure that exposures have returned to the level that existed prior to the incident.

(6) Accuracy of monitoring. Monitoring shall be accurate, at a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of BD at or above the 1 ppm TWA limit and to within plus or minus 35 percent for airborne concentrations of BD at or above the action level of 0.5 ppm and below the 1 ppm TWA limit.

(7) Employee notification of monitoring results.

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) The employer shall, within 15 business days after receipt of any monitoring performed under this section indicating the 8-hour TWA or STEL has been exceeded, provide the affected employees, in writing, with information on the corrective action being taken by the employer to reduce employee exposure to or below the 8-hour TWA or STEL and the schedule for completion of this action.

(8) Observation of monitoring.

(i) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to BD conducted in accordance with paragraph (d) of this section.

(ii) Observation procedures. When observation of the monitoring of employee exposure to BD requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer at no cost with protective clothing and equipment, and shall ensure that the observer uses this equipment and complies with all other applicable safety and health procedures.

(e) Regulated areas.

(1) The employer shall establish a regulated area wherever occupational exposures to airborne concentrations of BD exceed or can reasonably be expected to exceed the permissible exposure limits, either the 8-hr TWA or the STEL.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be demarcated from the rest of the workplace in any manner that minimizes the number of employees exposed to BD within the regulated area.

(4) An employer at a multi-employer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite whose employees may have access to these areas.

(f) Methods of compliance.

(1) Engineering controls and work practices.

(i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the PELs, except to the extent that the employer can establish that these controls are not feasible or where paragraph (h)(1)(i) of this section applies.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the 8-hour TWA or STEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (h) of this section.

(2) Compliance plan.

(i) Where any exposures are over the PELs, the employer shall establish and implement a written plan to reduce employee exposure to or below the PELs primarily by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section. No compliance plan is required if all exposures are under the PELs.

(ii) The written compliance plan shall include a schedule for the development and implementation of the engineering controls and work practice controls including periodic leak detection surveys.

(iii) Copies of the compliance plan required in paragraph (f)(2) of this section shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months, and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the PELs.

(g) Exposure Goal Program.

(1) For those operations and job classifications where employee exposures are greater than the action level, in addition to compliance with the PELs, the employer shall have an exposure goal program that is intended to limit employee exposures to below the action level during normal operations.

(2) Written plans for the exposure goal program shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives.

(3) Such plans shall be updated as necessary to reflect significant changes in the status of the exposure goal program.

(4) Respirator use is not required in the exposure goal program.

(5) The exposure goal program shall include the following items unless the employer can demonstrate that the item is not feasible, will have no significant effect in reducing employee exposures, or is not necessary to achieve exposures below the action level:

(i) A leak prevention, detection, and repair program.

(ii) A program for maintaining the effectiveness of local exhaust ventilation systems.

(iii) The use of pump exposure control technology such as, but not limited to, mechanical double-sealed or seal-less pumps.

(iv) Gauging devices designed to limit employee exposure, such as magnetic gauges on rail cars.

(v) Unloading devices designed to limit employee exposure, such as a vapor return system.

(vi) A program to maintain BD concentration below the action level in control rooms by use of engineering controls.

(h) Respiratory protection.

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work-practice controls.

(ii) Non-routine work operations that are performed infrequently and for which employee exposures are limited in duration.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposures to or below the PELs

(iv) Emergencies.

(2) Respirator program. [i] The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii), (d)(3)(iii)(B)(1), and (2)),

and (f) through (m), which covers each employee required by this section to use a respirator.

[ii] If air-purifying respirators are used, the employer must replace the air-purifying filter elements according to the replacement schedule set for the class of respirators listed in Table 1 of this section, and at the beginning of each work shift.

[iii] Instead of using the replacement schedule listed in Table 1 of this section, the employer may replace cartridges or canisters at 90% of their expiration service life, provided the employer:

(A) Demonstrates that employees will be adequately protected by this procedure.

(B) Uses BD breakthrough data for this purpose that have been derived from tests conducted under worst-case conditions of humidity, temperature, and air-flow rate through the filter element, and the employer also describes the data supporting the cartridge-or canister-change schedule, as well as the basis for using the data in the employer's respirator program.

(iv) A label must be attached to each filter element to indicate the date and time it is first installed on the respirator.

(v) If NIOSH approves an end-of-service-life indicator (ESLI) for an air-purifying filter element, the element may be used until the ESLI shows no further useful service life or until the element is replaced at the beginning of the next work shift, whichever occurs first.

(vi) Regardless of the air-purifying element used, if an employee detects the odor of BD, the employer must replace the air-purifying element immediately.

(3) Respirator selection.

(i) The employer must select appropriate respirators from Table 1 of this section.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE BD

| Concentration of airborne BD (ppm) or condition of use | Minimum required respirator |
|---|---|
| Less than or equal to 5 ppm (5 times PEL) | (a) Air-purifying half mask or full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 4 hours. |
| Less than or equal to 10 ppm (10 times PEL) ... | (a) Air-purifying half mask or full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 3 hours. |
| Less than or equal to 25 ppm (25 times PEL) ... | (a) Air-purifying full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 2 hours. (b) Any powered air-purifying respirator equipped with approved BD or organic vapor cartridges. PAPR cartridges shall be replaced every 2 hours. (c) Continuous flow supplied air respirator equipped with a hood or helmet. |
| Less than or equal to 50 ppm (50 times PEL) ... | (a) Air-purifying full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every (1) hour. (b) Powered air-purifying respirator equipped with a tight-fitting facepiece and an approved BD or organic vapor cartridges. PAPR cartridges shall be replaced every (1) hour. |
| Less than or equal to 1,000 ppm (1,000 times PEL). | (a) Supplied air respirator equipped with a half mask or full facepiece and operated in a pressure demand or other positive pressure mode. |
| Greater than 1000 ppm unknown concentration, or firefighting. | (a) Self-contained breathing apparatus equipped with a full facepiece and operated in a pressure demand or other positive pressure mode. (b) Any supplied air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode. |
| Escape from IDLH conditions | (a) Any positive pressure self-contained breathing apparatus with an appropriate service life. |

| Concentration of airborne BD (ppm) or condition of use | Minimum required respirator |
|--|---|
| | (b) A air-purifying full facepiece respirator equipped with a front or back mounted BD or organic vapor canister. |

NOTES: Respirators approved for use in higher concentrations are permitted to be used in lower concentrations. Full facepiece is required when eye irritation is anticipated.

(ii) Air-purifying respirators must have filter elements approved by NIOSH for organic vapors or BD.

(iii) When an employee whose job requires the use of a respirator cannot use a negative-pressure respirator, the employer must provide the employee with a respirator that has less breathing resistance than the negative-pressure respirator, such as a powered air-purifying respirator or supplied-air respirator, when the employee is able to use it and if it provides the employee adequate protection.

(4) Respirator use.

[i] Where air-purifying respirators are used, the employer shall replace the air purifying filter element(s) according to the replacement life interval set for the class of respirator listed in Table 1 in paragraph (h)(5) of this section and at the beginning of each work shift.

[ii] In lieu of the replacement intervals listed in Table 1, the employer may replace cartridges or canisters at 90% of the expiration of service life, provided the employer can demonstrate that employees will be adequately protected. BD breakthrough data relied upon by the employer must derive from tests conducted under worst case conditions of humidity, temperature, and air flow rate through the filter element. The employer shall describe the data supporting the cartridge/canister change schedule and the basis for reliance on the data in the employer's respirator program.

[iii] A label shall be attached to the filter element(s) to indicate the date and time it is first installed on the respirator. If an employee detects the odor of BD, the employer shall replace the air-purifying element(s) immediately.

[iv] If a NIOSH-approved end of service life indicator (ESLI) for BD becomes available for an air-purifying filter element, the element may be used until such time as the indicator shows no further useful service life or until replaced at the beginning of the next work shift, whichever comes first. If an employee detects the odor of BD, the employer shall replace the air-purifying element(s) immediately.

[v] The employer shall permit employees who wear respirators to leave the regulated area to wash their faces and respirator facepieces as necessary in order to prevent skin irritation associated with respirator use or to change the filter elements of air-purifying respirators whenever they detect a change in breathing resistance or whenever the odor of BD is detected.

(5) Respirator fit testing.

[i] The employer shall perform either qualitative fit testing (QLFT) or quantitative fit testing (QNFT), as required in Appendix E to this section, at the time of initial fitting and at least annually thereafter for employees who wear tight-fitting negative pressure respirators. Fit testing shall be used to select a respirator facepiece which exhibits minimum leakage and provides the required protection as prescribed in Table 1 in paragraph (h)(5)(ii) of this section.

[ii] For each employee wearing a tight-fitting full facepiece negative pressure respirator who is exposed to airborne concentrations of BD that exceed 10 times the TWA PEL (10 ppm), the employer shall perform quantitative fit testing as required in Appendix E to this section, at the time of initial fitting and at least annually thereafter.

[iii] The employer shall ensure that employees wearing tight fitting respirators perform a facepiece seal fit check to ensure that a proper facepiece seal is obtained prior to entry into a BD atmosphere. The recommended positive or negative pressure fit check procedures listed in Appendix E to this section or the respirator manufacturer's recommended fit check procedure shall be used.

(i) Protective clothing and equipment. Where appropriate to prevent eye contact and limit dermal exposure to BD, the employer shall provide protective clothing and equipment at no cost to the employee and shall ensure its use. Eye and face protection shall meet the requirements of 29 CFR 1910.133.

(j) Emergency situations. Written plan. A written plan for emergency situations shall be developed, or an existing plan shall be modified, to contain the applicable elements specified in 29 CFR 1910.38 and 29 CFR 1910.38 and 29 CFR 1910.39, " Emergency action plans and "Fire prevention plans," respectively, and in 29 CFR 1910.120, "Hazardous Waste Operations and Emergency Responses," for each workplace where there is a possibility of an emergency.

(k) Medical screening and surveillance.

(1) Employees covered. The employer shall institute a medical screening and surveillance program as specified in this paragraph for:

(i) Each employee with exposure to BD at concentrations at or above the action level on 30 or more days or for employees who have or may have exposure to BD at or above the PELs on 10 or more days a year;

(ii) Employers (including successor owners) shall continue to

provide medical screening and surveillance for employees, even after transfer to a non-BD exposed job and regardless of when the employee is transferred, whose work histories suggest exposure to BD:

(A) At or above the PELs on 30 or more days a year for 10 or more years;

(B) At or above the action level on 60 or more days a year for 10 or more years; or

(C) Above 10 ppm on 30 or more days in any past year; and

(iii) Each employee exposed to BD following an emergency situation.

(2) Program administration.

[i] The employer shall ensure that the health questionnaire, physical examination and medical procedures are provided without cost to the employee, without loss of pay, and at a reasonable time and place.

[ii] Physical examinations, health questionnaires, and medical procedures shall be performed or administered by a physician or other licensed health care professional.

[iii] Laboratory tests shall be conducted by an accredited laboratory.

(3) Frequency of medical screening activities. The employer shall make medical screening available on the following schedule:

(i) For each employee covered under paragraphs (j)(1)(i) and (ii) of this section, a health questionnaire and complete blood count with differential and platelet count (CBC) every year, and a physical examination as specified below:

[A] An initial physical examination that meets the requirements of this rule, if twelve months or more have elapsed since the last physical examination conducted as part of a medical screening program for BD exposure;

[B] Before assumption of duties by the employee in a job with BD exposure;

[C] Every 3 years after the initial physical examination;

[D] At the discretion of the physician or other licensed health care professional reviewing the annual health questionnaire and CBC;

[E] At the time of employee reassignment to an area where exposure to BD is

below the action level, if the employee's past exposure history does not meet the criteria of paragraph (j)(1)(ii) of this section for continued coverage in the screening and surveillance program, and if twelve months or more have elapsed since the last physical examination; and

[F] At termination of employment if twelve months or more have elapsed since the last physical examination.

(ii) Following an emergency situation, medical screening shall be conducted as quickly as possible, but not later than 48 hours after the exposure.

(iii) For each employee who must wear a respirator, physical ability to perform the work and use the respirator must be determined as required by 29 CFR 1910.134.

(4) Content of medical screening.

(i) Medical screening for employees covered by paragraphs (j)(1)(i) and (ii) of this section shall include:

(A) A baseline health questionnaire that includes a comprehensive occupational and health history and is updated annually. Particular emphasis shall be placed on the hematopoietic and reticuloendothelial systems, including exposure to chemicals, in addition to BD, that may have an adverse effect on these systems, the presence of signs and symptoms that might be related to disorders of these systems, and any other information determined by the examining physician or other licensed health care professional to be necessary to evaluate whether the employee is at increased risk of material impairment of health from BD exposure. Health questionnaires shall consist of the sample forms in Appendix C to this section, or be equivalent to those samples;

(B) A complete physical examination, with special emphasis on the liver, spleen, lymph nodes, and skin;

(C) A CBC; and

(D) Any other test which the examining physician or other licensed health care professional deems necessary to evaluate whether the employee may be at increased risk from exposure to BD.

(ii) Medical screening for employees exposed to BD in an emergency situation shall focus on the acute effects of BD exposure and at a minimum include: A CBC within 48 hours of the exposure and then monthly for three months; and a physical examination if the employee reports irritation of the eyes, nose throat, lungs, or skin, blurred vision, coughing, drowsiness, nausea, or headache. Continued employee participation in the medical screening and surveillance program, beyond these minimum requirements, shall be at the discretion of the physician or other licensed

health care professional.

(5) Additional medical evaluations and referrals.

(i) Where the results of medical screening indicate abnormalities of the hematopoietic or reticuloendothelial systems, for which a non-occupational cause is not readily apparent, the examining physician or other licensed health care professional shall refer the employee to an appropriate specialist for further evaluation and shall make available to the specialist the results of the medical screening.

(ii) The specialist to whom the employee is referred under this paragraph shall determine the appropriate content for the medical evaluation, e.g., examinations, diagnostic tests and procedures, etc.

(6) Information provided to the physician or other licensed health care professional. The employer shall provide the following information to the examining physician or other licensed health care professional involved in the evaluation:

(i) A copy of this section including its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's BD exposure;

(iii) The employee's actual or representative BD exposure level during employment tenure, including exposure incurred in an emergency situation;

(iv) A description of pertinent personal protective equipment used or to be used; and

(v) Information, when available, from previous employment-related medical evaluations of the affected employee which is not otherwise available to the physician or other licensed health care professional or the specialist.

(7) The written medical opinion.

(i) For each medical evaluation required by this section, the employer shall ensure that the physician or other licensed health care professional produces a written opinion and provides a copy to the employer and the employee within 15 business days of the evaluation. The written opinion shall be limited to the following information:

(A) The occupationally pertinent results of the medical evaluation;

(B) A medical opinion concerning whether the employee has any detected medical conditions which would place the employee's health at increased risk of material impairment from exposure to BD;

(C) Any recommended limitations upon the employee's exposure to BD; and

(D) A statement that the employee has been informed of the results of the medical evaluation and any medical conditions resulting from BD exposure that require further explanation or treatment.

(ii) The written medical opinion provided to the employer shall not reveal specific records, findings, and diagnoses that have no bearing on the employee's ability to work with BD.

Note: However, this provision does not negate the ethical obligation of the physician or other licensed health care professional to transmit any other adverse findings directly to the employee.

(8) Medical surveillance.

(i) The employer shall ensure that information obtained from the medical screening program activities is aggregated (with all personal identifiers removed) and periodically reviewed, to ascertain whether the health of the employee population of that employer is adversely affected by exposure to BD.

(ii) Information learned from medical surveillance activities must be disseminated to covered employees, as defined in paragraph (k)(1) of this section, in a manner that ensures the confidentiality of individual medical information.

(l) Communication of BD hazards to employees.

(1) ~~Hazard communication~~ Hazard communication—general.

~~The employer shall communicate the hazards associated with BD exposure in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, and 29 CFR 1926.59.~~

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for BD.

(ii) In classifying the hazards of BD at least the following hazards are to be addressed: Cancer; eye and respiratory tract irritation; center nervous system effects; and flammability.

(iii) Employers shall include BD in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of BD and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l)(2) of this section.

(2) Employee information and training.

(i) The employer shall provide all employees exposed to BD with information and

training in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, and 29 CFR 1926.59.

(ii) The employer shall train each employee who is potentially exposed to BD at or above the action level or the STEL in accordance with the requirements of this section. The employer shall institute a training program, ensure employee participation in the program, and maintain a record of the contents of such program.

(iii) Training shall be provided prior to or at the time of initial assignment to a job potentially involving exposure to BD at or above the action level or STEL and at least annually thereafter.

(iv) The training program shall be conducted in a manner that the employee is able to understand. The employer shall ensure that each employee exposed to BD over the action level or STEL is informed of the following:

[A] The health hazards associated with BD exposure, and the purpose and a description of the medical screening and surveillance program required by this section;

[B] The quantity, location, manner of use, release, and storage of BD and the specific operations that could result in exposure to BD, especially exposures above the PEL or STEL;

[C] The engineering controls and work practices associated with the employee's job assignment, and emergency procedures and personal protective equipment;

[D] The measures employees can take to protect themselves from exposure to BD.

[E] The contents of this standard and its appendices, and

[F] The right of each employee exposed to BD at or above the action level or STEL to obtain:

[1] medical examinations as required by paragraph (j) of this section at no cost to the employee;

[2] the employee's medical records required to be maintained by paragraph (m)(4) of this section; and

[3] all air monitoring results representing the employee's exposure to BD and required to be kept by paragraph (m)(2) of this section.

(3) Access to information and training materials.

(i) The employer shall make a copy of this standard and its appendices readily available without cost to all affected employees and their designated representatives and shall provide a copy if requested.

(ii) The employer shall provide to the Assistant Secretary or the Director, or the designated employee representatives, upon request, all materials relating to the employee information and the training program.

(m) Recordkeeping. --

(1) Objective data for exemption from initial monitoring.

(i) Where the processing, use, or handling of products or streams made from or containing BD are exempted from other requirements of this section under paragraph (a)(2) of this section, or where objective data have been relied on in lieu of initial monitoring under paragraph (d)(2)(ii) of this section, the employer shall establish and maintain a record of the objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product or activity qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and analysis of the material for the release of BD;

(D) A description of the operation exempted and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(ii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) Exposure measurements.

(i) The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to BD as prescribed in paragraph (d) of this section.

(ii) The record shall include at least the following information:

(A) The date of measurement;

(B) The operation involving exposure to BD which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of protective devices worn, if any; and

(F) Name, social security number and exposure of the employees whose exposures are represented.

(G) The written corrective action and the schedule for completion of this action required by paragraph (d)(7)(ii) of this section.

(iii) The employer shall maintain this record for at least 30 years in accordance with 29 CFR 1910.1020.

(3) Respirator Fit-test. [Reserved]

(4) Medical screening and surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical screening and surveillance under this section.\

(ii) The record shall include at least the following information:

(A) The name and social security number of the employee;

(B) Physician's or other licensed health care professional's written opinions as described in paragraph (k)(7) of this section;

(C) A copy of the information provided to the physician or other licensed health care professional as required by paragraphs (k)(7)(ii)-(iv) of this section.

(iii) Medical screening and surveillance records shall be maintained for each employee for the duration of employment plus 30 years, in accordance with 29 CFR 1910.1020.

(5) Availability.

(i) The employer, upon written request, shall make all records required to be maintained by this section available for examination and copying to the Assistant Secretary and the Director.

(ii) Access to records required to be maintained by paragraphs (1)(1)-(3) of this section shall be granted in accordance with 29 CFR 1910.1020(e).

(6) Transfer of records.

The employer shall transfer medical and exposure records as set forth in 29 CFR 1910.1020(h).

(n) [Reserved]

(o) Appendices.

(1) Appendix E to this section is mandatory.

(2) Appendices A, B, C, D, and F to this section are informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

[61 FR 56746, Nov. 4, 1996]

1910.1051 App A Substance Safety Data Sheet For 1,3-Butadiene

Substance Safety Data Sheet For 1,3-Butadiene (Non-Mandatory)

I. Substance Identification

A. Substance: 1,3-Butadiene (CH₂=CH-CH=CH₂).

B. Synonyms: 1,3-Butadiene (BD); butadiene; biethylene; bi-vinyl;divinyl;
butadiene-1,3; buta-1,3-diene; erythrene; NCI-C50602;CAS-106-99-0.

C. BD can be found as a gas or liquid.

D. BD is used in production of styrene-butadiene rubber and polybutadiene rubber for the tire industry. Other uses include copolymer latexes for carpet backing and paper coating, as well as resins and polymers for pipes and automobile and appliance parts. It is also used as an intermediate in the production of such chemicals as fungicides.

E. Appearance and odor: BD is a colorless, non-corrosive, flammable gas with a mild aromatic odor at standard ambient temperature and pressure.

F. Permissible exposure: Exposure may not exceed 1 part BD per million parts of air averaged over the 8-hour workday, nor may short-term exposure exceed 5 parts of BD per million parts of air averaged over any 15-minute period in the 8-hour workday.

II. Health Hazard Data

A. BD can affect the body if the gas is inhaled or if the liquid form, which is very cold (cryogenic), comes in contact with the eyes or skin.

B. Effects of overexposure: Breathing very high levels of BD for a short time can cause central nervous system effects, blurred vision, nausea, fatigue, headache, decreased blood pressure and pulse rate, and unconsciousness. There are no recorded cases of accidental exposures at high levels that have caused death in humans, but this could occur. Breathing lower levels of BD may cause irritation of the eyes, nose, and throat. Skin contact with liquefied BD can cause irritation and frostbite.

C. Long-term (chronic) exposure: BD has been found to be a potent carcinogen in rodents, inducing neoplastic lesions at multiple target sites in mice and rats. A recent study of BD-exposed workers showed that exposed workers have an increased risk of developing leukemia. The risk of leukemia increases with increased exposure to BD. OSHA has concluded that there is strong evidence that workplace exposure to BD poses an increased risk of death from cancers of the lymphohematopoietic system.

D. Reporting signs and symptoms: You should inform your supervisor if you develop any of these signs or symptoms and suspect that they are caused by exposure to BD.

III. Emergency First Aid Procedures

In the event of an emergency, follow the emergency plan and procedures designated for your work area. If you have been trained in first aid procedures, provide the necessary first aid measures. If necessary, call for additional assistance from co-workers and emergency medical personnel.

A. Eye and Skin Exposures: If there is a potential that liquefied BD can come in contact with eye or skin, face shields and skin protective equipment must be provided and used. If liquefied BD comes in contact with the eye, immediately flush the eyes with large amounts of water, occasionally lifting the lower and the upper lids. Flush repeatedly. Get medical attention immediately. Contact lenses should not be worn when working with this chemical. In the event of skin contact, which can cause frostbite, remove any contaminated clothing and flush the affected area repeatedly with large amounts of tepid water.

B. Breathing: If a person breathes in large amounts of BD, move the exposed person to fresh air at once. If breathing has stopped, begin cardiopulmonary resuscitation (CPR) if you have been trained in this procedure. Keep the affected person warm and at rest. Get medical attention immediately.

C. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, call for help and begin emergency rescue procedures. Use extreme caution so that you do not become a casualty. Understand the plant's emergency rescue procedures and know the locations of rescue equipment before the need arises.

IV. Respirators and Protective Clothing

A. Respirators: Good industrial hygiene practices recommend that engineering and work practice controls be used to reduce environmental concentrations to the permissible exposure level. However, there are some exceptions where respirators may be used to control exposure. Respirators may be used when engineering and work practice controls are not technically feasible, when such controls are in the process of being installed, or when these controls fail and need to be supplemented or during brief, non-routine, intermittent exposure. Respirators may also be used in situations involving non-routine work operations which are performed infrequently and in which exposures are limited in duration, and in emergency situations. In some instances cartridge respirator use is allowed, but only with strict time constraints. For example, at exposure below 5 ppm BD, a cartridge (or canister) respirator, either full or half face, may be used, but the cartridge must be replaced at least every 4 hours, and it must be replaced every 3 hours when the exposure is between 5 and 10 ppm. If the use of respirators is necessary, the only respirators permitted are those that have been approved by the National Institute for Occupational Safety and Health (NIOSH). In addition to respirator selection, a complete respiratory protection program must be instituted which includes regular training, maintenance, fit testing, inspection, cleaning, and evaluation of respirators. If you can smell BD while wearing a respirator, proceed immediately to fresh air, and change cartridge (or canister) before re-entering an area where there is BD exposure. If you experience difficulty in breathing while wearing a respirator, tell your supervisor.

B. Protective Clothing: Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent the skin from becoming frozen by contact with liquefied BD (or a vessel containing liquid BD). Employees should be provided with and required to use splash-proof safety goggles where liquefied BD may contact the eyes.

V. Precautions for Safe Use, Handling, and Storage

A. Fire and Explosion Hazards: BD is a flammable gas and can easily form explosive mixtures in air. It has a lower explosive limit of 2%, and an upper explosive limit of 11.5%. It has an autoignition temperature of 420 deg. C (788 deg. F). Its vapor is heavier than air (vapor density, 1.9) and may travel a considerable distance to a source of ignition and flash back. Usually it contains inhibitors to prevent self-polymerization (which is accompanied by evolution of heat) and to prevent formation of explosive peroxides. At elevated temperatures, such as in fire conditions, polymerization may take place. If the polymerization takes place in a container, there is a possibility of violent rupture of the container.

B. Hazard: Slightly toxic. Slight respiratory irritant. Direct contact of liquefied BD on skin may cause freeze burns and frostbite.

C. Storage: Protect against physical damage to BD containers. Outside or detached storage of BD containers is preferred. Inside storage should be in a cool, dry, well-ventilated, noncombustible location, away from all possible sources of ignition. Store cylinders vertically and do not stack. Do not store with oxidizing material.

D. Usual Shipping Containers: Liquefied BD is contained in steel pressure apparatus.

E. Electrical Equipment: Electrical installations in Class hazardous locations, as defined in Article 500 of the National Electrical Code, should be in accordance with Article 501 of the Code. If explosion-proof electrical equipment is necessary, it shall be suitable for use in Group B. Group D equipment may be used if such equipment is isolated in accordance with Section 501-5(a) by sealing all conduit 1/2-inch size or larger. See Venting of Deflagrations (NFPA No. 68, 1994), National Electrical Code (NFPA No. 70, 1996), Static Electricity (NFPA No. 77, 1993), Lightning Protection Systems (NFPA No. 780, 1995), and Fire Hazard Properties of Flammable Liquids, Gases and Volatile Solids (NFPA No. 325, 1994).

F. Fire Fighting: Stop flow of gas. Use water to keep fire-exposed containers cool. Fire extinguishers and quick drenching facilities must be readily available, and you should know where they are and how to operate them.

G. Spill and Leak: Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until clean-up has been completed. If BD is spilled or leaked, the following s should be taken:

1. Eliminate all ignition sources.
2. Ventilate area of spill or leak.
3. If in liquid form, for small quantities, allow to evaporate in a safe manner.
4. Stop or control the leak if this can be done without risk. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cylinder to a safe place and repair the leak or allow the cylinder to empty.

H. Disposal: This substance, when discarded or disposed of, is a hazardous waste according to Federal regulations (40 CFR part 261). It is listed as hazardous waste number D001 due to its ignitability. The transportation, storage, treatment, and disposal of this waste material must be conducted in compliance with 40 CFR parts 262, 263, 264, 268 and 270. Disposal can occur only in properly permitted facilities. Check state and local regulation of any additional requirements as these may be more restrictive than federal laws and regulation.

I. You should not keep food, beverages, or smoking materials in areas where there is BD

exposure, nor should you eat or drink in such areas.

J. Ask your supervisor where BD is used in your work area and ask for any additional plant safety and health rules.

VI. Medical Requirements

Your employer is required to offer you the opportunity to participate in a medical screening and surveillance program if you are exposed to BD at concentrations exceeding the action level (0.5 ppm BD as an 8-hour TWA) on 30 days or more a year, or at or above the 8 hr TWA (1 ppm) or STEL (5 ppm for 15 minutes) on 10 days or more a year. Exposure for any part of a day counts. If you have had exposure to BD in the past, but have been transferred to another job, you may still be eligible to participate in the medical screening and surveillance program. The OSHA rule specifies the past exposures that would qualify you for participation in the program. These past exposure are work histories that suggest the following:

(1) That you have been exposed at or above the PELs on 30 days a year for 10 or more years;

(2) that you have been exposed at or above the action level on 60 days a year for 10 or more years; or

(3) that you have been exposed above 10 ppm on 30 days in any past year. Additionally, if you are exposed to BD in an emergency situation, you are eligible for a medical examination within 48

hours. The basic medical screening program includes a health questionnaire, physical examination, and blood test. These medical evaluations must be offered to you at a reasonable time and place, and without cost or loss of pay.

VII. Observation of Monitoring

Your employer is required to perform measurements that are representative of your exposure to BD and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the s taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear, the protective clothing and equipment.

VIII. Access to Information

A. Each year, your employer is required to inform you of the information contained in this appendix. In addition, your employer must instruct you in the proper work practices for using BD, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to BD. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits and of the schedule to implement these actions.

C. Your employer is required to keep records of your exposures and medical examinations. These records must be kept by the employer for at least thirty (30) years.

D. Your employer is required to release your exposure and medical records to you or your representative upon your request.

[61 FR 56746, Nov. 4, 1996]

1910.1051 App B

Substance Technical Guidelines for 1,3-Butadiene (Non-Mandatory)

Subpart Z

1910.1051 App B, Toxic and Hazardous Substances

I. Physical and Chemical Data

A. Substance identification:

1. Synonyms: 1,3-Butadiene (BD); butadiene; biethylene; bivinyll; divinyl; butadiene-1,3; buta-1,3-diene; erythrene; NCI-C50620; CAS-106-99-0.
2. Formula: $\text{CH}_2=\text{CH}-\text{CH}=\text{CH}_2$.
3. Molecular weight: 54.1.

B. Physical data:

1. Boiling point (760 mm Hg): -4.7 deg. C (23.5 deg. F).
2. Specific gravity (water=1): 0.62 at 20 deg. C (68 deg. F).
3. Vapor density (air=1 at boiling point of BD): 1.87.
4. Vapor pressure at 20 deg. C (68 deg. F): 910 mm Hg.
5. Solubility in water, g/100 g water at 20 deg. C (68 deg. F): 0.05.
6. Appearance and odor: Colorless, flammable gas with a mildly aromatic odor. Liquefied BD is a colorless liquid with a mildly aromatic odor.

II. Fire, Explosion, and Reactivity Hazard Data

A. Fire:

1. Flash point: -76 deg. C (-105 deg. F) for take out; liquefied BD; Not applicable to BD gas.
2. Stability: A stabilizer is added to the monomer to inhibit formation of polymer during storage. Forms explosive peroxides in air in absence of inhibitor.
3. Flammable limits in air, percent by volume: Lower: 2.0; Upper: 11.5.
4. Extinguishing media: Carbon dioxide for small fires, polymer or alcohol foams for large fires.
5. Special fire fighting procedures: Fight fire from protected location or maximum possible distance. Stop flow of gas before extinguishing fire. Use water spray to keep fire-exposed cylinders cool.
6. Unusual fire and explosion hazards: BD vapors are heavier than air and may travel to a source of ignition and flash back. Closed containers may rupture violently when heated.
7. For purposes of compliance with the requirements of 29 CFR 191.106, BD is classified as a flammable gas. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.
8. For purposes of compliance with 29 CFR 1910.155, BD is classified as a Class B fire hazard.
9. For purposes of compliance with 29 CFR 1910.307, locations classified as hazardous due to the presence of BD shall be Class I.

B. Reactivity:

1. Conditions contributing to instability: Heat. Peroxides are formed when inhibitor concentration is not maintained at proper level. At elevated temperatures, such as in fire conditions, polymerization may take place.
2. Incompatibilities: Contact with strong oxidizing agents may cause fires and explosions. The contacting of crude BD (not BD monomer) with copper and copper alloys may cause formations of explosive copper compounds.
3. Hazardous decomposition products: Toxic gases (such as carbon monoxide) may be released in a fire involving BD.
4. Special precautions: BD will attack some forms of plastics, rubber, and coatings. BD in storage should be checked for proper inhibitor content, for self-polymerization, and for formation of peroxides when in contact with air and iron. Piping carrying BD may become plugged by formation of rubbery polymer.

C. Warning Properties:

1. Odor Threshold: An odor threshold of 0.45 ppm has been reported in The American Industrial Hygiene Association (AIHA) Report, Odor Thresholds for Chemicals with Established Occupational Health Standards. (Ex. 32-28C)
2. Eye Irritation Level: Workers exposed to vapors of BD (concentration or purity unspecified)

have complained of irritation of eyes, nasal passages, throat, and lungs. Dogs and rabbits exposed experimentally to as much as 6700 ppm for 7 1/2 hours a day for 8 months have developed no histologically demonstrable abnormality of the eyes.

3. Evaluation of Warning Properties: Since the mean odor threshold is about half of the 1 ppm PEL, and more than 10-fold below the 5 ppm STEL, most wearers of air purifying respirators should still be able to detect breakthrough before a significant overexposure to BD occurs.

III. Spill, Leak, and Disposal Procedures

A. Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until cleanup has been completed. If BD is spilled or leaked, the following should be taken:

1. Eliminate all ignition sources.
2. Ventilate areas of spill or leak.
3. If in liquid form, for small quantities, allow to evaporate in a safe manner.
4. Stop or control the leak if this can be done without risk. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cylinder to a safe place and repair the leak or allow the cylinder to empty.

B. Disposal: This substance, when discarded or disposed of, is a hazardous waste according to Federal regulations (40 CFR part 261). It is listed by the EPA as hazardous waste number D001 due to its ignitability. The transportation, storage, treatment, and disposal of this waste material must be conducted in compliance with 40 CFR parts 262, 263, 264, 268 and 270. Disposal can occur only in properly permitted facilities. Check state and local regulations for any additional requirements because these may be more restrictive than federal laws and regulations.

IV. Monitoring and Measurement Procedures

A. Exposure above the Permissible Exposure Limit (8-hr TWA) or Short-Term Exposure Limit (STEL):

1. 8-hr TWA exposure evaluation: Measurements taken for the purpose of determining employee exposure under this standard are best taken with consecutive samples covering the full shift. Air samples must be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

2. STEL exposure evaluation: Measurements must represent 15 minute exposures associated with operations most likely to exceed the STEL in each job and on each shift.

3. Monitoring frequencies: Table 1 gives various exposure scenarios and their required monitoring frequencies, as required by the final standard for occupational exposure to butadiene.

Table 1. -- Five Exposure Scenarios and Their Associated

Monitoring Frequencies

| Action level | 8-hr TWA | STEL | Required monitoring activity |
|--------------|----------|------|---|
| -(*) | - | - | No 8-hr TWA or STEL monitoring required. |
| +(*) | - | - | No STEL monitoring required. Monitor 8-hr TWA annually. |
| + | + | - | No STEL monitoring required. Periodic monitoring 8-hr TWA, in accordance with (d)(3)(ii).(**) |
| + | + | + | Periodic monitoring 8-hr TWA, in accordance with (d)(3)(ii)(**). Periodic monitoring STEL, in accordance with (d)(3)(iii). |
| + | - | + | Periodic monitoring STEL, in accordance with (d)(3)(iii). Monitor 8-hr TWA, annually. |

Footnote(*) Exposure Scenario, Limit Exceeded: + = Yes, - = No.
Footnote(**) The employer may decrease the frequency of exposure monitoring to annually when at least 2 consecutive measurements taken at least 7 days apart show exposures to be below the 8 hr TWA, but at or above the action level.

4. Monitoring techniques: Appendix D describes the validated method of sampling and analysis which has been tested by OSHA for use with BD. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his or her unique field conditions. The standard requires that the method of monitoring must be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of BD at or above 1 ppm, and to plus or minus 35 percent for concentrations below 1 ppm.

V. Personal Protective Equipment

A. Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent the skin from becoming frozen from contact with liquid BD.

B. Any clothing which becomes wet with liquid BD should be removed immediately and not re-worn until the butadiene has evaporated.

C. Employees should be provided with and required to use splash proof safety goggles where liquid BD may contact the eyes.

VI. Housekeeping and Hygiene Facilities

For purposes of complying with 29 CFR 1910.141, the following items should be emphasized:

- A. The workplace should be kept clean, orderly, and in a sanitary condition.
- B. Adequate washing facilities with hot and cold water are to be provided and maintained in a sanitary condition.

VII. Additional Precautions

- A. Store BD in tightly closed containers in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.
- B. Non-sparking tools must be used to open and close metal containers. These containers must be effectively grounded.
- C. Do not incinerate BD cartridges, tanks or other containers.
- D. Employers must advise employees of all areas and operations where exposure to BD might occur.

[61 FR 56746, Nov. 4, 1996]

1910.1051 App C Medical Screening and Surveillance for 1,3-Butadiene (Non-Mandatory)

I. Basis for Medical Screening and Surveillance Requirements

A. Route of Entry

Inhalation

B. Toxicology

Inhalation of BD has been linked to an increased risk of cancer, damage to the reproductive organs, and fetotoxicity. Butadiene can be converted via oxidation to epoxybutene and diepoxybutane, two genotoxic metabolites that may play a role in the expression of BD's toxic effects.

BD has been tested for carcinogenicity in mice and rats. Both species responded to BD exposure by developing cancer at multiple primary organ sites. Early deaths in mice were caused by malignant lymphomas, primarily lymphocytic type, originating in the thymus.

Mice exposed to BD have developed ovarian or testicular atrophy. Sperm head morphology tests also revealed abnormal sperm in mice exposed to BD; lethal mutations were found in a dominant lethal test. In light of these results in animals, the possibility that BD may adversely affect the reproductive systems of male and female workers must be considered.

Additionally, anemia has been observed in animals exposed to butadiene. In some cases, this anemia appeared to be a primary

response to exposure; in other cases, it may have been secondary to a neoplastic response.

C. Epidemiology

Epidemiologic evidence demonstrates that BD exposure poses an increased risk of leukemia. Mild alterations of hematologic parameters have also been observed in synthetic rubber workers exposed to BD.

II. Potential Adverse Health Effects

A. Acute

Skin contact with liquid BD causes characteristic burns or frostbite. BD in gaseous form can irritate the eyes, nasal passages, throat, and lungs. Blurred vision, coughing, and drowsiness may also occur. Effects are mild at 2,000 ppm and pronounced at 8,000 ppm for exposures occurring over the full workshift.

At very high concentrations in air, BD is an anesthetic, causing narcosis, respiratory paralysis, unconsciousness, and death. Such concentrations are unlikely, however, except in an extreme emergency because BD poses an explosion hazard at these levels.

B. Chronic

The principal adverse health effects of concern are BD-induced lymphoma, leukemia and potential reproductive toxicity. Anemia and other changes in the peripheral blood cells may be indicators of excessive exposure to BD.

C. Reproductive

Workers may be concerned about the possibility that their BD exposure may be affecting their ability to procreate a healthy child. For workers with high exposures to BD, especially those who have experienced difficulties in conceiving, miscarriages, or stillbirths, appropriate medical and laboratory evaluation of fertility may be necessary to determine if BD is having any adverse effect on the reproductive system or on the health of the fetus.

III. Medical Screening Components At-A-Glance

A. Health Questionnaire

The most important goal of the health questionnaire is to elicit information from the worker regarding potential signs or symptoms generally related to leukemia or other blood abnormalities. Therefore, physicians or other licensed health care professionals should be aware of the

presenting symptoms and signs of lymphohematopoietic disorders and cancers, as well as the procedures necessary to confirm or exclude such diagnoses. Additionally, the health questionnaire will assist with the identification of workers at greatest risk of developing leukemia or adverse reproductive effects from their exposures to BD.

Workers with a history of reproductive difficulties or a personal or family history of immune deficiency syndromes, blood dyscrasias, lymphoma, or leukemia, and those who are or have been exposed to medicinal drugs or chemicals known to affect the hematopoietic or lymphatic systems may be at higher risk from their exposure to BD. After the initial administration, the health questionnaire must be updated annually.

B. Complete Blood Count (CBC)

The medical screening and surveillance program requires an annual CBC, with differential and platelet count, to be provided for each employee with BD exposure. This test is to be performed on a blood sample obtained by phlebotomy of the venous system or, if technically feasible, from a fingerstick sample of capillary blood. The sample is to be analyzed by an accredited laboratory.

Abnormalities in a CBC may be due to a number of different etiologies. The concern for workers exposed to BD includes, but is not limited to, timely identification of lymphohematopoietic cancers, such as leukemia and non-Hodgkin's lymphoma. Abnormalities of portions of the CBC are identified by comparing an individual's results to those of an established range of normal values for males and females. A substantial change in any individual employee's CBC may also be viewed as "abnormal" for that individual even if all measurements fall within the population-based range of normal values. It is suggested that a flowsheet for laboratory values be included in each employee's medical record so that comparisons and trends in annual CBCs can be easily made.

A determination of the clinical significance of an abnormal CBC shall be the responsibility of the examining physician, other licensed health care professional, or medical specialist to whom the employee is referred. Ideally, an abnormal CBC should be compared to previous CBC measurements for the same employee, when available. Clinical common sense may dictate that a CBC value that is very slightly outside the normal range does not warrant medical concern. A CBC abnormality may also be the result of a temporary physical stressor, such as a transient viral illness, blood donation, or menorrhagia, or laboratory error. In these cases, the CBC should be repeated in a timely fashion, i.e., within 6 weeks, to verify that return to the normal range has occurred. A clinically significant abnormal CBC should result in removal of the employee from further exposure to BD. Transfer of the employee to other work duties in a BD-free environment would be the preferred recommendation.

C. Physical Examination

The medical screening and surveillance program requires an initial physical examination for workers exposed to BD; this examination is repeated once every three years. The initial physical

examination should assess each worker's baseline general health and rule out clinical signs of medical conditions that may be caused by or aggravated by occupational BD exposure. The physical examination should be directed at identification of signs of lymphohematopoietic disorders, including lymph node enlargement, splenomegaly, and hepatomegaly.

Repeated physical examinations should update objective clinical findings that could be indicative of interim development of a lymphohematopoietic disorder, such as lymphoma, leukemia, or other blood abnormality. Physical examinations may also be provided on an as needed basis in order to follow up on a positive answer on the health questionnaire, or in response to an abnormal CBC. Physical examination of workers who will no longer be working in jobs with BD exposure are intended to rule out lymphohematopoietic disorders.

The need for physical examinations for workers concerned about adverse reproductive effects from their exposure to BD should be identified by the physician or other licensed health care professional and provided accordingly. For these workers, such consultations and examinations may relate to developmental toxicity and reproductive capacity.

Physical examination of workers acutely exposed to significant levels of BD should be especially directed at the respiratory system, eyes, sinuses, skin, nervous system, and any region associated with particular complaints. If the worker has received a severe acute exposure, hospitalization may be required to assure proper medical management. Since this type of exposure may place workers at greater risk of blood abnormalities, a CBC must be obtained within 48 hours and repeated at one, two, and three months.

[61 FR 56746, Nov. 4, 1996]

1910.1051 App D Sampling and Analytical Method for 1,3-Butadiene (Non-Mandatory)

OSHA Method No.: 56.

Matrix: Air.

Target concentration: 1 ppm (2.21 mg/m³)

Procedure: Air samples are collected by drawing known volumes of air through sampling tubes containing charcoal adsorbent which has been coated with 4-tert-butylcatechol. The samples are desorbed with carbon disulfide and then analyzed by gas chromatography using a flame ionization detector.

Recommended sampling rate and air volume: 0.05 L/min and 3 L.

Detection limit of the overall procedure: 90 ppb (200 ug/m³)
(based on 3 L air volume).

Reliable quantitation limit: 155 ppb (343 ug/m³) (based on 3 L air volume).

Standard error of estimate at the target concentration: 6.5%.

Special requirements: The sampling tubes must be coated with 4-tert-butylcatechol. Collected samples should be stored in a freezer.

Status of method: A sampling and analytical method has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch, OSHA Analytical Laboratory, Salt Lake City, Utah 84165.

1. Background

This work was undertaken to develop a sampling and analytical procedure for BD at 1 ppm. The current method recommended by OSHA for collecting BD uses activated coconut shell charcoal as the sampling medium (Ref. 5.2). This method was found to be inadequate for use at low BD levels because of sample instability.

The stability of samples has been significantly improved through the use of a specially cleaned charcoal which is coated with 4-tert-butylcatechol (TBC). TBC is a polymerization inhibitor for BD (Ref. 5.3).

1.1.1 Toxic effects

Symptoms of human exposure to BD include irritation of the eyes, nose and throat. It can also cause coughing, drowsiness and fatigue. Dermatitis and frostbite can result from skin exposure to liquid BD. (Ref. 5.1)

NIOSH recommends that BD be handled in the workplace as a potential occupational carcinogen. This recommendation is based on two inhalation studies that resulted in cancers at multiple sites in rats and in mice. BD has also demonstrated mutagenic activity in the presence of a liver microsomal activating system. It has also been reported to have adverse reproductive effects. (Ref. 5.1)

1.1.2. Potential workplace exposure

About 90% of the annual production of BD is used to manufacture styrene-butadiene rubber and Polybutadiene rubber. Other uses include: Polychloroprene rubber, acrylonitrile butadiene-styrene resins, nylon intermediates, styrene-butadiene latexes, butadiene polymers, thermoplastic elastomers, nitrile resins, methyl methacrylate-butadiene styrene resins and chemical intermediates. (Ref. 5.1)

1.1.3. Physical properties (Ref. 5.1)

CAS No.: 106-99-0

Molecular weight: 54.1

Appearance: Colorless gas

Boiling point: -4.41 deg. C (760 mm Hg)
Freezing point: -108.9 deg. C
Vapor pressure: 2 atm @ 15.3 deg. C; 5 atm @ 47 deg. C
Explosive limits: 2 to 11.5% (by volume in air)
Odor threshold: 0.45 ppm
Structural formula: H(2)C:CHCH:CH(2)
Synonyms: BD; biethylene; bivinyl; butadiene; divinyl; buta-1,3-diene;
alpha-gamma-butadiene; erythrene; NCI-C50602; pyrrolylene; vinylethylene.

1.2. Limit defining parameters

The analyte air concentrations listed throughout this method are based on an air volume of 3 L and a desorption volume of 1 mL. Air concentrations listed in ppm are referenced to 25 deg. C and 760 mm Hg.

1.2.1. Detection limit of the analytical procedure

The detection limit of the analytical procedure was 304 pg per injection. This was the amount of BD which gave a response relative to the interferences present in a standard.

1.2.2. Detection limit of the overall procedure

The detection limit of the overall procedure was 0.60 ug per sample (90 ppb or 200 ug/m³). This amount was determined graphically. It was the amount of analyte which, when spiked on the sampling device, would allow recovery approximately equal to the detection limit of the analytical procedure.

1.2.3. Reliable quantitation limit

The reliable quantitation limit was 1.03 ug per sample (155 ppb or 343 ug/m³). This was the smallest amount of analyte which could be quantitated within the limits of a recovery of at least 75% and a precision (+/- 1.96 SD) of +/- 25% or better.

1.2.4. Sensitivity(1)

The sensitivity of the analytical procedure over a concentration range representing 0.6 to 2 times the target concentration, based on the recommended air volume, was 387 area units per ug/mL. This value was determined from the slope of the calibration curve. The sensitivity may vary with the particular instrument used in the analysis.

1.2.5. Recovery

The recovery of BD from samples used in storage tests remained above 77% when the samples were stored at ambient temperature and above 94% when the samples were stored at refrigerated temperature. These values were determined from regression lines which were calculated from the storage data. The recovery of the analyte from the collection device must be at least 75% following storage.

1.2.6. Precision (analytical method only)

The pooled coefficient of variation obtained from replicate determinations of analytical standards over the range of 0.6 to 2 times the target concentration was 0.011.

1.2.7. Precision (overall procedure)

The precision at the 95% confidence level for the refrigerated temperature storage test was +/- 12.7%. This value includes an additional +/- 5% for sampling error. The overall procedure must provide results at the target concentrations that are +/- 25% at the 95% confidence level.

Footnote(1) The reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operation parameters.

1.2.8. Reproducibility

Samples collected from a controlled test atmosphere and a draft copy of this procedure were given to a chemist unassociated with this evaluation. The average recovery was 97.2% and the standard deviation was 6.2%.

2. Sampling procedure

2.1. Apparatus

2.1.1. Samples are collected by use of a personal sampling pump that can be calibrated to within +/- 5% of the recommended 0.05 L/min sampling rate with the sampling tube in line.

2.1.2. Samples are collected with laboratory prepared sampling tubes. The sampling tube is constructed of silane-treated glass and is about 5-cm long. The ID is 4 mm and the OD is 6 mm. One end of the tube is tapered so that a glass wool end plug will hold the contents of the tube in place during sampling. The opening in the tapered end of the sampling tube is at least one-half the ID of the tube (2 mm). The other end of the sampling tube is open to its full 4-mm ID to facilitate packing of the tube. Both ends of the tube are fire-polished for

safety. The tube is packed with 2 sections of pretreated charcoal which has been coated with TBC. The tube is packed with a 50-mg backup section, located nearest the tapered end, and with a 100-mg sampling section of charcoal. The two sections of coated adsorbent are separated and retained with small plugs of silanized glass wool. Following packing, the sampling tubes are sealed with two 7/32 inch OD plastic end caps. Instructions for the pretreatment and coating of the charcoal are presented in Section 4.1 of this method.

2.2. Reagents

None required.

2.3. Technique

2.3.1. Properly label the sampling tube before sampling and then remove the plastic end caps.

2.3.2. Attach the sampling tube to the pump using a section of flexible plastic tubing such that the larger front section of the sampling tube is exposed directly to the atmosphere. Do not place any tubing ahead of the sampling tube. The sampling tube should be attached in the worker's breathing zone in a vertical manner such that it does not impede work performance.

2.3.3. After sampling for the appropriate time, remove the sampling tube from the pump and then seal the tube with plastic end caps. Wrap the tube lengthwise.

2.3.4. Include at least one blank for each sampling set. The blank should be handled in the same manner as the samples with the exception that air is not drawn through it.

2.3.5. List any potential interferences on the sample data sheet.

2.3.6. The samples require no special shipping precautions under normal conditions. The samples should be refrigerated if they are to be exposed to higher than normal ambient temperatures. If the samples are to be stored before they are shipped to the laboratory, they should be kept in a freezer. The samples should be placed in a freezer upon receipt at the laboratory.

2.4. Breakthrough

(Breakthrough was defined as the relative amount of analyte found on the backup section of the tube in relation to the total amount of analyte collected on the sampling tube. Five-percent breakthrough occurred after sampling a test atmosphere containing 2.0 ppm BD for 90 min at 0.05 L/min. At the end of this time 4.5 L of air had been sampled and 20.1 ug of the analyte was collected. The relative humidity of the sampled air was 80% at 23 deg. C.) Breakthrough studies have shown that the recommended sampling procedure can be used at air concentrations higher than the target concentration. The sampling time, however, should be reduced to 45 min if both

the expected BD level and the relative humidity of the sampled air are high.

2.5. Desorption efficiency

The average desorption efficiency for BD from TBC coated charcoal over the range from 0.6 to 2 times the target concentration was 96.4%. The efficiency was essentially constant over the range studied.

2.6. Recommended air volume and sampling rate

2.6.1. The recommended air volume is 3L.

2.6.2. The recommended sampling rate is 0.05 L/min for 1 hour.

2.7. Interferences

There are no known interferences to the sampling method.

2.8. Safety precautions

2.8.1. Attach the sampling equipment to the worker in such a manner that it will not interfere with work performance or safety.

2.8.2. Follow all safety practices that apply to the work area being sampled.

3. Analytical procedure

3.1. Apparatus

3.1.1. A gas chromatograph (GC), equipped with a flame ionization detector (FID).(2)

3.1.2. A GC column capable of resolving the analytes from any interference.(3)

3.1.3. Vials, glass 2-mL with Teflon-lined caps.

3.1.4. Disposable Pasteur-type pipets, volumetric flasks, pipets and syringes for preparing samples and standards, making dilutions and performing injections.

3.2. Reagents

3.2.1. Carbon disulfide.(4)

The benzene contaminant that was present in the carbon disulfide was used as an internal standard (ISTD) in this evaluation.

3.2.2. Nitrogen, hydrogen and air, GC grade.

3.2.3. BD of known high purity.(5)

3.3. Standard preparation

3.3.1. Prepare standards by diluting known volumes of BD gas with carbon disulfide. This can be accomplished by injecting the appropriate volume of BD into the headspace above the 1-mL of carbon disulfide contained in sealed 2-mL vial. Shake the vial after the needle is removed from the septum.(6)

Footnote(2) A Hewlett-Packard Model 5840A GC was used for this evaluation. Injections were performed using a Hewlett-Packard Model 7671A automatic sampler.

Footnote(3) A 20-ft x 1/8-inch OD stainless steel GC column containing 20% FFAP on 80/100 mesh Chromabsorb W-AW-DMCS was used for this evaluation.

Footnote(4) Fisher Scientific Company A.C.S. Reagent Grade solvent was used in this evaluation.

Footnote(5) Matheson Gas Products, CP Grade 1,3-butadiene was used in this study.

Footnote(6) A standard containing 7.71 ug/mL (at ambient temperature and pressure) was prepared by diluting 4 uL of the gas with 1-mL of carbon disulfide.

3.3.2. The mass of BD gas used to prepare standards can be determined by use of the following equations:

$$MV=(760/BP)(273+t)/(273)(22.41)$$

Where:

MV = ambient molar volume

BP = ambient barometric pressure

T = ambient temperature

ug/uL = 54.09/MV

ug/standard = (ug/uL)(uL) BD used to prepare the standard

3.4. Sample preparation

3.4.1. Transfer the 100-mg section of the sampling tube to a 2-mL vial. Place the 50-mg section in a separate vial. If the glass wool plugs contain a significant amount of charcoal, place them with the appropriate sampling tube section.

3.4.2. Add 1-mL of carbon disulfide to each vial.

3.4.3. Seal the vials with Teflon-lined caps and then allow them to desorb for one hour. Shake the vials by hand vigorously several times during the desorption period.

3.4.4. If it is not possible to analyze the samples within 4 hours, separate the carbon disulfide from the charcoal, using a disposable Pasteur-type pipet, following the one hour. This separation will improve the stability of desorbed samples.

3.4.5. Save the used sampling tubes to be cleaned and repacked with fresh adsorbent.

3.5. Analysis

3.5.1. GC Conditions

Column temperature: 95 deg. C

Injector temperature: 180 deg. C

Detector temperature: 275 deg. C

Carrier gas flow rate: 30 mL/min

Injection volume: 0.80 uL

GC column: 20-ft x 1/8-in OD stainless steel GC column
containing 20%

FFAP on 80/100 Chromabsorb W-AW-DMCS.

3.5.2. Chromatogram. See Section 4.2.

3.5.3. Use a suitable method, such as electronic or peak heights, to measure detector response.

3.5.4. Prepare a calibration curve using several standard solutions of different concentrations. Prepare the calibration curve daily. Program the integrator to report the results in ug/mL.

3.5.5. Bracket sample concentrations with standards.

3.6. Interferences (analytical)

3.6.1. Any compound with the same general retention time as the analyte and which also gives a detector response is a potential interference. Possible interferences should be reported by the industrial hygienist to the laboratory with submitted samples.

3.6.2. GC parameters (temperature, column, etc.) may be changed to circumvent interferences.

3.6.3. A useful means of structure designation is GC/MS. It is recommended that this procedure be used to confirm samples whenever possible.

3.7. Calculations

3.7.1. Results are obtained by use of calibration curves. Calibration curves are prepared by plotting detector response against concentration for each standard. The best line through the data points is determined by curve fitting.

3.7.2. The concentration, in ug/mL, for a particular sample is determined by comparing its detector response to the calibration curve. If any analyte is found on the backup section, this amount is added to the amount found on the front section. Blank corrections should be performed before adding the results together.

3.7.3. The BD air concentration can be expressed using the following equation:

$$\text{mg/m}^3 = (\text{A})(\text{B})/(\text{C})(\text{D})$$

Where:

A = ug/mL from Section 3.7.2

B = volume

C = L of air sampled

D = efficiency

3.7.4. The following equation can be used to convert results in mg/m³ to ppm:

$$\text{ppm} = (\text{mg/m}^3)(24.46)/54.09$$

Where:

mg/m³ = result from Section 3.7.3.

24.46 = molar volume of an ideal gas at 760 mm Hg and 25 deg.C.

3.8. Safety precautions (analytical)

3.8.1. Avoid skin contact and inhalation of all chemicals.

3.8.2. Restrict the use of all chemicals to a fume hood whenever possible.

3.8.3. Wear safety glasses and a lab coat in all laboratory areas.

4. Additional Information

4.1. A procedure to prepare specially cleaned charcoal coated with TBC

4.1.1. Apparatus.

4.1.1.1. Magnetic stirrer and stir bar.

4.1.1.2. Tube furnace capable of maintaining a temperature of 700 deg.C and equipped with a quartz tube that can hold 30 g of charcoal.(8)

4.1.1.3. A means to purge nitrogen gas through the charcoal inside the quartz tube.

4.1.1.4. Water bath capable of maintaining a temperature of 60 deg.C.

4.1.1.5. Miscellaneous laboratory equipment: One-liter vacuum flask, 1-L Erlenmeyer flask, 350-M1 Buchner funnel with a coarse fitted disc, 4-oz brown bottle, rubber stopper, Teflon tape etc.

4.1.2. Reagents

4.1.2.1. Phosphoric acid, 10% by weight, in water.(9)

4.1.2.2. 4-tert-Butylcatechol (TBC).(10)

4.1.2.3. Specially cleaned coconut shell charcoal, 20/40 mesh.(11)

4.1.2.4. Nitrogen gas, GC grade.

4.1.3. Procedure.

Footnote(8) A Lindberg Type 55035 Tube furnace was used in this evaluation.

Footnote(9) Baker Analyzed" Reagent grade was diluted with water for use in this evaluation.

Footnote(10) The Aldrich Chemical Company 99% grade was used in this evaluation.

Footnote(11) Specially cleaned charcoal was obtained from Supelco, Inc. for use in this evaluation. The cleaning process used by Supelco is proprietary.

Weigh 30g of charcoal into a 500-mL Erlenmeyer flask. Add about 250 mL of 10% phosphoric acid to the flask and then swirl the mixture. Stir the mixture for 1 hour using a magnetic stirrer. Filter the mixture using a fitted Buchner funnel. Wash the charcoal several times with 250-mL portions of deionized water to remove all traces of the acid. Transfer the washed charcoal to the tube furnace quartz tube. Place the quartz tube in the furnace and then connect the nitrogen gas purge to the tube. Fire the charcoal to 700 deg. C. Maintain that temperature for at least 1 hour. After the charcoal has cooled to room temperature, transfer it to a tared beaker. Determine the weight of the charcoal and then add an amount of TBC which is 10% of the charcoal, by weight.

CAUTION-TBC is toxic and should only be handled in a fume hood while wearing gloves.

Carefully mix the contents of the beaker and then transfer the mixture to a 4-oz bottle. Stopper the bottle with a clean rubber stopper which has been wrapped with Teflon tape. Clamp the bottle in a water bath so that the water level is above the charcoal level. Gently heat the bath to 60 deg. C and then maintain that temperature for 1 hour. Cool the charcoal to room temperature and then transfer the coated charcoal to a suitable container.

The coated charcoal is now ready to be packed into sampling tubes. The sampling tubes should be stored in a sealed container to prevent contamination. Sampling tubes should be stored in the dark at room temperature. The sampling tubes should be segregated by coated adsorbent lot number.

4.2 Chromatograms

The chromatograms were obtained using the recommended analytical method. The chart speed was set at 1 cm/min for the first three min and then at 0.2 cm/min for the time remaining in the analysis.

The peak which elutes just before BD is a reaction product between an impurity on the charcoal and TBC. This peak is always present, but it is easily resolved from the analyte. The peak which elutes immediately before benzene is an oxidation product of TBC.

5. References

5.1. "Current Intelligence Bulletin 41, 1,3-Butadiene", U.S. Dept. of Health and Human Services, Public Health Service, Center for Disease Control, NIOSH.

5.2. "NIOSH Manual of Analytical Methods", 2nd ed; U.S. Dept. of Health Education and Welfare, National Institute for Occupational Safety and Health: Cincinnati, OH. 1977, Vol. 2, Method No. S91 DHEW (NIOSH) Publ. (US), No. 77-157-B.

5.3. Hawley, G.C., Ed. "The Condensed Chemical Dictionary", 8th ed.; Van Nostrand Rienhold Company: New York, 1971; 139.5.4. Chem. Eng. News (June 10, 1985), (63), 22-66.

[61 FR 56746, Nov. 4, 1996]

1910.1051 App E Respirator Fit Testing Procedures (Mandatory) [Reserved]

APPENDIX F. MEDICAL QUESTIONNAIRES, (Non-mandatory)

1,3-Butadiene (BD) Initial Health Questionnaire

DIRECTIONS:

You have been asked to answer the questions on this form because you work with BD (butadiene). These questions are about your work, medical history, and health concerns. Please do your best to answer all of the questions. If you need help, please tell the doctor or health care professional who reviews this form.

This form is a confidential medical record. Only information directly related to your health and safety on the job may be given to your employer. Personal health information will not be given to anyone without your consent.

Date: _____

Name: _____ SSN ____/____/____
Last First MI

Job Title: _____

Company's Name: _____

Supervisor's Name: _____ Supervisor's
Phone No.: () ____-____

Work History

1. Please list all jobs you have had in the past, starting with the job you have now and moving back in time to your first job. (For more space, write on the back of this page.)

| Main Job Duty | Years | Company Name, City, State | Chemicals |
|---------------|-------|---------------------------|-----------|
| 1. | | | |

| | | | |
|----|--|--|--|
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |
| 7. | | | |
| 8. | | | |

2. Please describe what you do during a typical work day. Be sure to tell about you work with BD.

3. Please check any of these chemicals that you work with now or have worked with in the past:

- benzene
- glues
- toluene
- inks, dyes
- other solvents, grease cutters
- insecticides (like DDT, lindane, etc.)
- paints, varnishes, thinners, strippers
- dusts
- carbon tetrachloride ("carbon tet")
- arsine
- carbon disulfide
- lead
- cement
- petroleum products
- nitrites

4. Please check the protective clothing or equipment you use at the job you have now:

- gloves
- coveralls
- respirator
- dust mask
- safety glasses, goggles

Please circle your answer of yes or no.

5. Does your protective clothing or equipment fit you properly?

yes no

6. Have you ever made changes in your protective clothing or equipment to make it fit better?

yes no

7. Have you been exposed to BD when you were not wearing protective clothing or equipment?

yes no

8. Where do you eat, drink and/or smoke when you are at work?

(Please check all that apply.)

| | |
|--------------------------------|-------|
| Cafeteria/restaurant/snack bar | _____ |
| Break room/employee lounge | _____ |
| Smoking lounge | _____ |
| At my work station | _____ |

Please circle your answer.

9. Have you been exposed to radiation (like x-rays or nuclear material) at the job you have now or at past jobs?

yes no

10. Do you have any hobbies that expose you to dusts or chemicals (including paints, glues, etc.)?

yes no

11. Do you have any second or side jobs?

yes no

If yes, what are your duties there? _____

12. Were you in the military?

yes no

If yes, what did you do in the military? _____

Family Health History

1. In the FAMILY MEMBER column, across from the disease name, write which family member, if any, had the disease.

| DISEASE | FAMILY MEMBER |
|------------------------------|---------------|
| Cancer | |
| Lymphoma | |
| Sickle Cell Disease or Trait | |
| Immune Disease | |
| Leukemia | |
| Anemia | |

2. Please fill in the following information about family health:

| RELATIVE | ALIVE? | AGE AT DEATH? | CAUSE OF DEATH? |
|----------------|--------|---------------|-----------------|
| Father | | | |
| Mother | | | |
| Brother/Sister | | | |
| Brother/Sister | | | |
| Brother/Sister | | | |

PERSONAL HEALTH HISTORY

Birth Date ___/___/___ Age ___ Sex ___ Height ___ Weight ___

Please circle your answer.

1. Do you smoke any tobacco products?

yes no

2. Have you ever had any kind of surgery or operation?

yes no

If yes, what type of surgery: _____

3. Have you ever been in the hospital for any other reasons?

yes no

If yes, please describe the reason: _____

4. Do you have any on-going or current medical problems or conditions?

yes no

If yes, please describe: _____

5. Do you now have or have you ever had any of the following?

Please check all that apply to you.

| | |
|----------------------|-------|
| unexplained fever | _____ |
| anemia ("low blood") | _____ |
| HIV/AIDS | _____ |
| weakness | _____ |
| sickle cell | _____ |
| miscarriage | _____ |
| skin rash | _____ |
| bloody stools | _____ |
| leukemia/lymphoma | _____ |
| neck mass/swelling | _____ |
| wheezing | _____ |
| yellowing of skin | _____ |
| bruising easily | _____ |
| lupus | _____ |
| weight loss | _____ |
| kidney problems | _____ |
| enlarged lymph nodes | _____ |
| liver disease | _____ |
| cancer | _____ |

| | |
|-------------------------|-------|
| infertility | _____ |
| drinking problems | _____ |
| thyroid problems | _____ |
| night sweats | _____ |
| chest pain | _____ |
| still birth | _____ |
| eye redness | _____ |
| lumps you can feel | _____ |
| child with birth defect | _____ |
| autoimmune disease | _____ |
| overly tired | _____ |
| lung problems | _____ |
| rheumatoid arthritis | _____ |
| mononucleosis("mono") | _____ |
| nagging cough | _____ |

Please circle your answer.

6. Do you have any symptoms or health problems that you think may be related to your work with BD?

yes no

If yes, please describe: _____

7. Have any of your co-workers had similar symptoms or problems?

yes no don't know

If yes, please describe: _____

8. Do you notice any irritation of your eyes, nose, throat, lungs, or skin when working with BD?

yes no

9. Do you notice any blurred vision, coughing, drowsiness, nausea, or headache when working with BD?

yes no

10. Do you take any medications (including birth control or over-the-counter)?

yes no

If yes, please list: _____

11. Are you allergic to any medication, food, or chemicals?

yes no

If yes, please list: _____

12. Do you have any health conditions not covered by this questionnaire that you think are affected by your work with BD?

yes no

If yes, please explain: _____

13. Did you understand all the questions?

yes no

Signature

1,3-Butadiene (BD) Update Health Questionnaire

DIRECTIONS:

You have been asked to answer the questions on this form because you work with BD (butadiene). These questions ask about changes in your work, medical history, and health concerns since the last time you were evaluated. Please do your best to answer all of the questions. If you need help, please tell the doctor or health care professional who reviews this form.

This form is a confidential medical record. Only information directly related to your health and safety on the job may be given to your employer. Personal health information will not be given to anyone without your consent.

Date: _____

Name: _____ SSN ____/____/____
Last First MI

Job Title: _____

Company's Name: _____

Supervisor's Name: _____ Supervisor's
Phone No.: () _____-_____

Present Work History

1. Please describe any NEW duties that you have at your job: _____

2. Please list any additional job titles you have:

| | |
|-------|-------|
| <hr/> | <hr/> |
| <hr/> | <hr/> |
| <hr/> | <hr/> |

Please circle your answer.

3. Are you exposed to any other chemicals in your work since the last time you were evaluated for exposure to BD?

yes no

If yes, please list what they are: _____

4. Does your personal protective equipment and clothing fit you properly?

yes no

5. Have you made changes in this equipment or clothing to make it fit better?

yes no

6. Have you been exposed to BD when you were not wearing protective equipment or clothing?

yes no

7. Are you exposed to any NEW chemicals at home or while working on hobbies?

yes no

If yes, please list what they are: _____

8. Since your last BD health evaluation, have you started working any new second or side jobs?

yes no

If yes, what are your duties there? _____

1. What is your current weight? _____ pounds

2. Have you been diagnosed with any new medical conditions or illness since your last evaluation?

yes no

If yes, please tell what they are: _____

3. Since your last evaluation, have you been in the hospital for any illnesses, injuries, or surgery?

yes no

If yes, please describe: _____

4. Do you have any of the following?

Please place a check for all that apply to you.

- unexplained fever _____
- anemia ("low blood") _____
- HIV/AIDS _____
- weakness _____
- sickle cell _____
- miscarriage _____
- skin rash _____
- bloody rash _____
- leukemia/lymphoma _____
- neck mass/swelling _____
- wheezing _____
- chest pain _____
- bruising easily _____
- lupus _____
- weight loss _____
- kidney problems _____
- enlarged lymph nodes _____
- liver disease _____
- cancer _____
- infertility _____
- drinking problems _____
- thyroid problems _____
- night sweats _____
- still birth _____
- eye redness _____
- lumps you can feel _____
- child with birth defect _____
- autoimmune disease _____
- overly tired _____
- lung problems _____
- rheumatoid arthritis _____
- mononucleosis "mono" _____
- nagging cough _____
- yellowing of skin _____

Please circle your answer.

5. Do you have any symptoms or health problems that you think may be related to your work with BD?

yes no

If yes, please describe: _____

6. Have any of your co-workers had similar symptoms or problems?

yes no don't know

If yes, please describe: _____

7. Do you notice any irritation of your eyes, nose, throat, lungs, or skin when working with BD?

yes no

8. Do you notice any blurred vision, coughing, drowsiness, nausea, or headache when working with BD?

yes no

9. Have you been taking any NEW medications (including birth control or over-the-counter)?

yes no

If yes, please list:

10. Have you developed any NEW allergies to medications, foods, or chemicals?

yes no

If yes, please list:

11. Do you have any health conditions not covered by this questionnaire that you think are affected by your work with BD?

yes no

If yes, please explain: _____

12. Did you understand all the questions?

yes no

Signature

[61 FR 56746, Nov. 4, 1996]

1910.1052 - Methylene Chloride

This occupational health standard establishes requirements for employers to control occupational exposure to methylene chloride (MC). Employees exposed to MC are at increased risk of developing cancer, adverse effects on the heart, central nervous system and liver, and skin or eye irritation. Exposure may occur through inhalation, by absorption through the skin, or through contact with the skin. MC is a solvent which is used in many different types of work activities, such as paint stripping, polyurethane foam manufacturing, and cleaning and degreasing. Under the requirements of paragraph (d) of this section, each covered employer must make an initial determination of each employee's exposure to MC. If the employer determines that employees are exposed below the action level, the only other provisions of this section that apply are that a record must be made of the determination, the employees must receive information and training under paragraph (l) of this section and, where appropriate, employees must be protected from contact with liquid MC under paragraph (h) of this section. The provisions of the MC standard are as follows:

(a) Scope and application. This section applies to all occupational exposures to methylene chloride (MC), *Chemical Abstracts Service Registry Number 75-09-2*, in general industry, construction and shipyard employment.

(b) Definitions. For the purposes of this section, the following definitions shall apply:

AAction level@ means a concentration of airborne MC of 12.5 parts per million (ppm) calculated as an eight (8)-hour time-weighted average (TWA).

AAssistant Secretary@ means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

AAuthorized person@ means any person specifically authorized by the employer and required by work duties to be present in regulated areas, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (d) of this section, or any other person authorized by the OSH Act or regulations issued under the Act.

ADirector@ means the Director of the National Institute for Occupational Safety and Health,

U.S. Department of Health and Human Services, or designee.

Emergency@ means any occurrence, such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which results, or is likely to result in an uncontrolled

release of MC. If an incidental release of MC can be controlled by employees such as maintenance personnel at the time of release and in accordance with the leak/spill provisions required by paragraph (f) of this section, it is not considered an emergency as defined by this standard.

Employee exposure@ means exposure to airborne MC which occurs or would occur if the employee were not using respiratory protection.

Methylene chloride@ [MC] means an organic compound with chemical formula, CH₂Cl₂. Its *Chemical Abstracts Service Registry Number* is 75-09-2. Its molecular weight is 84.9 g/mole.

Physician or other licensed health care professional@ is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide some or all of the

health care services required by paragraph (j) of this section.

Regulated area@ means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of MC exceeds or can reasonably be expected to exceed either the 8-hour TWA PEL or the STEL.

Symptom@ means central nervous system effects such as headaches, disorientation, dizziness, fatigue, and decreased attention span; skin effects such as chapping, erythema, cracked skin, or skin burns; and cardiac effects such as chest pain or shortness of breath.

This section@ means this methylene chloride standard.

(c) Permissible exposure limits (PELs).

(1) Eight-hour time-weighted average (TWA) PEL. The employer shall ensure that no employee is exposed to an airborne concentration of MC in excess of twenty-five parts of MC per million parts of air (25 ppm) as an 8-hour TWA.

(2) Short-term exposure limit (STEL). The employer shall ensure that no employee is exposed to an airborne concentration of MC in excess of one hundred and twenty-five parts of MC per million parts of air (125 ppm) as determined over a sampling period of fifteen minutes.

(d) Exposure monitoring.

(1) Characterization of employee exposure.

(i) Where MC is present in the workplace, the employer shall determine each employee's exposure by either:

(A) Taking a personal breathing zone air sample of each employee's exposure; or

(B) Taking personal breathing zone air samples that are representative of each employee's exposure.

(ii) Representative samples. The employer may consider personal breathing zone air samples to be representative of employee exposures when they are taken as follows:

(A) 8-hour TWA PEL. The employer has taken one or more personal breathing zone air samples for at least one employee in each job classification in a work area during every work shift, and the employee sampled is expected to have the highest MC exposure.

(B) Short-term exposure limits. The employer has taken one or more personal breathing zone air samples which indicate the highest likely 15-minute exposures during such operations for at least one employee in each job classification in the work area during every work shift, and the employee sampled is expected to have the highest MC exposure.

(C) Exception. Personal breathing zone air samples taken during one work shift may be used to represent employee exposures on other work shifts where the employer can document that the tasks performed and conditions in the workplace are similar across shifts.

(iii) Accuracy of monitoring. The employer shall ensure that the methods used to perform exposure monitoring produce results that are accurate to a confidence level of 95 percent, and are:

(A) Within plus or minus 25 percent for airborne concentrations of MC above the 8-hour TWA PEL or the STEL; or

(B) Within plus or minus 35 percent for airborne concentrations of MC at or above the action level but at or below the 8-hour TWA PEL.

(2) Initial determination. Each employer whose employees are exposed to MC shall perform initial exposure monitoring to determine each affected employee's exposure, except under the following conditions:

(i) Where objective data demonstrate that MC cannot be released in the workplace in airborne concentrations at or above the action level or above the STEL. The objective data shall represent the highest MC exposures likely to occur under reasonably foreseeable conditions of processing, use, or handling. The employer shall document the objective data exemption as specified in paragraph (m) of this section;

(ii) Where the employer has performed exposure monitoring within 12 months prior to April 10, 1997 and that exposure monitoring meets all other requirements of this section, and was conducted under conditions substantially equivalent to existing conditions; or

(iii) Where employees are exposed to MC on fewer than 30 days per year (e.g., on a

construction site), and the employer has measurements by direct-reading instruments which give immediate results (such as a detector tube) and which provide sufficient information regarding employee exposures to determine what control measures are necessary to reduce exposures to acceptable levels.

(3) Periodic monitoring. Where the initial determination shows employee exposures at or above the action level or above the STEL, the employer shall establish an exposure monitoring program for periodic monitoring of employee exposure to MC in accordance with Table 1:

Table 1 - Initial Determination Exposure Scenarios And Their Associated Monitoring Frequencies

| Exposure Scenario | Required monitoring activity |
|--------------------------|-------------------------------------|
|--------------------------|-------------------------------------|

| | |
|--|---|
| <p>Below the action level and at or below the STEL</p> | <p>No 8-hour TWA or STEL monitoring required.</p> |
| <p>Below the action level and above the STEL.....</p> | <p>No 8-hour TWA monitoring required; monitor STEL exposures every three months.</p> |
| <p>At or above the action level, at or below the TWA, and at or below the STEL</p> | <p>Monitor 8-hour TWA level every six months.</p> |
| <p>At or above the action level, at or below the TWA, and above the STEL</p> | <p>Monitor 8-hour TWA exposures every six months and monitor STEL exposures every three months.</p> |
| <p>Above the TWA and at or below the STEL.....</p> | <p>Monitor 8-hour TWA exposures every three months. In addition, without regard to the last sentence of the note to paragraph (d)(3), the following employers must monitor STEL exposures every three months until either the date by which they must achieve the 8-hour TWA PEL under paragraph (n) of this section or the date by which they in fact archive the 8-hour TWA PEL, whichever comes first. Employers engaged in polyurethane foam manufacturing, foam fabrication, furniture refinishing, general aviation aircraft stripping, product formulation, use of MC-based adhesives for boat building and repair, recreational vehicle manufacturing, van conversion, or upholstery, and use of MC in construction work for restoration and preservation of buildings, painting and paint removal, cabinet making, or floor refinishing and resurfacing.</p> |
| <p>Above the TWA and above the STEL.....</p> | <p>Monitor 6-hour TWA exposures and STEL exposures every three months.</p> |

[Note to paragraph (d)(3): The employer may decrease the frequency of 8-hour TWA exposure monitoring to every six months when at least two consecutive measurements taken at least seven days apart show exposures to be at or below the 8-hour TWA PEL. The employer may discontinue the periodic 8-hour TWA monitoring for employees where at least two consecutive measurements taken at least seven days apart are below the action level. The employer may discontinue the periodic STEL monitoring for employees where at least two consecutive measurements taken at least 7 days apart are at or below the STEL.]

(4) Additional monitoring.

(i) The employer shall perform exposure monitoring when a change in workplace conditions indicates that employee exposure may have increased. Examples of situations that may require additional monitoring include changes in production, process, control equipment, or work practices, or a leak, rupture, or other breakdown.

(ii) Where exposure monitoring is performed due to a spill, leak, rupture or equipment breakdown, the employer shall clean-up the MC and perform the appropriate repairs before monitoring.

(5) Employee notification of monitoring results.

(i) The employer shall, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results in writing, either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) Whenever monitoring results indicate that employee exposure is above the 8-hour TWA PEL or the STEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the 8-hour TWA PEL or STEL and the schedule for completion of this action.

(6) Observation of monitoring.

(i) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to MC conducted in accordance with this section.

(ii) Observation procedures. When observation of the monitoring of employee exposure to MC requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide, at no cost to the observer(s), and the observer(s) shall be required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

(e) Regulated areas.

(1) The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of MC exceeds or can reasonably be expected to exceed either the 8-hour TWA PEL or the STEL.

(2) The employer shall limit access to regulated areas to authorized persons.

(3) The employer shall supply a respirator, selected in accordance with paragraph (g)(3) of this section, to each person who enters a regulated area and shall require each affected employee to use that respirator whenever MC exposures are likely to exceed the 8-hour TWA PEL or STEL.

[Note to paragraph (e)(3): An employer who has implemented all feasible engineering, work practice and administrative controls (as required in paragraph (f) of this section), and who has established a regulated area (as required by paragraph (e)(1) of this section) where MC exposure can be reliably predicted to exceed the 8-hour TWA PEL or the STEL only on certain days (for example, because of work or process schedule) would need to have affected employees use respirators in that regulated area only on those days.]

(4) The employer shall ensure that, within a regulated area, employees do not engage in non-work activities which may increase dermal or oral MC exposure.

(5) The employer shall ensure that while employees are wearing respirators, they do not engage in activities (such as taking medication or chewing gum or tobacco) which interfere with respirator seal or performance.

(6) The employer shall demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts employees to the boundaries of the area and minimizes the

number of authorized employees exposed to MC within the regulated area.

(7) An employer at a multi-employer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to all other employers with work operations at that worksite.

(f) Methods of compliance.

(1) Engineering and work practice controls. The employer shall institute and maintain the effectiveness of engineering controls and work practices to reduce employee exposure to or below the PELs except to the extent that the employer can demonstrate that such controls are not feasible. Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the 8-TWA PEL or STEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) Prohibition of rotation. The employer shall not implement a schedule of employee rotation as a means of compliance with the PELs.

(3) Leak and spill detection.

(i) The employer shall implement procedures to detect leaks of MC in the workplace. In work areas where spills may occur, the employer shall make provisions to contain any spills and to safely dispose of any MC-contaminated waste materials.

(ii) The employer shall ensure that all incidental leaks are repaired and that incidental spills are cleaned promptly by employees who use the appropriate personal protective equipment and are trained in proper methods of cleanup.

[Note to paragraph (f)(3)(ii): See Appendix A of this section for examples of procedures that satisfy this requirement. Employers covered by this standard may also be subject to the hazardous waste and emergency response provisions contained in 29 CFR 1910.120 (q).]

(g) Respiratory protection.

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that comply with the requirements of this paragraph. Respirators must be used during:

(i) Periods when an employee's exposure to MC exceeds the 8-hour TWA PEL, or STEL (for example, when an employee is using MC in a regulated area).

(ii) Periods necessary to install or implement feasible engineering and work-practice controls.

(iii) A few work operations, such as some maintenance operations and repair activities, for which the employer demonstrates that engineering and work-practice controls are infeasible.

(iv) Work operations for which feasible engineering and work-practice controls are not sufficient to reduce employee exposures to or below the PELs.

(v) Emergencies.

(2) Respirator program.

(i) The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (m) (except (d)(1)(iii)), which covers each employee required by this section to use a respirator.

(ii) Employers who provide employees with gas masks with organic-vapor canisters for the purpose of emergency escape must replace the canisters after any emergency use and before the gas masks are returned to service.

(3) Respirator selection. Employers must:

(i) Select, and provide to employees, the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use half masks of any type because MC may cause eye irritation or damage.

(ii) For emergency escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the continuous-flow or pressure-demand mode; or a gas mask with an organic vapor canister.

(4) Medical evaluation. Before having an employee use a supplied-air respirator in the negative-pressure mode, or a gas mask with an organic-vapor canister for emergency escape, the employer must:

(i) Have a physician or other licensed health-care professional (PLHCP) evaluate the employee's ability to use such respiratory protection.

(ii) Ensure that the PLHCP provides their findings in a written opinion to the employee and the employer.

(h) Protective Work Clothing and Equipment.

(1) Where needed to prevent MC-induced skin or eye irritation, the employer shall provide

clean protective clothing and equipment which is resistant to MC, at no cost to the employee, and shall ensure that each affected employee uses it. Eye and face protection shall meet the requirements of 29 CFR 1910.133 or 29 CFR 1915.153, as applicable.

(2) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this paragraph as needed to maintain their effectiveness.

(3) The employer shall be responsible for the safe disposal of such clothing and equipment.

[Note to paragraph (h)(3): See Appendix A for examples of disposal procedures that will satisfy this requirement.]

(i) Hygiene facilities.

(1) If it is reasonably foreseeable that employees' skin may contact solutions containing 0.1 percent or greater MC (for example, through splashes, spills or improper work practices), the employer shall provide conveniently located washing facilities capable of removing the MC, and shall ensure that affected employees use these facilities as needed.

(2) If it is reasonably foreseeable that an employee's eyes may contact solutions containing 0.1 percent or greater MC (for example through splashes, spills or improper work practices), the employer shall provide appropriate eyewash facilities within the immediate work area for emergency use, and shall ensure that affected employees use those facilities when necessary.

(j) Medical surveillance.

(1) Affected employees. The employer shall make medical surveillance available for employees who are or may be exposed to MC as follows:

(i) At or above the action level on 30 or more days per year, or above the 8-hour TWA PEL or the STEL on 10 or more days per year;

(ii) Above the 8-TWA PEL or STEL for any time period where an employee has been identified by a physician or other licensed health care professional as being at risk from cardiac disease or from some other serious MC-related health condition and such employee requests inclusion in the medical surveillance program;

(iii) During an emergency.

(2) Costs. The employer shall provide all required medical surveillance at no cost to affected employees, without loss of pay and at a reasonable time and place.

(3) Medical personnel. The employer shall ensure that all medical surveillance procedures are performed by a physician or other licensed health care professional, as defined in paragraph (b) of this section.

(4) Frequency of medical surveillance. The employer shall make medical surveillance available to each affected employee as follows: (i) Initial surveillance. The employer shall provide initial medical surveillance under the schedule provided by paragraph (n)(2)(iii) of this section, or before the time of initial assignment of the employee, whichever is later. The employer need not provide the initial surveillance if medical records show that an affected employee has been provided with medical surveillance that complies with this section within 12 months before April 10, 1997.

(ii) Periodic medical surveillance. The employer shall update the medical and work history for each affected employee annually. The employer shall provide periodic physical examinations, including appropriate laboratory surveillance, as follows:

(A) For employees 45 years of age or older, within 12 months of the initial surveillance or any subsequent medical surveillance; and

(B) For employees younger than 45 years of age, within 36 months of the initial surveillance or any subsequent medical surveillance.

(iii) Termination of employment or reassignment. When an employee leaves the employer's workplace, or is reassigned to an area where exposure to MC is consistently at or below the action level and STEL, medical surveillance shall be made available if six months or more have elapsed since the last medical surveillance.

(iv) Additional surveillance. The employer shall provide additional medical surveillance at frequencies other than those listed above when recommended in the written medical opinion. (For example, the physician or other licensed health care professional may determine an examination is warranted in less than 36 months for employees younger than 45 years of age based upon evaluation of the results of the annual medical and work history.)

(5) Content of medical surveillance.

(i) Medical and work history. The comprehensive medical and work history shall emphasize neurological symptoms, skin conditions, history of hematologic or liver disease, signs or symptoms suggestive of heart disease (angina, coronary artery disease), risk factors for cardiac disease, MC exposures, and work practices and personal protective equipment used during such exposures.

[Note to paragraph (j)(5)(i): See Appendix B of this section for an example of a medical and work history format that would satisfy this requirement.]

(ii) Physical examination. Where physical examinations are provided as required above, the physician or other licensed health care professional shall accord particular attention to the lungs, cardiovascular system (including blood pressure and pulse), liver, nervous system, and skin. The physician or other licensed health care professional shall determine the extent and nature of the

physical examination based on the health status of the employee and analysis of the medical and work history.

(iii) Laboratory surveillance. The physician or other licensed health care professional shall determine the extent of any required laboratory surveillance based on the employee's observed health status and the medical and work history.

[Note to paragraph (j)(5)(iii): See Appendix B of this section for information regarding medical tests. Laboratory surveillance may include before- and after-shift carboxyhemoglobin determinations, resting ECG, hematocrit, liver function tests and cholesterol levels.]

(iv) Other information or reports. The medical surveillance shall also include any other information or reports the physician or other licensed health care professional determines are necessary to assess the employee's health in relation to MC exposure.

(6) Content of emergency medical surveillance. The employer shall ensure that medical surveillance made available when an employee has been exposed to MC in emergency situations includes, at a minimum:

(i) Appropriate emergency treatment and decontamination of the exposed employee;

(ii) Comprehensive physical examination with special emphasis on the nervous system, cardiovascular system, lungs, liver and skin, including blood pressure and pulse;

(iii) Updated medical and work history, as appropriate for the medical condition of the employee; and

(iv) Laboratory surveillance, as indicated by the employee's health status.

[Note to paragraph (j)(6)(iv): See Appendix B for examples of tests which may be appropriate.]

(7) Additional examinations and referrals. Where the physician or other licensed health care professional determines it is necessary, the scope of the medical examination shall be expanded and the appropriate additional medical surveillance, such as referrals for consultation or examination, shall be provided.

(8) Information provided to the physician or other licensed health care professional. The employer shall provide the following information to a physician or other licensed health care professional who is involved in the diagnosis of MC-induced health effects:

(i) A copy of this section including its applicable appendices;

(ii) A description of the affected employee's past, current and anticipated future duties as they relate to the employee's MC exposure;

(iii) The employee's former or current exposure levels or, for employees not yet occupationally exposed to MC, the employee's anticipated exposure levels and the frequency and exposure levels anticipated to be associated with emergencies;

(iv) A description of any personal protective equipment, such as respirators, used or to be used; and

(v) Information from previous employment-related medical surveillance of the affected employee which is not otherwise available to the physician or other licensed health care professional.

(9) Written medical opinions.

(i) For each physical examination required by this section, the employer shall ensure that the physician or other licensed health care professional provides to the employer and to the affected employee a written opinion regarding the results of that examination within 15 days of completion of the evaluation of medical and laboratory findings, but not more than 30 days after the examination. The written medical opinion shall be limited to the following information:

(A) The physician or other licensed health care professional's opinion concerning whether exposure to MC may contribute to or aggravate the employee's existing cardiac, hepatic, neurological (including stroke) or dermal disease or whether the employee has any other medical condition(s) that would place the employee's health at increased risk of material impairment from exposure to MC.

(B) Any recommended limitations upon the employee's exposure to MC, including removal from MC exposure, or upon the employee's use of respirators, protective clothing, or other protective equipment.

(C) A statement that the employee has been informed by the physician or other licensed health care professional that MC is a potential occupational carcinogen, of risk factors for heart disease, and the potential for exacerbation of underlying heart disease by exposure to MC through its metabolism to carbon monoxide; and

(D) A statement that the employee has been informed by the physician or other licensed health care professional of the results of the medical examination and any medical conditions resulting from MC exposure which require further explanation or treatment.

(ii) The employer shall instruct the physician or other licensed health care professional not to reveal to the employer, orally or in the written opinion, any specific records, findings, and diagnoses that have no bearing on occupational exposure to MC.

[Note to paragraph (j)(9)(ii): The written medical opinion may also include information and opinions generated to comply with other OSHA health standards.]

(10) Medical Presumption. For purposes of this paragraph (j) of this section, the physician or other licensed health care professional shall presume, unless medical evidence indicates to the contrary, that a medical condition is unlikely to require medical removal from MC exposure if the employee is not exposed to MC above the 8-hour TWA PEL. If the physician or other licensed health care professional recommends removal for an employee exposed below the 8-hour TWA PEL, the physician or other licensed health care professional shall cite specific medical evidence, sufficient to rebut the presumption that exposure below the 8-hour TWA PEL is unlikely to require removal, to support the recommendation. If such evidence is cited by the physician or other licensed health care professional, the employer must remove the employee. If such evidence is not cited by the physician or other licensed health care professional, the employer is not required to remove the employee.

(11) Medical Removal Protection (MRP).

(i) Temporary medical removal and return of an employee.

(A) Except as provided in paragraph (j)(10) of this section, when a medical determination recommends removal because the employee's exposure to MC may contribute to or aggravate the employee's existing cardiac, hepatic, neurological (including stroke), or skin disease, the employer must provide medical removal protection benefits to the employee and either:

(1) Transfer the employee to comparable work where methylene chloride exposure is below the action level; or

(2) Remove the employee from MC exposure.

(B) If comparable work is not available and the employer is able to demonstrate that removal and the costs of extending MRP benefits to an additional employee, considering feasibility in relation to the size of the employer's business and the other requirements of this standard, make further reliance on MRP an inappropriate remedy, the employer may retain the additional employee in the existing job until transfer or removal becomes appropriate, provided:

(1) The employer ensures that the employee receives additional medical surveillance, including a physical examination at least every 60 days until transfer or removal occurs; and

(2) The employer or PLHCP informs the employee of the risk to the employee's health from continued MC exposure.

(C) The employer shall maintain in effect any job-related protective measures or limitations, other than removal, for as long as a medical determination recommends them to be necessary.

(ii) End of MRP benefits and return of the employee to former job status.

(A) The employer may cease providing MRP benefits at the earliest of the following:

(1) Six months;

(2) Return of the employee to the employee's former job status following receipt of a medical determination concluding that the employee's exposure to MC no longer will aggravate any cardiac, hepatic, neurological (including stroke), or dermal disease;

(3) Receipt of a medical determination concluding that the employee can never return to MC exposure.

(B) For the purposes of this paragraph (j), the requirement that an employer return an employee to the employee's former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

(12) Medical Removal Protection Benefits.

(i) For purposes of this paragraph (j), the term medical removal protection benefits means that, for each removal, an employer must maintain for up to six months the earnings, seniority, and other employment rights and benefits of the employee as though the employee had not been removed from MC exposure or transferred to a comparable job.

(ii) During the period of time that an employee is removed from exposure to MC, the employer may condition the provision of medical removal protection benefits upon the employee's participation in follow-up medical surveillance made available pursuant to this section.

(iii) If a removed employee files a workers' compensation claim for a MC-related disability, the employer shall continue the MRP benefits required by this paragraph until either the claim is resolved or the 6-month period for payment of MRP benefits has passed, whichever occurs first. To the extent the employee is entitled to indemnity payments for earnings lost during the period of removal, the employer's obligation to provide medical removal protection benefits to the employee shall be reduced by the amount of such indemnity payments.

(iv) The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal from either a publicly or an employer-funded compensation program, or receives income from employment with another employer made possible by virtue of the employee's removal.

(13) Voluntary Removal or Restriction of an Employee. Where an employer, although not required by this section to do so, removes an employee from exposure to MC or otherwise places any limitation on an employee due to the effects of MC exposure on the employee's medical

condition, the employer shall provide medical removal protection benefits to the employee equal to those required by paragraph (j)(12) of this section.

(14) Multiple Health Care Professional Review Mechanism.

(i) If the employer selects the initial physician or licensed health care professional (PLHCP) to conduct any medical examination or consultation provided to an employee under this paragraph (j)(11), the employer shall notify the employee of the right to seek a second medical opinion each time the employer provides the employee with a copy of the written opinion of that PLHCP.

(ii) If the employee does not agree with the opinion of the employer-selected PLHCP, notifies the employer of that fact, and takes steps to make an appointment with a second PLHCP within 15 days of receiving a copy of the written opinion of the initial PLHCP, the employer shall pay for the PLHCP chosen by the employee to perform at least the following:

(A) Review any findings, determinations or recommendations of the initial PLHCP; and

(B) conduct such examinations, consultations, and laboratory tests as the PLHCP deems necessary to facilitate this review.

(iii) If the findings, determinations or recommendations of the second PLHCP differ from those of the initial PLHCP, then the employer and the employee shall instruct the two health care professionals to resolve the disagreement.

(iv) If the two health care professionals are unable to resolve their disagreement within 15 days, then those two health care professionals shall jointly designate a PLHCP who is a specialist in the field at issue. The employer shall pay for the specialist to perform at least the following:

(A) Review the findings, determinations, and recommendations of the first two PLHCPs; and

(B) Conduct such examinations, consultations, laboratory tests and discussions with the prior PLHCPs as the specialist deems necessary to resolve the disagreements of the prior health care professionals.

(v) The written opinion of the specialist shall be the definitive medical determination. The employer shall act consistent with the definitive medical determination, unless the employer and employee agree that the written opinion of one of the other two PLHCPs shall be the definitive medical determination.

(vi) The employer and the employee or authorized employee representative may agree upon the use of any expeditious alternate health care professional determination mechanism in lieu of the multiple health care professional review mechanism provided by this paragraph so long as the alternate mechanism otherwise satisfies the requirements contained in this paragraph.

(k) Hazard communication. ~~The employer shall communicate the following hazards associated with MC on labels and in material safety data sheets in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate: cancer, cardiac effects (including elevation of carboxyhemoglobin), central nervous system effects, liver effects, and skin and eye irritation.~~

(1) Hazard communication—general.

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for MC.

(ii) In classifying the hazards of MC at least the following hazards are to be addressed: Cancer, cardiac effects (including elevation of carboxyhemoglobin), central nervous system effects, liver effects, and skin and eye irritation.

(iii) Employers shall include MC in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of MC and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l) of this section.

(l) Employee information and training.

(1) The employer shall provide information and training for each affected employee prior to or at the time of initial assignment to a job involving potential exposure to MC.

(2) The employer shall ensure that information and training is presented in a manner that is understandable to the employees.

(3) In addition to the information required under the Hazard Communication Standard at 29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate:

(i) The employer shall inform each affected employee of the requirements of this section and information available in its appendices, as well as how to access or obtain a copy of it in the workplace;

(ii) Wherever an employee's exposure to airborne concentrations of MC exceeds or can reasonably be expected to exceed the action level, the employer shall inform each affected employee of the quantity, location, manner of use, release, and storage of MC and the specific operations in the workplace that could result in exposure to MC, particularly noting where exposures may be above the 8-hour TWA PEL or STEL;

(4) The employer shall train each affected employee as required under the Hazard Communication standard at 29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate.

(5) The employer shall re-train each affected employee as necessary to ensure that each

employee exposed above the action level or the STEL maintains the requisite understanding of the principles of safe use and handling of MC in the workplace.

(6) Whenever there are workplace changes, such as modifications of tasks or procedures or the institution of new tasks or procedures, which increase employee exposure, and where those exposures exceed or can reasonably be expected to exceed the action level, the employer shall update the training as necessary to ensure that each affected employee has the requisite proficiency.

(7) An employer whose employees are exposed to MC at a multi-employer worksite shall notify the other employers with work operations at that site in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate.

(8) The employer shall provide to the Assistant Secretary or the Director, upon request, all available materials relating to employee information and training.

(m) Record keeping.

(1) Objective data. (i) Where an employer seeks to demonstrate that initial monitoring is unnecessary through reasonable reliance on objective data showing that any materials in the workplace containing MC will not release MC at levels which exceed the action level or the STEL under foreseeable conditions of exposure, the employer shall establish and maintain an accurate record of the objective data relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The MC-containing material in question;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of MC;

(D) A description of the operation exempted under paragraph (d)(2)(i) of this section and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) Exposure measurements. (i) The employer shall establish and keep an accurate record of all measurements taken to monitor employee exposure to MC as prescribed in paragraph (d) of

this section.

(ii) Where the employer has 20 or more employees, this record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation involving exposure to MC which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of personal protective equipment, such as respiratory protective devices, worn, if any; and

(F) Name, social security number, job classification and exposure of all of the employees represented by monitoring, indicating which employees were actually monitored.

(iii) Where the employer has fewer than 20 employees, the record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) Number, duration, and results of samples taken; and

(C) Name, social security number, job classification and exposure of all of the employees represented by monitoring, indicating which employees were actually monitored.

(iv) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.1020.

(3) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under paragraph (j) of this section.

(ii) The record shall include at least the following information:

(A) The name, social security number and description of the duties of the employee;

(B) Written medical opinions; and

(C) Any employee medical conditions related to exposure to MC.

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

(4) Availability. (i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying in accordance with 29 CFR 1910.1020.

[Note to paragraph (m)(4)(i): All records required to be maintained by this section may be kept in the most administratively convenient form (for example, electronic or computer records would satisfy this requirement).]

(ii) The employer, upon request, shall make any employee exposure and objective data records required by this section available for examination and copying by affected employees, former employees, and designated representatives in accordance with 29 CFR 1910.1020.

(iii) The employer, upon request, shall make employee medical records required to be kept by this section available for examination and copying by the subject employee and by anyone having the specific written consent of the subject employee in accordance with 29 CFR 1910.1020.

(5) Transfer of records. The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

(n) [Reserved]

(o) Appendices. The information contained in the appendices does not, by itself, create any additional obligations not otherwise imposed or detract from any existing obligation.

[Note to paragraph (o): The requirement of 29 CFR 1910.1052(g)(1) to use respiratory protection whenever an employee's exposure to methylene chloride exceeds or can reasonably be expected to exceed the 8-hour TWA PEL is hereby stayed until August 31, 1998 for employers engaged in polyurethane foam manufacturing; foam fabrication; furniture refinishing; general aviation aircraft stripping; formulation of products containing methylene chloride; boat building and repair; recreational vehicle manufacture; van conversion; upholstery; and use of methylene chloride in construction work for restoration and preservation of buildings, painting and paint removal, cabinet making and/or floor refinishing and resurfacing. The requirement of 29 CFR 1910.1052(f)(1) to implement engineering controls to achieve the 8-hour TWA PEL and STEL is hereby stayed until December 10, 1998 for employers with more than 100 employees engaged in polyurethane foam manufacturing and for employers with more than 20 employees engaged in foam fabrication; furniture refinishing; general aviation aircraft stripping; formulation of products containing methylene chloride; boat building and repair; recreational vehicle manufacture; van conversion; upholstery; and use of methylene chloride in construction work for restoration and preservation of buildings, painting and paint removal, cabinet making and/or floor refinishing and resurfacing.]

[62 FR 1493, Jan. 10, 1997; 62 FR 42666, Aug. 8, 1997; 62 FR 48175, Sept. 15, 1997; 62 FR 54383, Oct. 20, 1997; 62 FR 66275, Dec. 18, 1997; 63 FR 1152, Jan. 8, 1998; 63 FR 20098, April 23, 1998; 63 FR 50729 Sept. 22, 1998; 64 FR 13700, March 22, 1999]

1910.1101 Asbestos. REMOVED-JUNE 8, 1992

[51 FR 37004, Oct. 17, 1986, as amended at 52 FR 15723, Apr. 30, 1987; 54 FR 24334, June 7, 1989; 54 FR 30705, July 21, 1989; 55 FR 50687, Dec. 10, 1991; 57 FR 24310, JUNE 8, 1992]

1910.1096 Ionizing radiation.

(a) Definitions applicable to this section.

(1) "Radiation" includes alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other atomic particles; but such term does not include sound or radio waves, or visible light, or infrared or ultraviolet light.

(2) "Radioactive material" means any material which emits, by spontaneous nuclear disintegration, corpuscular or electromagnetic emanations.

(3) "Restricted area" means any area access to which is controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.

(4) "Unrestricted area" means any area access to which is not controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.

(5) "Dose" means the quantity of ionizing radiation absorbed, per unit of mass, by the body or by any portion of the body. When the provisions in this section specify a dose during a period of time, the dose is the total quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body during such period of time. Several different units of dose are in current use. Definitions of units used in this section are set forth in paragraphs (a) (6) and (7) of this section.

(6) "Rad" means a measure of the dose of any ionizing radiation to body tissues in terms of the energy absorbed per unit of mass of the tissue. One rad is the dose corresponding to the absorption of 100 ergs per gram of tissue (1 millirad (mrad)=0.001 rad).

(7) "Rem" means a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of 1 roentgen (r) of X-rays (1 millirem (mrem)=0.001 rem). The relation of the rem to other dose units depends upon the biological effect under consideration and upon the conditions for irradiation. Each of the following is considered to be equivalent to a dose of 1 rem:

(i) A dose of 1 roentgen due to X- or gamma radiation;

(ii) A dose of 1 rad due to X-, gamma, or beta radiation;

(iii) A dose of 0.1 rad due to neutrons or high energy protons;

(iv) A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye;

(v) If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, as provided in paragraph (a)(7)(iii) of this section, 1 rem of neutron radiation may, for purposes of the provisions in this section be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there is sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to 1 rem may be estimated from Table G-17:

TABLE G-17 - NEUTRON FLUX DOSE EQUIVALENTS

| Neutron energy (million electron volts (Mev)) | Number of neutrons per square centimeter equivalent to a dose of 1 rem (neutrons/cm(2)) | Average flux to deliver 100 millirem in 40 hours (neutrons/cm(2) per sec) |
|---|---|---|
| Thermal | 970 X 10(6) | 670 |
| 0.0001 | 720 X 10(6) | 500 |
| 0.005 | 820 X 10(6) | 570 |
| 0.02 | 400 X 10(6) | 280 |
| 0.1 | 120 X 10(6) | 80 |
| 0.5 | 43 X 10(6) | 30 |
| 1.0 | 26 X 10(6) | 18 |
| 2.5 | 29 X 10(6) | 20 |
| 5.0 | 26 X 10(6) | 18 |
| 7.5 | 24 X 10(6) | 17 |
| 10 | 24 X 10(6) | 17 |
| 10 to 30 | 14 X 10(6) | 10 |

(8) For determining exposures to X- or gamma rays up to 3 Mev., the dose limits specified in this section may be assumed to be equivalent to the "air dose". For the purpose of this section "air dose" means that the dose is measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dosage rate.

(b) Exposure of individuals to radiation in restricted areas.

(1) Except as provided in paragraph (b)(2) of this section, no employer shall possess, use, or transfer sources of ionizing radiation in such a manner as to cause any individual in a restricted area

to receive in any period of one calendar quarter from sources in the employer's possession or control a dose in excess of the limits specified in Table G-18:

TABLE G-18

| | Rems per calendar quarter |
|--|---------------------------|
| Whole body: Head and trunk; active blood-forming organs; lens of eyes; or gonads | 1 1/4 |
| Hands and forearms; feet and ankles | 18 3/4 |
| Skin of whole body | 7 1/2 |

(2) An employer may permit an individual in a restricted area to receive doses to the whole body greater than those permitted under subparagraph (1) of this paragraph, so long as:

(i) During any calendar quarter the dose to the whole body shall not exceed 3 rems; and

(ii) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N-18) rems, where "N" equals the individual's age in years at his last birthday; and

(iii) The employer maintains adequate past and current exposure records which show that the addition of such a dose will not cause the individual to exceed the amount authorized in this subparagraph. As used in this subparagraph "Dose to the whole body" shall be deemed to include any dose to the whole body, gonad, active bloodforming organs, head and trunk, or lens of the eye.

(3) No employer shall permit any employee who is under 18 years of age to receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in Table G-18.

(4) "Calendar quarter" means any 3-month period determined as follows:

(i) The first period of any year may begin on any date in January: Provided, That the second, third, and fourth periods accordingly begin on the same date in April, July, and October, respectively, and that the fourth period extends into January of the succeeding year, if necessary to complete a 3-month quarter. During the first year of use of this method of determination, the first period for that year shall also include any additional days in January preceding the starting date for the first period; or

(ii) The first period in a calendar year of 13 complete, consecutive calendar weeks; the second period in a calendar year of 13 complete, consecutive weeks; the third period in a calendar year of 13 complete, consecutive calendar weeks; the fourth period in a calendar year of 13 complete, consecutive calendar weeks. If at the end of a calendar year there are any days not falling

within a complete calendar week of that year, such days shall be included within the last complete calendar week of that year. If at the beginning of any calendar year there are days not falling within a complete calendar week of that year, such days shall be included within the last complete calendar week of the previous year; or

(iii) The four periods in a calendar year may consist of the first 14 complete, consecutive calendar weeks; the next 12 complete, consecutive calendar weeks, the next 14 complete, consecutive calendar weeks, and the last 12 complete, consecutive calendar weeks. If at the end of a calendar year there are any days not falling within a complete calendar week of that year, such days shall be included (for purposes of this section) within the last complete calendar week of the year. If at the beginning of any calendar year there are days not falling within a complete calendar week of that year, such days shall be included (for purposes of this section) within the last complete week of the previous year.

(c) Exposure to airborne radioactive material.

(1) No employer shall possess, use or transport radioactive material in such a manner as to cause any employee, within a restricted area, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Table 1 of Appendix B to 10 CFR Part 20. The limits given in Table 1 are for exposure to the concentrations specified for 40 hours in any workweek of 7 consecutive days. In any such period where the number of hours of exposure is less than 40, the limits specified in the table may be increased proportionately. In any such period where the number of hours of exposure is greater than 40, the limits specified in the table shall be decreased proportionately.

(2) No employer shall possess, use, or transfer radioactive material in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Table II of Appendix B to 10 CFR Part 20. For purposes of this paragraph, concentrations may be averaged over periods not greater than 1 week.

(3) "Exposed" as used in this paragraph means that the individual is present in an airborne concentration. No allowance shall be made for the use of protective clothing or equipment, or particle size.

(d) Precautionary procedures and personal monitoring.

(1) Every employer shall make such surveys as may be necessary for him to comply with the provisions in this section. "Survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.

(2) Every employer shall supply appropriate personnel monitoring equipment, such as film

badges, pocket chambers, pocket dosimeters, or film rings, and shall require the use of such equipment by:

(i) Each employee who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in paragraph (b)(1) of this section; and

(ii) Each employee under 18 years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in paragraph (b)(1) of this section; and

(iii) Each employee who enters a high radiation area.

(3) As used in this section:

(i) "Personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received (e.g., film badges, pocket chambers, pocket dosimeters, film rings, etc.);

(ii) "Radiation area" means any area, accessible to personnel, in which there exists radiation at such levels that a major portion of the body could receive in any 1 hour a dose in excess of 5 millirem, or in any 5 consecutive days a dose in excess of 100 millirem; and

(iii) "High radiation area" means any area, accessible to personnel, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

(e) Caution signs, labels, and signals

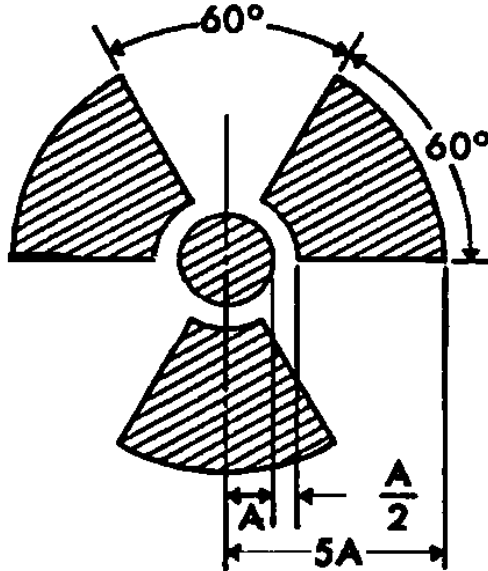
(1) General.

(i) Symbols prescribed by this paragraph shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this paragraph is the conventional three-bladed design:

FIGURE G-10 RADIATION SYMBOL

RADIATION SYMBOL

1. Cross-hatched area is to be magenta or purple.
2. Background is to be yellow.



(2) Radiation area. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in subparagraph (1) of this paragraph and the words:

CAUTION

RADIATION AREA

(3) High radiation area.

(i) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION

HIGH RADIATION AREA

(ii) Each high radiation area shall be equipped with a control device which shall either cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area or shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering and the employer or a supervisor of the activity are made aware of the entry. In the case of a high radiation area established for a period of 30 days or less, such control device is not required.

(4) Airborne radioactivity area.

(i) As used in the provisions of this section, "airborne radioactivity area" means:

(a) Any room, enclosure, or operating area in which airborne radioactive materials, composed wholly or partly of radioactive material, exist in concentrations in excess of the amounts specified in column 1 of Table 1 of Appendix B to 10 CFR Part 20 or

(b) Any room, enclosure, or operating area in which airborne radioactive materials exist in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in column 1 of Table 1 of Appendix B to 10 CFR Part 20.

(ii) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

AIRBORNE RADIOACTIVITY AREA

(5) Additional requirements.

(i) Each area or room in which radioactive material is used or stored and which contains any radioactive material (other than natural uranium or thorium) in any amount exceeding 10 times the quantity of such material specified in Appendix C to 10 CFR Part 20 shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

RADIOACTIVE MATERIALS

(ii) Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity of such material specified in 10 CFR Part 20 shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

RADIOACTIVE MATERIALS

(6) Containers.

(i) Each container in which is transported, stored, or used a quantity of any

radioactive material (other than natural uranium or thorium) greater than the quantity of such material specified in Appendix C to 10 CFR Part 20 shall bear a durable, clearly visible label bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

RADIOACTIVE MATERIALS

(ii) Each container in which natural uranium or thorium is transported, stored, or used in a quantity greater than 10 times the quantity specified in Appendix C to 10 CFR Part 20 shall bear a durable, clearly visible label bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

RADIOACTIVE MATERIALS

(iii) Notwithstanding the provisions of paragraphs (e)(6) (i) and (ii) of this section a label shall not be required:

(a) If the concentration of the material in the container does not exceed that specified in column 2 of Table 1 of Appendix B to 10 CFR Part 20, or

(b) For laboratory containers, such as beakers, flasks, and test tubes, used transiently in laboratory procedures, when the user is present.

(iv) Where containers are used for storage, the labels required in this subparagraph shall state also the quantities and kinds of radioactive materials in the containers and the date of measurement of the quantities.

(f) Immediate evacuation warning signal

(1) Signal characteristics.

(i) The signal shall be a midfrequency complex sound wave amplitude modulated at a subsonic frequency. The complex sound wave in free space shall have a fundamental frequency (f(1)) between 450 and 500 hertz (Hz) modulated at a subsonic rate between 4 and 5 hertz.

(ii) The signal generator shall not be less than 75 decibels at every location where an individual may be present whose immediate, rapid, and complete evacuation is essential.

(iii) A sufficient number of signal units shall be installed such that the requirements of paragraph (f)(1)(ii) of this section are met at every location where an individual may be present whose immediate, rapid, and complete evacuation is essential.

(iv) The signal shall be unique in the plant or facility in which it is installed.

(v) The minimum duration of the signal shall be sufficient to insure that all affected persons hear the signal.

(vi) The signal-generating system shall respond automatically to an initiating event without requiring any human action to sound the signal.

(2) Design objectives.

(i) The signal-generating system shall be designed to incorporate components which enable the system to produce the desired signal each time it is activated within one-half second of activation.

(ii) The signal-generating system shall be provided with an automatically activated secondary power supply which is adequate to simultaneously power all emergency equipment to which it is connected, if operation during power failure is necessary, except in those systems using batteries as the primary source of power.

(iii) All components of the signal-generating system shall be located to provide maximum practicable protection against damage in case of fire, explosion, corrosive atmosphere, or other environmental extremes consistent with adequate system performance.

(iv) The signal-generating system shall be designed with the minimum number of components necessary to make it function as intended, and should utilize components which do not require frequent servicing such as lubrication or cleaning.

(v) Where several activating devices feed activating information to a central signal generator, failure of any activating device shall not render the signal-generator system inoperable to activating information from the remaining devices.

(vi) The signal-generating system shall be designed to enhance the probability that alarm occurs only when immediate evacuation is warranted. The number of false alarms shall not be so great that the signal will come to be disregarded and shall be low enough to minimize personal injuries or excessive property damage that might result from such evacuation.

(3) Testing.

(i) Initial tests, inspections, and checks of the signal-generating system shall be made to verify that the fabrication and installation were made in accordance with design plans and specifications and to develop a thorough knowledge of the performance of the system and all components under normal and hostile conditions.

(ii) Once the system has been placed in service, periodic tests, inspections, and checks shall be made to minimize the possibility of malfunction.

(iii) Following significant alterations or revisions to the system, tests and checks similar to the initial installation tests shall be made.

(iv) Tests shall be designed to minimize hazards while conducting the tests.

(v) Prior to normal operation the signal-generating system shall be checked physically and functionally to assure reliability and to demonstrate accuracy and performance. Specific tests shall include:

(a) All power sources.

(b) Calibration and calibration stability.

(c) Trip levels and stability.

(d) Continuity of function with loss and return of required services such as AC or DC power, air pressure, etc.

(e) All indicators.

(f) Trouble indicator circuits and signals, where used.

(g) Air pressure (if used)

(h) Determine that sound level of the signal is within the limit of paragraph (f)(1)(ii) of this section at all points that require immediate evacuation.

(vi) In addition to the initial startup and operating tests, periodic scheduled performance tests and status checks must be made to insure that the system is at all times operating within design limits and capable of the required response. Specific periodic tests or checks or both shall include:

(a) Adequacy of signal activation device.

(b) All power sources.

(c) Function of all alarm circuits and trouble indicator circuits including trip levels.

(d) Air pressure (if used).

(e) Function of entire system including operation without power where required.

(f) Complete operational tests including sounding of the signal and

determination that sound levels are adequate.

(vii) Periodic tests shall be scheduled on the basis of need, experience, difficulty, and disruption of operations. The entire system should be operationally tested at least quarterly.

(viii) All employees whose work may necessitate their presence in an area covered by the signal shall be made familiar with the actual sound of the signal-preferably as it sounds at their work location. Before placing the system into operation, all employees normally working in the area shall be made acquainted with the signal by actual demonstration at their work locations.

(g) Exceptions from posting requirements. Notwithstanding the provisions of paragraph (e) of this section:

(1) A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level 12 inches from the surface of the source container or housing does not exceed 5 millirem per hour.

(2) Rooms or other areas in onsite medical facilities are not required to be posted with caution signs because of the presence of patients containing radioactive material, provided that there are personnel in attendance who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in the provisions of this section.

(3) Caution signs are not required to be posted at areas or rooms containing radioactive materials for periods of less than 8 hours: Provided, That

(i) The materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in the provisions of this section; and

(ii) Such area or room is subject to the employer's control.

(h) Exemptions for radioactive materials packaged for shipment. Radioactive materials packaged and labeled in accordance with regulations of the Department of Transportation published in 49 CFR Chapter I, are exempt from the labeling and posting requirements of this subpart during shipment, provided that the inside containers are labeled in accordance with the provisions of paragraph (e) of this section.

(i) Instruction of personnel, posting.

(1) Employers regulated by the Nuclear Regulatory Commission shall be governed by 10 CFR Part 20 standards. Employers in a State named in paragraph (p)(3) of this section shall be governed by the requirements of the laws and regulations of that State. All other employers shall be regulated by the following:

(2) All individuals working in or frequenting any portion of a radiation area shall be informed of the occurrence of radioactive materials or of radiation in such portions of the radiation area; shall be instructed in the safety problems associated with exposure to such materials or radiation and in precautions or devices to minimize exposure; shall be instructed in the applicable provisions of this section for the protection of employees from exposure to radiation or radioactive materials; and shall be advised of reports of radiation exposure which employees may request pursuant to the regulations in this section.

(3) Each employer to whom this section applies shall post a current copy of its provisions and a copy of the operating procedures applicable to the work conspicuously in such locations as to insure that employees working in or frequenting radiation areas will observe these documents on the way to and from their place of employment, or shall keep such documents available for examination of employees upon request.

(j) Storage of radioactive materials. Radioactive materials stored in a non-radiation area shall be secured against unauthorized removal from the place of storage.

(k) Waste disposal. No employer shall dispose of radioactive material except by transfer to an authorized recipient, or in a manner approved by the Nuclear Regulatory Commission or a State named in paragraph (p)(3) of this section.

(l) Notification of incidents

(1) Immediate notification. Each employer shall immediately notify the Assistant Secretary of Labor or his duly authorized representative, for employees not protected by the Nuclear Regulatory Commission by means of 10 CFR Part 20; paragraph (p)(2) of this section, or the requirements of the laws and regulations of States named in paragraph (p)(3) of this section, by telephone or telegraph of any incident involving radiation which may have caused or threatens to cause:

(i) Exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms of any individual to 375 rems or more of radiation; or

(ii) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limit specified for such materials in Table II of Appendix B to 10 CFR Part 20.

(2) Twenty-four hour notification. Each employer shall within 24 hours following its occurrence notify the Assistant Secretary of Labor or his duly authorized representative for employees not protected by the Nuclear Regulatory Commission by means of 10 CFR Part 20; paragraph (p)(2) of this section, or the requirements of the laws and applicable regulations of States named in paragraph (p)(3) of this section, by telephone or telegraph of any incident involving radiation which may have caused or threatens to cause:

(i) Exposure of the whole body of any individual to 5 rems or more of radiation; exposure of the skin of the whole body of any individual to 30 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms to 75 rems or more of radiation; or

(m) Reports of overexposure and excessive levels and concentrations.

(1) In addition to any notification required by paragraph (1) of this section each employer shall make a report in writing within 30 days to the Assistant Secretary of Labor or his duly authorized representative, for employees not protected by the Nuclear Regulatory Commission by means of 10 CFR Part 20; or under paragraph (p)(2) of this section, or the requirements of the laws and regulations of States named in paragraph (p)(3) of this section, of each exposure of an individual to radiation or concentrations of radioactive material in excess of any applicable limit in this section. Each report required under this paragraph shall describe the extent of exposure of persons to radiation or to radioactive material; levels of radiation and concentration of radioactive material involved, the cause of the exposure, levels of concentrations; and corrective steps taken or planned to assure against a recurrence.

(2) In any case where an employer is required pursuant to the provisions of this paragraph to report to the U.S. Department of Labor any exposure of an individual to radiation or to concentrations of radioactive material, the employer shall also notify such individual of the nature and extent of exposure. Such notice shall be in writing and shall contain the following statement: "You should preserve this report for future reference."

(n) Records.

(1) Every employer shall maintain records of the radiation exposure of all employees for whom personnel monitoring is required under paragraph (d) of this section and advise each of his employees of his individual exposure on at least an annual basis.

(2) Every employer shall maintain records in the same units used in tables in paragraph (b) of this section and Appendix B to 10 CFR Part 20.

(o) Disclosure to former employee of individual employee's record.

(1) At the request of a former employee an employer shall furnish to the employee a report of the employee's exposure to radiation as shown in records maintained by the employer pursuant to paragraph (n)(1) of this section. Such report shall be furnished within 30 days from the time the request is made, and shall cover each calendar quarter of the individual's employment involving exposure to radiation or such lesser period as may be requested by the employee. The report shall also include the results of any calculations and analysis of radioactive material deposited in the body of the employee. The report shall be in writing and contain the following statement: "You should preserve this report for future reference."

(p) Nuclear Regulatory Commission licensees - NRC contractors operating NRC plants and

facilities - NRC Agreement State licensees or registrants.

(1) Any employer who possesses or uses source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended, under a license issued by the Nuclear Regulatory Commission and in accordance with the requirements of 10 CFR Part 20 shall be deemed to be in compliance with the requirements of this section with respect to such possession and use.

(2) NRC contractors operating NRC plants and facilities: Any employer who possesses or uses source material, byproduct material, special nuclear material, or other radiation sources under a contract with the Nuclear Regulatory Commission for the operation of NRC plants and facilities and in accordance with the standards, procedures, and other requirements for radiation protection established by the Commission for such contract pursuant to the Atomic Energy Act of 1954 as amended (42 U.S.C. 2011 et seq.), shall be deemed to be in compliance with the requirements of this section with respect to such possession and use.

(3) NRC-agreement State licensees or registrants:

(i) Atomic Energy Act sources. Any employer who possesses or uses source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), and has either registered such sources with, or is operating under a license issued by, a State which has an agreement in effect with the Nuclear Regulatory Commission pursuant to section 274(b) (42 U.S.C. 2021(b)) of the Atomic Energy Act of 1954, as amended, and in accordance with the requirements of that State's laws and regulations shall be deemed to be in compliance with the radiation requirements of this section, insofar as his possession and use of such material is concerned, unless the Secretary of Labor, after conference with the Nuclear Regulatory Commission, shall determine that the State's program for control of these radiation sources is incompatible with the requirements of this section. Such agreements currently are in effect only in the States of Alabama, Arkansas, California, Kansas, Kentucky, Florida, Mississippi, New Hampshire, New York, North Carolina, Texas, Tennessee, Oregon, Idaho, Arizona, Colorado, Louisiana, Nebraska, Washington, Maryland, North Dakota, South Carolina, and Georgia.

(ii) Other sources. Any employer who possesses or uses radiation sources other than source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), and has either registered such sources with, or is operating under a license issued by a State which has an agreement in effect with the Nuclear Regulatory Commission pursuant to section 274(b) (42 U.S.C. 2021(b)) of the Atomic Energy Act of 1954, as amended, and in accordance with the requirements of that State's laws and regulations shall be deemed to be in compliance with the radiation requirements of this section, insofar as his possession and use of such material is concerned, provided the State's program for control of these radiation sources is the subject of a currently effective determination by the Assistant Secretary of Labor that such program is compatible with the requirements of this section. Such determinations currently are in effect only in the States of Alabama, Arkansas, California, Kansas, Kentucky, Florida, Mississippi, New Hampshire, New York, North Carolina, Texas, Tennessee, Oregon, Idaho,

Arizona, Colorado, Louisiana, Nebraska, Washington, Maryland, North Dakota, South Carolina, and Georgia.

(Approved by the Office of Management and Budget under control number 1218-0103)

[39 FR 23502, June 27, 1974, as amended at 43 FR 49746, Oct. 24, 1978; 43 FR 51759, Nov. 7, 1978; 49 FR 18295, Apr. 30, 1984; 58 FR 35309, June 30, 1993; 61 FR 5507, Feb. 13, 1996; 61 FR 31427, June 20, 1996]

1910.1200 Hazard communication. STD 2.1 CPL 2-2.38C CPL 2-2.39

(a) Purpose.

(1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported are ~~evaluated~~ classified, and that information concerning their ~~classified~~ classified hazards is transmitted to employers and employees. The requirements of this section are intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Revision 3. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, ~~material safety data sheet~~ safety data sheets and employee training.

(2) This occupational safety and health standard is intended to address comprehensively the issue of ~~evaluating~~ classifying the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any ~~legal~~ legislative or regulatory enactments ~~requirements~~ of a state, or political subdivision of a state, pertaining to this subject. Evaluating Classifying the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, may include, for example, but is not limited to, provisions for: developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of ~~material safety data sheets~~ safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures. Under section 18 of the Act, no state or political subdivision of a state may adopt or enforce, ~~through any court or agency~~, any requirement relating to the issue addressed by this Federal standard, except pursuant to a Federally-approved state plan.

(b) Scope and application.

(1) This section requires chemical manufacturers or importers to ~~assess~~ classify the hazards of chemicals which they produce or import, and all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, ~~material safety data sheets~~ safety data sheets, and information and training. In addition, this section requires distributors to transmit

the required information to employers. (Employers who do not produce or import chemicals need only focus on those parts of this rule that deal with establishing a workplace program and communicating information to their workers. ~~Appendix E of this section is a general guide for such employers to help them determine their compliance obligations under the rule.~~)

(2) This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

(3) This section applies to laboratories only as follows:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

(ii) Employers shall maintain any ~~material safety data sheets~~ safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible during each workshift to laboratory employees when they are in their work areas;

(iii) Employers shall ensure that laboratory employees are provided information and training in accordance with paragraph (h) of this section, except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section; and,

(iv) Laboratory employers that ship hazardous chemicals are considered to be either a chemical manufacturer or a distributor under this rule, and thus must ensure that any containers of hazardous chemicals leaving the laboratory are labeled in accordance with paragraph (f)(4) of this section, and that a ~~material safety data sheet~~ safety data sheet is provided to distributors and other employers in accordance with paragraphs (g)(6) and (g)(7) of this section.

(4) In work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing, or retail sales), this section applies to these operations only as follows:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

(ii) Employers shall maintain copies of any ~~material safety data sheets~~ safety data sheets that are received with incoming shipments of the sealed containers of hazardous chemicals, shall obtain a ~~material safety data sheet~~ safety data sheet as soon as possible for sealed containers of hazardous chemicals received without a ~~material safety data sheet~~ safety data sheet sheet if an employee requests the ~~material safety data sheets~~ safety data sheets, and shall ensure that the ~~material safety data sheets~~ safety data sheet are readily accessible during each work shift to employees when they are in their work area(s); and,

(iii) Employers shall ensure that employees are provided with information and training in accordance with paragraph (h) of this section (except for the location and availability of the

written hazard communication program under paragraph (h)(2)(iii) of this section), to the extent necessary to protect them in the event of a spill or leak of a hazardous chemical from a sealed container.

(5) This section does not require labeling of the following chemicals:

(i) Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

(ii) Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (42 U.S.C. 9601 et seq.) when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA in accordance with Environmental Protection Agency regulations.

(iii) Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;

(iv) Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, ~~and~~ Firearms and Explosives;

(v) Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission; and,

(vi) Agricultural or vegetable seed treated with pesticides and labeled in accordance with the Federal Seed Act (7 U.S.C. 1551 et seq.) and the labeling regulations issued under that Act by the Department of Agriculture.

(6) This section does not apply to:

(i) Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

(ii) Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)(42 U.S.C. 9601 et seq.), when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA in accordance with Environmental Protection Agency regulations.

(iii) Tobacco or tobacco products;

(iv) Wood or wood products, including lumber which will not be processed, where the chemical manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (wood or wood products which have been treated with a hazardous chemical covered by this standard, and wood which may be subsequently sawed or cut, generating dust, are not exempted);

(v) Articles (as that term is defined in paragraph (c) of this section);

(vi) Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while in the workplace;

(vii) Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies);

(viii) Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;

(ix) Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;

(x) Nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered under this section;

(xi) Ionizing and nonionizing radiation; and,

(xii) Biological hazards.

(c) Definitions.

Article means a manufactured item other than a fluid or particle:

- (i) which is formed to a specific shape or design during manufacture;
- (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and
- (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chemical means any ~~element substance, chemical compound~~ or mixture of ~~elements and/or compounds~~ substances.

Chemical manufacturer means an employer with a workplace where chemical(s) are produced for use or distribution.

Chemical name means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name which that will clearly identify the chemical for the purpose of conducting a hazard ~~evaluation~~ classification.

Classification means to identify the relevant data regarding the hazards of a chemical; review those data to ascertain the hazards associated with the chemical; and decide whether the chemical will be classified as hazardous according to the definition of hazardous chemical in this section. In addition, classification for health and physical hazards includes the determination of the degree of hazard, where appropriate, by comparing the data with the criteria for health and physical hazards.

~~Combustible liquid means any liquid having a flashpoint at or above 100 deg. F (37.8 deg. C), but below 200 deg. F (93.3 deg. C), except any mixture having components with flashpoints of 200 deg. F (93.3 deg. C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.~~

Commercial account means an arrangement whereby a retail distributor sells hazardous chemicals to an employer, generally in large quantities over time and/or at costs that are below the regular retail price.

Common name means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

~~Compressed gas means:~~

- ~~(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70 deg. F (21.1 deg. C); or~~
- ~~(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at~~

130 deg. F (54.4 deg. C) regardless of the pressure at 70 deg. F (21.1 deg. C); or
–(iii) A liquid having a vapor pressure exceeding 40 psi at 100 deg. F (37.8 deg. C) as determined by ASTM D 323-72.

Container means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

Designated representative means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

Director means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Distributor means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers.

Employee means a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Workers such as office workers or bank tellers who encounter hazardous chemicals only in non-routine, isolated instances are not covered.

Employer means a person engaged in a business where chemicals are either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.

~~Explosive means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.~~

Exposure or exposed means that an employee is subjected in the course of employment to a chemical that is a physical or health hazard, and includes potential (e.g. accidental or possible) exposure. ``Subjected" in terms of health hazards includes any route of entry (e.g. inhalation, ingestion, skin contact or absorption.)

~~Flammable means a chemical that falls into one of the following categories:~~

~~–(i) Aerosol, flammable means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame projection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening;~~

~~–(ii) Gas, flammable means:~~

~~–(A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of thirteen (13) percent by volume or less; or~~

~~–(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than twelve (12) percent by volume, regardless of the lower limit;~~

~~–(iii) Liquid, flammable means any liquid having a flashpoint below 100 deg. F (37.8 deg. C),~~

except any mixture having components with flashpoints of 100 deg. F (37.8 deg. C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

~~–(iv) Solid, flammable means a solid, other than a blasting agent or explosive as defined in 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.~~

Flashpoint means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

~~–(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24-1979 (ASTM D 56-79)) for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100 deg. F (37.8 deg. C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or~~

~~–(ii) Pensky Martens Closed Tester (See American National Standard Method of Test for Flash Point by Pensky Martens Closed Tester, Z11.7-1979 (ASTM D 93-79)) for liquids with a viscosity equal to or greater than 45 SUS at 100 deg. F (37.8 deg. C), or that contain suspended solids, or that have a tendency to form a surface film under test; or~~

~~–(iii) Setaflash Closed Tester (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester (ASTM D 3278-78)).~~

~~Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flashpoint determination methods specified above.~~

Foreseeable emergency means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

Hazard category means the division of criteria within each hazard class, e.g., oral acute toxicity and flammable liquids include four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally.

Hazard class means the nature of the physical or health hazards, e.g., flammable solid, carcinogen, oral acute toxicity.

Hazard not otherwise classified (HNOC) means an adverse physical or health effect identified through evaluation of scientific evidence during the classification process that does not meet the specified criteria for the physical and health hazard classes addressed in this section. This does not extend coverage to adverse physical and health effects for which there is a hazard class addressed in this section, but the effect either falls below the cut-off value/concentration limit of the hazard class or is under a GHS hazard category that has not been adopted by OSHA (e.g., acute toxicity Category 5).

Hazard statement means a statement assigned to a hazard class and category that describes the nature of the hazard(s) of a chemical, including, where appropriate, the degree of hazard.

Hazardous chemical means any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified or.

~~Hazard warning means any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the specific physical and health hazard(s), including target organ effects, of the chemical(s) in the container(s). (See the definitions for "physical hazard" and "health hazard" to determine the hazards which must be covered.)~~

~~Health hazard means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. Appendix A provides further definitions and explanations of the scope of health hazards covered by this section, and Appendix B describes the criteria to be used to determine whether or not a chemical is to be considered hazardous for purposes of this standard which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to §1910.1200 -- Health Hazard Criteria.~~

~~Identity means any chemical or common name which is indicated on the material safety data sheet (MSDS) for the chemical. The identity used shall permit cross references to be made among the required list of hazardous chemicals, the label and the MSDS.~~

~~Immediate use means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.~~

~~Importer means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or employers within the United States.~~

~~Label means any written, printed, or graphic material displayed on or affixed to containers of hazardous chemicals which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for~~

determining whether a chemical is classified as a health hazard are detailed in Appendix A to §1910.1200 -- Health Hazard Criteria.

Label elements means the specified pictogram, hazard statement, signal word and precautionary statement of each hazard class and category.

~~Material safety data sheet (MSDS) means written or printed material concerning a hazardous chemical which is prepared in accordance with paragraph (g) of this section.~~

Mixture means any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction a combination or a solution composed of two or more substances in which they do not react.

~~Organic peroxide means an organic compound that contains the bivalent -O-O- structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.~~

~~Oxidizer means a chemical other than a blasting agent or explosive as defined in 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.~~

Physical hazard means a chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas. See Appendix B to §1910.1200 -- Physical Hazard Criteria.

~~Physical hazard means a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water reactive.~~
Pictogram means a composition that may include a symbol plus other graphic elements, such as a border, background pattern, or color, that is intended to convey specific information about the hazards of a chemical. Eight pictograms are designated under this standard for application to a hazard category.

Precautionary statement means a phrase that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous chemical, or improper storage or handling.

Product identifier means the name or number used for a hazardous chemical on a label or in the SDS. It provides a unique means by which the user can identify the chemical. The product identifier used shall permit cross-references to be made among the list of hazardous chemicals required in the written hazard communication program, the label and the SDS.

Produce means to manufacture, process, formulate, blend, extract, generate, emit, or repackage.

~~Pyrophoric means a chemical that will ignite spontaneously in air at a temperature of 130 deg. F (54.4 deg. C) or below.~~

Pyrophoric gas means a chemical in a gaseous state that will ignite spontaneously in air at a temperature of 130 degrees F (54.4 degrees C) or below.

Responsible party means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

Safety data sheet (SDS) means written or printed material concerning a hazardous chemical that is prepared in accordance with paragraph (g) of this section.

Signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The signal words used in this section are "danger" and "warning." "Danger" is used for the more severe hazards, while "warning" is used for the less severe.

Simple asphyxiant means a substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death.

Specific chemical identity means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Trade secret means any confidential formula, pattern, process, device, information or compilation of information that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it. Appendix D sets out the criteria to be used in evaluating trade secrets.

~~Unstable (reactive) means a chemical which in the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self reactive under conditions of shocks, pressure or temperature.~~

Use means to package, handle, react, emit, extract, generate as a byproduct, or transfer.

~~Water reactive means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.~~

Work area means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

Workplace means an establishment, job site, or project, at one geographical location containing one or more work areas.

(d) Hazard ~~determination~~ classification.

(1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to ~~determine if they are hazardous~~ classify the chemicals in accordance with this section. Employers are not required to ~~evaluate~~ classify chemicals unless they choose not to rely on the ~~evaluation~~ classification performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

(2) Chemical manufacturers, importers or employers ~~evaluating~~ classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning such the potential hazards. ~~There is no requirement to test the chemical to determine how to classify its hazards. For health hazards, evidence which is statistically significant and which is based on at least one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a hazardous effect if the results of the study meet the definitions of health hazards in this section.~~ Appendix A§1910.1200 shall be consulted for classification of the scope of health hazards covered, and Appendix B§1910.1200 shall be consulted for the criteria to be followed with respect to the completeness of the evaluation, and the data to be reported classification of physical hazards.

(3) ~~The chemical manufacturer, importer or employer evaluating chemicals shall treat the following sources as establishing that the chemicals listed in them are hazardous:~~

~~–(i) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA); or,~~

~~–(ii) Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment, American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition). The chemical manufacturer, importer, or employer is still responsible for evaluating the hazards associated with the chemicals in these source lists in accordance with the requirements of this standard.~~

~~–(4) Chemical manufacturers, importers and employers evaluating chemicals shall treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes:~~

~~–(i) National Toxicology Program (NTP), Annual Report on Carcinogens (latest edition);~~

~~–(ii) International Agency for Research on Cancer (IARC) Monographs (latest editions); or~~

~~–(iii) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration. Note: The Registry of Toxic Effects of Chemical Substances published by the National Institute for Occupational Safety and Health indicates whether a chemical has been found by NTP or IARC to be a potential carcinogen.~~

~~–(5) The chemical manufacturer, importer or employer shall determine the hazards of mixtures~~

of chemicals as follows:

~~–(i) If a mixture has been tested as a whole to determine its hazards, the results of such testing shall be used to determine whether the mixture is hazardous;~~

~~–(ii) If a mixture has not been tested as a whole to determine whether the mixture is a health hazard, the mixture shall be assumed to present the same health hazards as do the components which comprise one percent (by weight or volume) or greater of the mixture, except that the mixture shall be assumed to present a carcinogenic hazard if it contains a component in concentrations of 0.1 percent or greater which is considered to be a carcinogen under paragraph (d)(4) of this section;~~

~~–(iii) If a mixture has not been tested as a whole to determine whether the mixture is a physical hazard, the chemical manufacturer, importer, or employer may use whatever scientifically valid data is available to evaluate the physical hazard potential of the mixture; and,~~

~~–(iv) If the chemical manufacturer, importer, or employer has evidence to indicate that a component present in the mixture in concentrations of less than one percent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health risk to employees in those concentrations, the mixture shall be assumed to present the same hazard.~~

(3) Mixtures

~~(6) Chemical manufacturers, importers, or employers evaluating chemicals shall describe in writing follow the procedures described in Appendixes A and B to §1910.1200 they use to classify determine the hazards of the chemicals, including determinations regarding when mixtures of the classified chemicals are covered by this section. they evaluate.~~

~~The written procedures are to be made available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director. The written description may be incorporated into the written hazard communication program required under paragraph (e) of this section.~~
(ii) When classifying mixtures they produce or import, chemical manufacturers and importers of mixtures may rely on the information provided on the current safety data sheets of the individual ingredients, except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence should know, that the safety data sheet misstates or omits information required by this section.

(e) Written hazard communication program.

(1) Employers shall develop, implement, and maintain at each workplace, a written hazard communication program which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, ~~material safety data sheets~~ safety data sheets, and employee information and training will be met, and which also includes the

following:

(i) A list of the hazardous chemicals known to be present using ~~an identity product identifier~~ product identifier that is referenced on the appropriate ~~material safety data sheet~~ safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas); and,

(ii) The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas.

(2) Multi-employer workplaces. Employers who produce, use, or store hazardous chemicals at a workplace in such a way that the employees of other employer(s) may be exposed (for example, employees of a construction contractor working on-site) shall additionally ensure that the hazard communication programs developed and implemented under this paragraph (e) include the following:

(i) The methods the employer will use to provide the other employer(s) on-site access to ~~material safety data sheets~~ safety data sheets for each hazardous chemical the other employer(s)' employees may be exposed to while working;

(ii) The methods the employer will use to inform the other employer(s) of any precautionary measures that need to be taken to protect employees during the workplace's normal operating conditions and in foreseeable emergencies; and,

(iii) The methods the employer will use to inform the other employer(s) of the labeling system used in the workplace.

(3) The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

(4) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of 29 CFR 1910.1020 (e).

(5) Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the written hazard communication program may be kept at the primary workplace facility.

(f) Labels and other forms of warning.

(1 Labels on shipped containers. The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked with the ~~following information~~ Hazards not otherwise classified do not have to be

addressed on the container. Where the chemical manufacturer or importer is required to label, tag or mark the following shall be provided:

~~(i) Identity of the hazardous chemical(s)~~ Product identifier;

~~(ii) Appropriate hazard warnings; and~~ Product identifier;

(iii) Hazard statement(s);

(iv) Pictogram(s);

(v) Precautionary statement(s); and,

~~(iii)~~(iv) Name, and address, and telephone number of the chemical manufacturer, importer, or other responsible party.

(2) The chemical manufacturer, importer, or distributor shall ensure that the information provided under paragraphs (f)(1)(i) through (v) is in accordance with Appendix C, Allocation of Label Elements, for each hazard class and associated hazard category for the hazardous chemical, prominently displayed, and in English (other languages may also be included if appropriate).

(3) The chemical manufacturer, importer, or distributor shall ensure that the information provided under paragraphs (f)(1)(ii) through (iv) is located together on the label, tag, or mark.

(4) Solid materials

(i) For solid metal (such as a steel beam or a metal casting), solid wood, or plastic items that are not exempted as articles due to their downstream use, or shipments of whole grain, the required label may be transmitted to the customer at the time of the initial shipment, and need not be included with subsequent shipments to the same employer unless the information on the label changes;

(ii) The label may be transmitted with the initial shipment itself, or with the ~~material safety data sheet~~ safety data sheet that is to be provided prior to or at the time of the first shipment; and,

(iii) This exception to requiring labels on every container of hazardous chemicals is only for the solid material itself, and does not apply to hazardous chemicals used in conjunction with, or known to be present with, the material and to which employees handling the items in transit may be exposed (for example, cutting fluids or pesticides in grains).

~~(3)~~ Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.

(5) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials

Transportation Act (49 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.

~~(4) If the hazardous chemical is regulated by OSHA in a substance-specific health standard, the chemical manufacturer, importer, distributor or employer shall ensure that the labels or other forms of warning used are in accordance with the requirements of that standard.~~

~~(5)~~ (6) Workplace labeling. Except as provided in paragraphs ~~(67)~~ and ~~(78)~~ of this section, the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with or marked with either:

(i) The information specified under paragraphs (f)(1)(i) through (v) for labels on shipped containers; the following information or,

~~(i) Identity of the hazardous chemical(s) contained therein; and,~~

(ii) Product identifier

~~(ii) Appropriate hazard warnings, or alternatively, words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.~~

~~(6)~~ (7) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(5) of this section to be on a label. The employer shall ensure the written materials shall be are readily accessible to the employees in their work area throughout each work shift.

~~(7)~~ (8) The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. For purposes of this section, drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling.

~~(8)~~ (9) The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

~~(9)~~ (10) The employer shall ensure that workplace labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

~~(10) The chemical manufacturer, importer, distributor or employer need not affix new labels~~

~~to comply with this section if existing labels already convey the required information.~~

(11) Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within ~~three~~ six months of becoming aware of the new information, and shall ensure that ~~Labels on containers of hazardous chemicals shipped after that time shall~~ contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importers, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

(g) ~~Material safety data sheets~~ Safety data sheets.

(1) Chemical manufacturers and importers shall obtain or develop a ~~material safety data sheet~~ safety data sheet for each hazardous chemical they produce or import. Employers shall have a ~~material safety data sheet~~ safety data sheet in the workplace for each hazardous chemical which they use.

(2) ~~Each material safety data sheet shall be~~ The chemical manufacturer or importer preparing the safety data sheet shall ensure that it is in English (although the employer may maintain copies in other languages as well), and ~~shall contain at least the following information~~ includes at least the following section numbers and headings, and associated information under each heading, in the order listed (See Appendix D to §1910.1200--Safety Data Sheets, for the specific content of each section of the safety data sheet):

- (i) Section 1, Identification;
- (ii) Section 2, Hazard(s) identification;
- (iii) Section 3, Composition/information on ingredients;
- (iv) Section 4, First-aid measures;
- (v) Section 5, Fire-fighting measures;
- (vi) Section 6, Accidental release measures;
- (vii) Section 7, Handling and storage;
- (viii) Section 8, Exposure controls/personal protection;
- (ix) Section 9, Physical and chemical properties;
- (x) Section 10, Stability and reactivity;
- (xi) Section 11, Toxicological information.

Note 1 to paragraph (g)(2): To be consistent with the GHS, an SDS must also include the following headings in this order:

(xii) Section 12, Ecological information;

(xiii) Section 13, Disposal considerations;

(xiv) Section 14, Transport information; and

(xv) Section 15, Regulatory information.

Note 2 to paragraph (g)(2): OSHA will not be enforcing information requirements in sections 12 through 15, as these areas are not under its jurisdiction.

~~(i) The identity used on the label, and, except as provided for in paragraph (i) of this section on trade secrets:—~~

~~—(A) If the hazardous chemical is a single substance, its chemical and common name(s);—~~

~~—(B) If the hazardous chemical is a mixture which has been tested as a whole to determine its hazards, the chemical and common name(s) of the ingredients which contribute to these known hazards, and the common name(s) of the mixture itself; or,—~~

~~—(C) If the hazardous chemical is a mixture which has not been tested as a whole:~~

~~—(1) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except that chemicals identified as carcinogens under paragraph (d) of this section shall be listed if the concentrations are 0.1% or greater; and,—~~

~~—(2) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise less than 1% (0.1% for carcinogens) of the mixture, if there is evidence that the ingredient(s) could be released from the mixture in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH-Threshold Limit Value, or could present a health risk to employees; and,~~

~~—(3) The chemical and common name(s) of all ingredients which have been determined to present a physical hazard when present in the mixture;—~~

~~—(ii) Physical and chemical characteristics of the hazardous chemical (such as vapor pressure, flash point);—~~

~~—(iii) The physical hazards of the hazardous chemical, including the potential for fire, explosion, and reactivity;—~~

~~—(iv) The health hazards of the hazardous chemical, including signs and symptoms of exposure, and any medical conditions which are generally recognized as being aggravated by exposure to the chemical;—~~

~~—(v) The primary route(s) of entry;—~~

~~–(vi) The OSHA permissible exposure limit, ACGIH Threshold Limit Value, and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available;–~~

~~–(vii) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Annual Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest editions), or by OSHA;–~~

~~–(viii) Any generally applicable precautions for safe handling and use which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for clean-up of spills and leaks;–~~

~~–(ix) Any generally applicable control measures which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, such as appropriate engineering controls, work practices, or personal protective equipment;–~~

~~–(x) Emergency and first aid procedures;–~~

~~–(xi) The date of preparation of the material safety data sheet or the last change to it; and,–~~

~~–(xii) The name, address and telephone number of the chemical manufacturer, importer, employer or other responsible party preparing or distributing the material safety data sheet, who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.–~~

(3) If no relevant information is found for any sub-heading within a section given category on the ~~material safety data sheet~~ safety data sheet, the chemical manufacturer, importer or employer preparing the ~~material safety data sheet~~ safety data sheet shall mark it to indicate that no applicable information was found.

(4) Where complex mixtures have similar hazards and contents (i.e. the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one ~~material safety data sheet~~ safety data sheet to apply to all of these similar mixtures.

(5) The chemical manufacturer, importer or employer preparing the ~~material safety data sheet~~ safety data sheet shall ensure that the information ~~recorded~~ provided accurately reflects the scientific evidence used in making the hazard ~~determination~~ classification. If the chemical manufacturer, importer or employer preparing the ~~material safety data sheet~~ safety data sheet becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the ~~material safety data sheet~~ safety data sheet within three months. If the chemical is not currently being produced or

imported the chemical manufacturer or importer shall add the information to the ~~material safety data sheet~~ safety data sheet before the chemical is introduced into the workplace again.

(6)

(i) Chemical manufacturers or importers shall ensure that distributors and employers are provided an appropriate ~~material safety data sheet~~ safety data sheet with their initial shipment, and with the first shipment after a ~~material safety data sheet is updated~~ safety data sheet;

(ii) The chemical manufacturer or importer shall either provide ~~material safety data sheets~~ safety data sheets with the shipped containers or send them to the distributor or employer prior to or at the time of the shipment;

(iii) If the ~~material safety data sheet~~ safety data sheet is not provided with a shipment that has been labeled as a hazardous chemical, the distributor or employer shall obtain one from the chemical manufacturer or importer as soon as possible; and,

(iv) The chemical manufacturer or importer shall also provide distributors or employers with a ~~material safety data~~ safety data sheet sheet upon request.

(7)

(i) Distributors shall ensure that ~~material safety data sheets~~ safety data sheets, and updated information, are provided to other distributors and employers with their initial shipment and with the first shipment after a ~~material safety data sheet~~ a safety data sheet is updated;

(ii) The distributor shall either provide ~~material safety data sheets~~ safety data sheets with the shipped containers, or send them to the other distributor or employer prior to or at the time of the shipment;

(iii) Retail distributors selling hazardous chemicals to employers having a commercial account shall provide a ~~material safety data sheet~~ safety data sheet to such employers upon request, and shall post a sign or otherwise inform them that a ~~material safety data sheet~~ safety data sheet is available;

(iv) Wholesale distributors selling hazardous chemicals to employers over-the-counter may also provide material safety data sheets, provide ~~material safety data sheets~~ safety data sheets upon the request of the employer at the time of the over-the-counter purchase, and shall post a sign or otherwise inform such employers that a ~~material safety data sheet~~ safety data sheet is available;

(v) If an employer without a commercial account purchases a hazardous chemical from a retail distributor not required to have ~~material safety data sheets~~ safety data sheets on file (i.e., the retail distributor does not have commercial accounts and does not use the materials), the retail distributor shall provide the employer, upon request, with the name, address, and telephone

number of the chemical manufacturer, importer, or distributor from which a ~~material safety data sheet~~ safety data sheet can be obtained;

(vi) Wholesale distributors shall also provide ~~material safety data sheets~~ safety data sheets to employers or other distributors upon request; and,

(vii) Chemical manufacturers, importers, and distributors need not provide ~~material safety data sheets~~ safety data sheets to retail distributors that have informed them that the retail distributor does not sell the product to commercial accounts or open the sealed container to use it in their own workplaces.

(8) The employer shall maintain in the workplace copies of the required ~~material safety data sheets~~ safety data sheets for each hazardous chemical, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s). (Electronic access, ~~microfiche~~, and other alternatives to maintaining paper copies of the ~~material safety data sheets~~ safety data sheets are permitted as long as no barriers to immediate employee access in each workplace are created by such options.)

(9) Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the ~~material safety data sheets~~ safety data sheets may be kept at the primary workplace facility. In this situation, the employer shall ensure that employees can immediately obtain the required information in an emergency.

(10) ~~Material safety data sheets~~ Safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in ~~in~~ their work area(s).

(11) ~~Material safety data sheets~~ Safety data sheets shall also be made readily available, upon request, to designated representatives and to the Assistant Secretary, in accordance with the requirements of 29 CFR 1910.1020(e). The Director shall also be given access to material safety data sheets in the same manner.

(h) Employee information and training.

(1) Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new ~~physical or health~~ chemical hazard ~~hazard~~ the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and ~~material safety data sheets~~ safety data sheets.

(2) Information. Employees shall be informed of:

(i) The requirements of this section;

(ii) Any operations in their work area where hazardous chemicals are present; and,

(iii) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and ~~material safety data sheets~~ safety data sheets required by this section.

(3) Training. Employee training shall include at least:

(i) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(ii) The physical, ~~and health~~, simple asphyxiation, combustible dust, and pyrophoric gas hazards, as well as hazards not otherwise classified, ~~hazards~~ of the chemicals in the work area;

(iii) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,

(iv) The details of the hazard communication program developed by the employer, including an explanation of the labels received on shipped containers and the workplace labeling system ~~and the material safety data sheet~~ safety data sheet, including the order of information and how employees can obtain and use the appropriate hazard information.

(i) Trade secrets.

(1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name ~~and~~ other specific identification of a hazardous chemical, or the exact percentage (concentration) of the substance in a mixture, from the ~~material safety data sheet~~ safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the ~~material safety data sheet~~ safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

(iii) The ~~material safety data sheet~~ safety data sheet indicates that the specific chemical identity and/or percentage of composition is being withheld as a trade secret; and,

(iv) The specific chemical identity and percentage is made available to health professionals,

employees, and designated representatives in accordance with the applicable provisions of this paragraph (i).

(2) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity and/or specific percentage of composition of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer shall immediately disclose the specific chemical identity or percentage composition of a trade secret chemical to that treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i) (3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity or percentage composition, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (i.e. physician, industrial hygienist, toxicologist, epidemiologist, or occupational health nurse) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and,

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity or percentage composition is essential and that, in lieu thereof, the disclosure of the following information to the health professional, employee, or designated representative, would not satisfy the purposes described in paragraph (i)(3)(ii) of this section:

- (A) The properties and effects of the chemical;
- (B) Measures for controlling workers' exposure to the chemical;
- (C) Methods of monitoring and analyzing worker exposure to the chemical; and,
- (D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, and the employer or contractor of the services of the health professional (i.e. downstream employer, labor organization, or individual employee), employee, or designated representative, agree in a written confidentiality agreement that the health professional, employee, or designated representative, will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

(4) The confidentiality agreement authorized by paragraph (i)(3)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre- estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(5) Nothing in this standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(6) If the health professional, employee, or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the chemical manufacturer, importer, or employer who provided the information shall be informed by the health professional, employee, or designated representative prior to, or at the same time as, such disclosure.

(7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity or percentage composition, the denial must:

(i) Be provided to the health professional, employee, or designated representative, within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity or percent of composition is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the ~~specific chemical identity~~ trade secret.

(8) The health professional, employee, or designated representative whose request for information is denied under paragraph (i)(3) of this section may refer the request and the written denial of the request to OSHA for consideration.

(9) When a health professional, employee, or designated representative refers the denial to OSHA under paragraph (i)(8) of this section, OSHA shall consider the evidence to determine if:

(i) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity or percentage composition is a trade secret;

(ii) The health professional, employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and,

(iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

(10)

(i) If OSHA determines that the specific chemical identity or percentage composition requested under paragraph (i)(3) of this section is not a bona fide trade secret, or that it is a trade secret, but the requesting health professional, employee, or designated representative has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by OSHA.

(ii) If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret ~~specific chemical identity~~, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

(11) If a citation for a failure to release ~~specific chemical identity~~ trade secret information is

contested by the chemical manufacturer, importer, or employer, the matter will be adjudicated before the Occupational Safety and Health Review Commission in accordance with the Act's enforcement scheme and the applicable Commission rules of procedure. In accordance with the Commission rules, when a chemical manufacturer, importer, or employer continues to withhold the information during the contest, the Administrative Law Judge may review the citation and supporting documentation in camera or issue appropriate orders to protect the confidentiality of such matters.

(12) Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process ~~or percentage of mixture~~ information which is a trade secret.

(j) Effective dates. (1) Employers shall train employees regarding the new label elements and safety data sheets format by December 1, 2013. Chemical manufacturers, importers, distributors, and employers shall be in compliance with all ~~provisions of this section by March 11, 1994.~~

(2) Chemical manufacturers, importers, distributors, and employers shall be in compliance with all modified provisions of this section no later than June 1, 2015, except:

(i) After December 1, 2015, the distributor shall not ship containers labeled by the chemical manufacturer or importer unless the label has been modified to comply with paragraph (f)(1) of this section.

(ii) All employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6), update the hazard communication program required by paragraph (h)(1), and provide any additional employee training in accordance with paragraph (h)(3) for newly identified physical or health hazards no later than June 1, 2016.

(3) Chemical manufacturers, importers, distributors, and employers may comply with either §1910.1200 revised as of October 1, 2011, or the current version of this standard, or both during the transition period.

~~Note: The effective date of the clarification that the exemption of wood and wood products from the Hazard Communication standard in paragraph (b)(6)(iv) only applies to wood and wood products including lumber which will not be processed, where the manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility, and that the exemption does not apply to wood or wood products which have been treated with a hazardous chemical covered by this standard, and wood which may be subsequently sawed or cut generating dust has been stayed from March 11, 1994 to August 11, 1994.~~

Appendix A to 1910.1200 - Health Hazard Definitions (Mandatory)

Although safety hazards related to the physical characteristics of a chemical can be objectively defined in terms of testing requirements (e.g. flammability), health hazard definitions are less precise and more subjective. Health hazards may cause measurable changes in the body such as decreased pulmonary function. These changes are generally indicated by the occurrence of signs and symptoms in the exposed employees such as shortness of breath, a non-measurable, subjective feeling. Employees exposed to such hazards must be apprised of both the change in body function and the signs and symptoms that may occur to signal that change. The determination of occupational health hazards is complicated by the fact that many of the effects or signs and symptoms occur commonly in non-occupationally exposed populations, so that effects of exposure are difficult to separate from normally occurring illnesses. Occasionally, a substance causes an effect that is rarely seen in the population at large, such as angiosarcomas caused by vinyl chloride exposure, thus making it easier to ascertain that the occupational exposure was the primary causative factor. More often, however, the effects are common, such as lung cancer. The situation is further complicated by the fact that most chemicals have not been adequately tested to determine their health hazard potential, and data do not exist to substantiate these effects. There have been many attempts to categorize effects and to define them in various ways. Generally, the terms "acute" and "chronic" are used to delineate between effects on the basis of severity or duration. "Acute" effects usually occur rapidly as a result of short term exposures, and are of short duration. "Chronic" effects generally occur as a result of long term exposure, and are of long duration. The acute effects referred to most frequently are those defined by the American National Standards Institute (ANSI) standard for Precautionary Labeling of Hazardous Industrial Chemicals (Z129.1-1988) irritation, corrosivity, sensitization and lethal dose. Although these are important health effects, they do not adequately cover the considerable range of acute effects which may occur as a result of occupational exposure, such as, for example, narcosis. Similarly, the term chronic effect is often used to cover only carcinogenicity, teratogenicity, and mutagenicity. These effects are obviously a concern in the workplace, but again, do not adequately cover the area of chronic effects, excluding, for example, blood dyscrasias (such as anemia), chronic bronchitis and liver atrophy. The goal of defining precisely, in measurable terms, every possible health effect that may occur in the workplace as a result of chemical exposures cannot realistically be accomplished. This does not negate the need for employees to be informed of such effects and protected from them. Appendix B, which is also mandatory, outlines the principles and procedures of hazard assessment. For purposes of this section, any chemicals which meet any of the following definitions, as determined by the criteria set forth in Appendix B are health hazards. However, this is not intended to be an exclusive categorization scheme. If there are available scientific data that involve other animal species or test methods, they must also be evaluated to determine the applicability of the HCS.

1. Carcinogen: A chemical is considered to be a carcinogen if:

(a) It has been evaluated by the International Agency for Research on Cancer (IARC), and found to be a carcinogen or potential carcinogen; or

~~(b) It is listed as a carcinogen or potential carcinogen in the Annual Report on Carcinogens published by the National Toxicology Program (NTP) (latest edition); or,~~

~~(c) It is regulated by OSHA as a carcinogen.~~

~~2. Corrosive: A chemical that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. For example, a chemical is considered to be corrosive if, when tested on the intact skin of albino rabbits by the method described by the U.S. Department of Transportation in appendix A to 49 CFR part 173, it destroys or changes irreversibly the structure of the tissue at the site of contact following an exposure period of four hours. This term shall not refer to action on inanimate surfaces.~~

~~3. Highly toxic: A chemical falling within any of the following categories:~~

~~(a) A chemical that has a median lethal dose (LD50) of 50 milligrams or less per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.~~

~~(b) A chemical that has a median lethal dose (LD50) of 200 milligrams or less per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.~~

~~(c) A chemical that has a median lethal concentration (LC50) in air of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter or less of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.~~

~~4. Irritant: A chemical, which is not corrosive, but which causes a reversible inflammatory effect on living tissue by chemical action at the site of contact. A chemical is a skin irritant if, when tested on the intact skin of albino rabbits by the methods of 16 CFR 1500.41 for four hours exposure or by other appropriate techniques, it results in an empirical score of five or more. A chemical is an eye irritant if so determined under the procedure listed in 16 CFR 1500.42 or other appropriate techniques.~~

~~5. Sensitizer: A chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.~~

~~6. Toxic. A chemical falling within any of the following categories:~~

~~(a) A chemical that has a median lethal dose (LD50) of more than 50 milligrams per kilogram but not more than 500 milligrams per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.~~

~~(b) A chemical that has a median lethal dose (LD50) of more than 200 milligrams per kilogram but not more than 1,000 milligrams per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of~~

albino rabbits weighing between two and three kilograms each.

~~(c) A chemical that has a median lethal concentration (LC50) in air of more than 200 parts per million but not more than 2,000 parts per million by volume of gas or vapor, or more than two milligrams per liter but not more than 20 milligrams per liter of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.~~

~~7. Target organ effects. The following is a target organ categorization of effects which may occur, including examples of signs and symptoms and chemicals which have been found to cause such effects. These examples are presented to illustrate the range and diversity of effects and hazards found in the workplace, and the broad scope employers must consider in this area, but are not intended to be all inclusive.~~

~~a. Hepatotoxins: Chemicals which produce liver damage Signs & Symptoms: Jaundice; liver enlargement Chemicals: Carbon tetrachloride; nitrosamines~~

~~b. Nephrotoxins: Chemicals which produce kidney damage Signs & Symptoms: Edema; proteinuria Chemicals: Halogenated hydrocarbons; uranium~~

~~c. Neurotoxins: Chemicals which produce their primary toxic effects on the nervous system Signs & Symptoms: Noreosis; behavioral changes; decrease in motor functions Chemicals: Mercury; carbon disulfide~~

~~d. Agents which act on the blood or hemato poietic system: Decrease hemoglobin function; deprive the body tissues of oxygen Signs & Symptoms: Cyanosis; loss of consciousness Chemicals: Carbon monoxide; cyanides~~

~~e. Agents which damage the lung: Chemicals which irritate or damage pulmonary tissue Signs & Symptoms: Cough; tightness in chest; shortness of breath Chemicals: Silica; asbestos~~

~~f. Reproductive toxins: Chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis) Signs & Symptoms: Birth defects; sterility Chemicals: Lead; DBCP~~

~~g. Cutaneous hazards: Chemicals which affect the dermal layer of the body Signs & Symptoms: Defatting of the skin; rashes; irritation Chemicals: Ketones; chlorinated compounds~~

~~h. Eye hazards: Chemicals which affect the eye or visual capacity Signs & Symptoms: Conjunctivitis; corneal damage Chemicals: Organic solvents; acids~~

A.0.1 Classification

A.0.1.1 The term “hazard classification” is used to indicate that only the intrinsic hazardous properties of chemicals are considered. Hazard classification incorporates three steps:

- (a) Identification of relevant data regarding the hazards of a chemical;
- (b) Subsequent review of those data to ascertain the hazards associated with the chemical;
- (c) Determination of whether the chemical will be classified as hazardous and the degree of hazard.

A.0.1.2 For many hazard classes, the criteria are semi-quantitative or qualitative and expert judgment is required to interpret the data for classification purposes.

A.0.2 Available data, test methods and test data quality

A.0.2.1 There is no requirement for testing chemicals.

A.0.2.2 The criteria for determining health hazards are test method neutral, i.e., they do not specify particular test methods, as long as the methods are scientifically validated.

A.0.2.3 The term “scientifically validated” refers to the process by which the reliability and the relevance of a procedure are established for a particular purpose. Any test that determines hazardous properties, which is conducted according to recognized scientific principles, can be used for purposes of a hazard determination for health hazards. Test conditions need to be standardized so that the results are reproducible with a given substance, and the standardized test yields “valid” data for defining the hazard class of concern.

A.0.2.4 Existing test data are acceptable for classifying chemicals, although expert judgment also may be needed for classification purposes.

A.0.2.5 The effect of a chemical on biological systems is influenced, by the physico-chemical properties of the substance and/or ingredients of the mixture and the way in which ingredient substances are biologically available. A chemical need not be classified when it can be shown by conclusive experimental data from scientifically validated test methods that the chemical is not biologically available.

A.0.2.6 For classification purposes, epidemiological data and experience on the effects of chemicals on humans (e.g., occupational data, data from accident databases) shall be taken into account in the evaluation of human health hazards of a chemical.

A.0.3 Classification based on weight of evidence

A.0.3.1 For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a chemical shall be determined on the basis of the total weight of evidence using expert judgment. This means that all available information bearing on the classification of hazard shall be considered together, including the results of valid *in vitro* tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.

A.0.3.2 The quality and consistency of the data shall be considered. Information on

chemicals related to the material being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be considered together in a single weight-of-evidence determination.

A.0.3.3 Positive effects which are consistent with the criteria for classification, whether seen in humans or animals, shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Reliable, good quality human data shall generally have precedence over other data. However, even well-designed and conducted epidemiological studies may lack a sufficient number of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Therefore, positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness, quality and statistical power of both the human and animal data.

A.0.3.4 Route of exposure, mechanistic information, and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence demonstrating that the mechanism or mode of action is not relevant to humans, the chemical should not be classified.

A.0.3.5 Both positive and negative results are considered together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.

A.0.4 Considerations for the classification of mixtures

A.0.4.1 For most hazard classes, the recommended process of classification of mixtures is based on the following sequence:

- (a) Where test data are available for the complete mixture, the classification of the mixture will always be based on those data;
- (b) Where test data are not available for the mixture itself, the bridging principles designated in each health hazard chapter of this appendix shall be considered for classification of the mixture;
- (c) If test data are not available for the mixture itself, and the available information is not sufficient to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture (e.g., application of cut-off values/concentration limits).

A.0.4.2 An exception to the above order or precedence is made for Carcinogenicity, Germ

Cell Mutagenicity, and Reproductive Toxicity. For these three hazard classes, mixtures shall be classified based upon information on the ingredient substances, unless on a case-by-case basis, justification can be provided for classifying based upon the mixture as a whole. See chapters A.5, A.6, and A.7 for further information on case-by-case bases.

A.0.4.3 Use of cut-off values/concentration limits

A.0.4.3.1 When classifying an untested mixture based on the hazards of its ingredients, cut-off values/concentration limits for the classified ingredients of the mixture are used for several hazard classes. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified cut-off values/concentration limits that still pose an identifiable hazard. There may also be cases where the cut-off value/concentration limit is considerably lower than the established non-hazardous level for an ingredient.

A.0.4.3.2 If the classifier has information that the hazard of an ingredient will be evident (i.e., it presents a health risk) below the specified cut-off value/concentration limit, the mixture containing that ingredient shall be classified accordingly.

A.0.4.3.3 In exceptional cases, conclusive data may demonstrate that the hazard of an ingredient will not be evident (i.e., it does not present a health risk) when present at a level above the specified cut-off value/concentration limit(s). In these cases the mixture may be classified according to those data. The data must exclude the possibility that the ingredient will behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture must not contain ingredients that would affect that determination.

A.0.4.4 Synergistic or antagonistic effects

When performing an assessment in accordance with these requirements, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

A.0.5 Bridging principles for the classification of mixtures where test data are not available for the complete mixture

A.0.5.1 Where the mixture itself has not been tested to determine its toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles, subject to any specific provisions for mixtures for each hazard class. These principles ensure that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

A.0.5.1.1 Dilution

For mixtures classified in accordance with A.1 through A.10 of this Appendix, if a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then:

- (a) The new diluted mixture shall be classified as equivalent to the original tested mixture; or
- (b) For classification of acute toxicity in accordance with A.1 of this Appendix, paragraph A.1.3.6 (the additivity formula) shall be applied.

A.0.5.1.2 Batching

For mixtures classified in accordance with A.1 through A.10 of this Appendix, the toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same mixture, when produced by or under the control of the same *chemical manufacturer*, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary.

A.0.5.1.3 Concentration of mixtures

For mixtures classified in accordance with A.1, A.2, A.3, A.8, A.9, or A.10 of this Appendix, if a tested mixture is classified in Category 1, and the concentration of the ingredients of the tested mixture that are in Category 1 is increased, the resulting untested mixture shall be classified in Category 1.

A.0.5.1.4 Interpolation within one toxicity category

For mixtures classified in accordance with A.1, A.2, A.3, A.8, A.9, or A.10 of this Appendix, for three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.

A.0.5.1.5 Substantially similar mixtures

For mixtures classified in accordance with A.1 through A.10 of this Appendix, given the following set of conditions:

- (a) Where there are two mixtures:
 - (i) A + B;

(ii) C + B;

(b) The concentration of ingredient B is essentially the same in both mixtures;

(c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);

(d) And data on toxicity for A and C are available and substantially equivalent; i.e., they are in the same hazard category and are not expected to affect the toxicity of B; then

If mixture (i) or (ii) is already classified based on test data, the other mixture can be assigned the same hazard category.

A.0.5.1.6 Aerosols

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, or A.9 of this Appendix, an aerosol form of a mixture shall be classified in the same hazard category as the tested, non-aerosolized form of the mixture, provided the added propellant does not affect the toxicity of the mixture when spraying. Table B.3.1: Criteria for flammable aerosols

A.1 ACUTE TOXICITY

A.1.1 Definition

Acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.

A.1.2 Classification criteria for substances

A.1.2.1 Substances can be allocated to one of four toxicity categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in Table A.1.1. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates (ATE). See the footnotes following Table A.1.1 for further explanation on the application of these values.

Table A.1.1: Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories

| Exposure route | Category 1 | Category 2 | Category 3 | Category 4 |
|--|------------|-----------------|-----------------|-------------------|
| Oral (mg/kg bodyweight) <i>see: Note (a)</i> Note (b) | ≤ 5 | >5 and ≤ 50 | >50 and ≤ 300 | >300 and ≤ 2000 |
| Dermal (mg/kg bodyweight) <i>see: Note (a)</i> Note (b) | ≤ 5 | >50 and ≤ 200 | >200 and ≤ 1000 | >1000 and ≤ 2000 |
| Inhalation - Gases (ppmV) <i>see: Note (a)</i> Note (b) Note (c) | ≤ 100 | >100 and ≤ 500 | >500 and ≤ 2500 | >2500 and ≤ 20000 |
| Inhalation - Vapors (mg/l) <i>see: Note (a)</i> Note (b) Note (c) Note (d) | ≤ 0.5 | >0.5 and ≤ 2.0 | >2.0 and ≤ 10.0 | >10.0 and ≤ 20.0 |
| Inhalation – Dusts and Mists (mg/l) <i>see: Note (a)</i> Note (b) Note (c) | ≤ 0.05 | >0.05 and ≤ 0.5 | >0.5 and ≤ 1.0 | >1.0 and ≤ 5.0 |

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

Notes to Table A.1.1:

(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD₅₀/LC₅₀ where available;

(b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:

(i) the LD₅₀/LC₅₀ where available. Otherwise, (ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or

(iii) the appropriate conversion value from Table 1.2 that relates to a classification category;

(c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposure is achieved by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;

(d) For some substances the test atmosphere will be a vapor which consists of a combination of liquid and gaseous phases. For other substances the test atmosphere may consist of a vapor which is nearly all the gaseous phase. In these latter cases, classification is based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

The terms “dust”, “mist” and “vapor” are defined as follows:

(i) Dust: solid particles of a substance or mixture suspended in a gas (usually air);

(ii) Mist: liquid droplets of a substance or mixture suspended in a gas (usually air);

(iii) Vapor: the gaseous form of a substance or mixture released from its liquid or solid state.

A.1.2.3 The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity. Test data already generated for the classification of chemicals under existing systems should be accepted when reclassifying these chemicals under the harmonized system. When experimental data for acute toxicity are available in several animal species, scientific judgment should be used in selecting the most appropriate LD₅₀ value from among scientifically validated tests.

A.1.3 Classification criteria for mixtures

A.1.3.1 The approach to classification of mixtures for acute toxicity is tiered, and is dependent upon the amount of information available for the mixture itself and for its ingredients.

The flow chart of Figure A.1.1 indicates the process that must be followed:

Figure A.1.1: Tiered approach to classification of mixtures for acute toxicity

| Test data on the mixture as a whole | | | |
|--|------------|--|-----------------|
| No | | Yes | |
| Sufficient data available on similar mixtures to estimate hazards | Yes | Apply bridging principles in A.1.3.5 | CLASSIFY |
| No | | Apply formula in A.1.3.6.1 | CLASSIFY |
| Available data for all ingredients | Yes | | |
| No | | Apply formula in A.1.3.6.1 | CLASSIFY |
| Other data available to estimate conversion values for classification | Yes | | |
| No | | Apply formula in A.1.3.6.1 (unknown ingredients ≤ 10%) or Apply formula in A.1.3.6.2.3 (unknown ingredients > 10%) | CLASSIFY |
| Convey hazards of the known ingredients | | | |

A.1.3.2 Classification of mixtures for acute toxicity may be carried out for each route of exposure, but is only required for one route of exposure as long as this route is followed (estimated or tested) for all ingredients and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of acute toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information shall be considered. The pictogram and signal word used shall reflect the most severe hazard category; and all relevant hazard statements shall be used.

A.1.3.3 For purposes of classifying the hazards of mixtures in the tiered approach:

- (a) The “relevant ingredients” of a mixture are those which are present in concentrations $\geq 1\%$ (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If there is reason to suspect that an ingredient present at

a concentration < 1% will affect classification of the mixture for acute toxicity, that ingredient shall also be considered relevant. Consideration of ingredients present at a concentration < 1% is particularly important when classifying untested mixtures which contain ingredients that are classified in Category 1 and Category 2;

(b) Where a classified mixture is used as an ingredient of another mixture, the actual or derived acute toxicity estimate (ATE) for that mixture is used when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.9

(c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category.

(d) When only range data (or acute toxicity hazard category information) are available for ingredients in a mixture, they may be converted to point estimates in accordance with Table A.1.2 when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

A.1.3.4 Classification of mixtures where acute toxicity test data are available for the complete mixture

Where the mixture itself has been tested to determine its acute toxicity, it is classified according to the same criteria as those used for substances, presented in Table A.1.1. If test data for the mixture are not available, the procedures presented below must be followed.

A.1.3.5 Classification of mixtures where acute toxicity test data are not available for the complete mixture: bridging principles

A.1.3.5.1 Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.1.3.6 Classification of mixtures based on ingredients of the mixture (additivity formula)

A.1.3.6.1 Data available for all ingredients

The acute toxicity estimate (ATE) of ingredients is considered as follows:

(a) Include ingredients with a known acute toxicity, which fall into any of the acute toxicity categories, or have an oral or dermal LD₅₀ greater than 2000 but less than or equal to 5000 mg/kg body weight (or the equivalent dose for inhalation);

(b) Ignore ingredients that are presumed not acutely toxic (e.g., water, sugar);

(c) Ignore ingredients if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table A.1.1) and do not show acute toxicity.

Ingredients that fall within the scope of this paragraph are considered to be ingredients with a known acute toxicity estimate (ATE). See note (b) to Table A.1.1 and paragraph A.1.3.3 for appropriate application of available data to the equation below, and paragraph A.1.3.6.2.4.10

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula below for oral, dermal or inhalation toxicity:

$$\frac{100}{\text{ATF}_{\text{mix}}} = \sum_{i=1}^n \frac{C_i}{\text{ATE}_i}$$

where:

C_i = concentration of ingredient i
 n ingredients and i is running from 1 to n
 ATE_i = acute toxicity estimate of ingredient i .

A.1.3.6.2 Data are not available for one or more ingredients of the mixture

A.1.3.6.2.1 Where an ATE is not available for an individual ingredient of the mixture, but available information provides a derived conversion value, the formula in A.1.3.6.1 may be applied. This information may include evaluation of:

- (a) Extrapolation between oral, dermal and inhalation acute toxicity estimates. Such an evaluation requires appropriate pharmacodynamic and pharmacokinetic data;
- (b) Evidence from human exposure that indicates toxic effects but does not provide lethal dose data;
- (c) Evidence from any other toxicity tests/assays available on the substance that indicates toxic acute effects but does not necessarily provide lethal dose data; or
- (d) Data from closely analogous substances using structure/activity relationships.

A.1.3.6.2.2 This approach requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity. If sufficient information is not available to reliably estimate acute toxicity, proceed to the provisions of A.1.3.6.2.3.

A.1.3.6.2.3 In the event that an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq 1\%$, and the mixture has not been classified based on testing of the mixture as a whole, the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture is classified based on the known ingredients only. (Note: A statement that \times percent of the mixture consists of ingredient(s) of unknown toxicity is required on the label and safety data sheet in such cases; see Appendix C to this section, Allocation of Label Elements and Appendix D to this section, Safety Data Sheets.)

Where an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq 1\%$, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is 11 required on the label and safety data sheet in such cases; see Appendix C to this section, Allocation of Label Elements and Appendix D to this section, Safety Data Sheets.)

A.1.3.6.2.4 If the total concentration of the relevant ingredient(s) with unknown acute toxicity is $\leq 10\%$ then the formula presented in A.1.3.6.1 must be used. If the total concentration of the relevant ingredient(s) with unknown acute toxicity is $> 10\%$, the formula presented in A.1.3.6.1 is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

$$\frac{100 - (\sum C_{\text{unknown if } > 10\%})}{ATE_{\text{mix}}} \times \frac{\sum C_i}{n ATE_i}$$

Table A.1.2: Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for use in the formulas for the classification of mixtures

| Exposure routes | Classification category or experimentally obtained acute toxicity range estimate | Converted Acute Toxicity point estimate |
|-------------------------------------|--|---|
| Oral (mg/kg bodyweight) | 0 < Category 1 \leq 5 | 0.5 |
| | 5 < Category 2 \leq 50 | 5 |
| | 50 < Category 3 \leq 300 | 100 |
| | 300 < Category 4 \leq 2000 | 500 |
| Dermal (mg/kg bodyweight) | 0 < Category 1 \leq 50 | 5 |
| | 50 < Category 2 \leq 200 | 50 |
| | 200 < Category 3 \leq 1000 | 300 |
| | 1000 < Category 4 \leq 2000 | 1100 |
| Gases (ppmV) | 0 < Category 1 \leq 100 | 10 |
| | 100 < Category 2 \leq 500 | 100 |
| | 500 < Category 3 \leq 2500 | 700 |
| | 2500 < Category 4 \leq 20000 | 4500 |
| Vapors (mg/l) | 0 < Category 1 \leq 0.5 | 0.05 |
| | 0.5 < Category 2 \leq 2.0 | 0.5 |
| | 2.0 < Category 3 \leq 10.0 | 3 |
| | 10.0 < Category 4 \leq 20.0 | 11 |

| | | |
|----------------------------|-------------------------|-------|
| Dust/mist (mg/l) | 0 < Category 1 ≤ 0.05 | 0.005 |
| | 0.05 < Category 2 ≤ 0.5 | 0.05 |
| | 0.5 < Category 3 ≤ 1.0 | 0.5 |
| | 1.0 < Category 4 ≤ 5.0 | 1.5 |

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

A.2 SKIN CORROSION/IRRITATION

A.2.1 Definitions and general considerations

A.2.1.1 *Skin corrosion* is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology should be considered to evaluate questionable lesions.

Skin irritation is the production of reversible damage to the skin following the application of a test substance for up to 4 hours.

A.2.1.2 Skin corrosion/irritation shall be classified using a tiered approach as detailed in figure A.2.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of skin corrosion/irritation is considered together, including the results of appropriate scientifically validated in-vitro tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.2.2 Classification criteria for substances using animal test data

A.2.2.1 Corrosion

A.2.2.1.1 A corrosive substance is a chemical that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 of 3 tested animals after exposure up to a 4-hour duration. Corrosive reactions are typified by ulcers, bleeding, bloody scabs and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia and scars. Histopathology should be considered to discern questionable lesions.

A.2.2.1.2 Three sub-categories of Category 1 are provided in Table A.2.1, all of which shall be regulated as Category 1.

Table A.2.1: Skin corrosion category and sub-categories

| Category 1: Corrosive | Corrosive sub-categories | Corrosive in ≥ 1 of 3 animals | |
|-----------------------|--------------------------|------------------------------------|----------------|
| | | Exposure | Observation |
| | 1A | ≤ 3 min | ≤ 1 h |
| | 1B | > 3 min ≤ 1 h | ≤ 14 days |
| | 1C | > 1 h ≤ 4 h | ≤ 14 days |

A.2.2.2 Irritation

A.2.2.2.1 A single irritant category (Category 2) is presented in the Table A.2.2. The major criterion for the irritant category is that at least 2 tested animals have a mean score of $\geq 2.3 \leq 4.0$.

Table A.2.2 Skin irritation category

| | Criteria |
|-----------------------|---|
| Irritant (Category 2) | <p>(1) Mean value of $\geq 2.3 \leq 4.0$ for erythema/eschar or for edema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or</p> <p>(2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or</p> <p>(3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.</p> |

A.2.2.2.2 Animal irritant responses within a test can be quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a substance might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also fulfil this criterion. However, it should be ascertained that the responses are the result of chemical exposure. Addition of this criterion increases the sensitivity of the classification system.

A.2.2.2.3. Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2 or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a chemical should be considered to be an irritant.

A.2.3 Classification Criteria for Substances Using Other Data Elements

A.2.3.1 Existing human and animal data including information from single or repeated exposure should be the first line of analysis, as they give information directly relevant to effects on the skin. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may

not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/irritation in acute toxicity studies and are observed up through the limit dose, these data may be used for classification provided that the dilutions used and species tested are equivalent. *In vitro* alternatives that have been scientifically validated shall be used to make classification decisions. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. Likewise, pH extremes like ≤ 2 and ≥ 11.5 may indicate skin effects, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (Skin Category 1) if it has a $\text{pH} \leq 2$ or a $\text{pH} \geq 11.5$. However, if consideration of alkali/acid reserve suggests the substance or mixture may not be corrosive despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.

A.2.3.2 A *tiered approach* to the evaluation of initial information shall be used (Figure A.2.1) recognizing that all elements may not be relevant in certain cases.

A.2.3.3 The tiered approach explains how to organize information on a substance and to make a weight-of-evidence decision about hazard assessment and hazard classification.

A.2.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, there is merit in considering the totality of existing information and making an overall weight of evidence determination. This is especially true when there is information available on some but not all parameters. Emphasis shall be placed upon existing human experience and data, followed by animal experience and testing data, followed by other sources of information, but case-by-case determinations are necessary.

Figure A.2.1: Tiered evaluation of skin corrosion and irritation potential

| Step | Parameter | Finding | Conclusion |
|------|-----------|---------|------------|
|------|-----------|---------|------------|

| | | | |
|------------|---|---|--|
| 1a: | Existing human or animal data ¹ Not corrosive or no data | Skin corrosive | Category 1 ² |
| 1b: | Existing human or animal data ¹ Not an irritant or no data | Skin irritant | Category 2 ² |
| 1c: | Existing human or animal data ¹ No/Insufficient data | Not a skin corrosive or skin irritant | Not classified |
| 2: | Other, existing skin data in animals ³ No/Insufficient data | Skin corrosive Skin irritant | Category 1 ² Category 2 ² |
| 3: | Existing skin corrosive <i>ex vivo</i> / <i>in vitro</i> data ⁴ Not corrosive or no data | Positive: Skin corrosive | Category 1 ² |
| | Existing skin irritation <i>ex vivo</i> / <i>in vitro</i> data ⁴ No/Insufficient data | Positive: Skin irritant Negative: Not a skin irritant ⁵ | Category 2 ² Not classified |
| 4: | pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data) ⁵ Not a pH extreme, No pH data or extreme pH with low/no buffering capacity | pH ≤ 2 or ≥ 11.5 | Category 1 ² |
| 5: | Validated Structure/Activity Relationship (SAR) models No/Insufficient data | Skin corrosive Skin irritant | Category 1 ² Category 2 ² |
| 6: | Consideration of the total Weight of Evidence ⁶ No concern based on consideration of the sum of available data | Skin corrosive Skin irritant | Category 1 ² Category 2 ² |
| 7: | Not Classified | | Not classified |

Notes to Figure A.2.1:

- ¹ *Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods (at present, there is no internationally accepted test method for human skin irritation testing).*
- ² *Classify in the appropriate harmonized category, as shown in Tables A.2.1 and A.2.2.*
- ³ *Pre-existing animal data (e.g. from an acute dermal toxicity test or a sensitisation test) should be carefully reviewed to determine if sufficient skin corrosion/irritation evidence is available through other, similar information. For example, classification/categorization may be done on the basis of whether a chemical has or has not produced any skin irritation in an acute dermal toxicity test in animals at the limit dose, or produces very toxic effects in an acute dermal toxicity test in animals. In the latter case, the chemical would be classified as being very hazardous by the dermal route for acute toxicity, and it would be moot whether the chemical is also irritating or corrosive on the skin. It should be kept in mind in evaluating acute dermal toxicity information that the reporting of dermal lesions may be incomplete, testing and observations may be made on a species other than the rabbit, and species may differ in sensitivity in their responses.*
- ⁴ *Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, non-tissue-based, though scientifically validated, protocols should be assessed. Examples of scientifically validated test methods for skin corrosion include OECD TG 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test), and 435 (Membrane Barrier Test Method). OECD TG 439 (Reconstructed Human Epidermis Test Method) is a scientifically validated in vitro test method for skin irritation.*
- ⁵ *Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable. Presently, there is no scientifically validated and internationally accepted method for assessing this parameter.*
- ⁶ *All information that is available on a chemical should be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. Professional judgment should be exercised in making such a determination.*

A.2.4 Classification criteria for mixtures

A.2.4.1 Classification of mixtures when data are available for the complete mixture

A.2.4.1.1 The mixture shall be classified using the criteria for substances (See A.2.3).

A.2.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.2.4.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.2.4.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.2.4.3.1 For purposes of classifying the skin corrosion/irritation hazards of mixtures in the tiered approach:

The “relevant ingredients” of a mixture are those which are present in concentrations >1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.

A.2.4.3.2 In general, the approach to classification of mixtures as irritant or corrosive to skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.

A.2.4.3.3 Table A.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be an irritant or a corrosive to the skin.

A.2.4.3.4 Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.2.4.3.1 and A.2.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1%. For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limits of Table A.2.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table A.2.3, due to chemical

characteristics that make this approach unworkable, should be classified as Skin Category 1 if it contains $\geq 1\%$ of a corrosive ingredient and as Skin Category 2 when it contains $\geq 3\%$ of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.2.3 does not apply is summarized in Table A.2.4 below.

A.2.4.3.5 On occasion, reliable data may show that the skin corrosion/irritation of an ingredient will not be evident when present at a level above the generic concentration cut-off values mentioned in Tables A.2.3 and A.2.4. In these cases the mixture could be classified according to those data (See Use of cut-off values/concentration limits, paragraph A.0.4.3 of this Appendix).

A.2.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of $< 1\%$ (corrosive) or $< 3\%$ (irritant), the mixture shall be classified accordingly (See Use of cut-off values /concentration limits, paragraph A.0.4.3 of this Appendix).

Table A.2.3: Concentration of ingredients of a mixture classified as skin Category 1 or 2 that would trigger classification of the mixture as hazardous to skin (Category 1 or 2)

| Sum of ingredients classified as: | Concentration triggering classification of a mixture as: | |
|---|--|------------------------|
| | Skin corrosive | Skin irritant |
| | Category 1 | Category 2 |
| Skin Category 1 | $\geq 5\%$ | $\geq 1\%$ but $< 5\%$ |
| Skin Category 2 | | $\geq 10\%$ |
| (10 \times Skin Category 1) + Skin Category 2 | | $\geq 10\%$ |

Table A.2.4: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin

| Ingredient: | Concentration: | Mixture classified as: Skin |
|--|----------------|-----------------------------|
| Acid with $\text{pH} \leq 2$ | $\geq 1\%$ | Category 1 |
| Base with $\text{pH} \geq 11.5$ | $\geq 1\%$ | Category 1 |
| Other corrosive (Category 1) ingredients for which additivity does not apply | $\geq 1\%$ | Category 1 |
| Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases | $\geq 3\%$ | Category 2 |

A.3 SERIOUS EYE DAMAGE /EYE IRRITATION

A.3.1 Definitions and general considerations

A.3.1.1 *Serious eye damage* is the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

Eye irritation is the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.

A.3.1.2 Serious eye damage/eye irritation shall be classified using a tiered approach as detailed in figure A.3.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by animal data, followed by other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of serious eye damage/eye irritation is considered together, including the results of appropriate scientifically validated *in vitro* tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.3.2 Classification criteria for substances using animal test data

A.3.2.1 Irreversible effects on the eye/serious damage to eyes (Category 1)

A single hazard category is provided in Table A.3.1, for substances that have the potential to seriously damage the eyes. Category 1, irreversible effects on the eye, includes the criteria listed below. These observations include animals with grade 4 cornea lesions and other severe reactions (e.g. destruction of cornea) observed at any time during the test, as well as persistent corneal opacity, discoloration of the cornea by a dye substance, adhesion, pannus, and interference with the function of the iris or other effects that impair sight. In this context, persistent lesions are considered those which are not fully reversible within an observation period of normally 21 days. Category 1 also contains substances fulfilling the criteria of corneal opacity ≥ 3 and/or iritis > 1.5 detected in a Draize eye test with rabbits, because severe lesions like these usually do not reverse within a 21-day observation period.

Table A.3.1: Irreversible eye effects

A substance is classified as **Serious Eye Damage Category 1 (irreversible effects on the eye)** when it produces:

- (a) at least in one tested animal, effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or
- (b) at least in 2 of 3 tested animals, a positive response of:
 - (i) corneal opacity ≥ 3 ; and/or
 - (ii) iritis > 1.5 ;
calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance.

A.3.2.2 Reversible effects on the eye (Category 2)

A single category is provided in Table A.3.2 for substances that have the potential to induce reversible eye irritation.

Table A.3.2: Reversible eye effects

A substance is classified as **Eye irritant Category 2A (irritating to eyes)** when it produces in at least in 2 of 3 tested animals a positive response of:

- (i) corneal opacity ≥ 1 ; and/or
- (ii) iritis ≥ 1 ; and/or
- (iii) conjunctival redness ≥ 2 ; and/or
- (iv) conjunctival edema (chemosis) ≥ 2

calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance, and which fully reverses within an observation period of normally 21 days.

An eye irritant is considered **mildly irritating to eyes (Category 2B)** when the effects listed above are fully reversible within 7 days of observation.

A.3.2.3 For those chemicals where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.

A.3.3 Classification Criteria for Substances Using Other Data Elements

A.3.3.1 Existing human and animal data should be the first line of analysis, as they give information directly relevant to effects on the eye. Possible skin corrosion shall be evaluated prior to consideration of serious eye damage/eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances. *In vitro* alternatives that have been scientifically validated

and accepted shall be used to make classification decisions. Likewise, pH extremes like ≤ 2 and ≥ 11.5 , may indicate serious eye damage, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the eyes. In the absence of any other information, a mixture/substance is considered to cause serious eye damage (Eye Category 1) if it has a pH ≤ 2 or ≥ 11.5 . However, if consideration of acid/alkaline reserve suggests the substance may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.

A.3.3.2 A tiered approach to the evaluation of initial information shall be used where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).

A.3.3.3 The tiered approach explains how to organize existing information on a substance and to make a weight-of-evidence decision, where appropriate, about hazard assessment and hazard classification.

A.3.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

**Figure A.3.1 Evaluation strategy for serious eye damage and eye irritation
(See also Figure A.2.1)**

| Step | Parameter | Finding | Conclusion |
|--|--|--|---|
| 1a: | Existing human or animal data, eye ¹ No/insufficient data or unknown | Serious Eye Damage Eye Irritant | Category 1 ² Category 2 ² |
| 1b: | Existing human or animal data, skin corrosion No/insufficient data or unknown | Skin corrosive | Category 1 ² |
| 1c: | Existing human or animal data, eye ¹ No/insufficient data | Existing data that show that substance does not cause serious eye damage or eye irritation | Not Classified |
| 2: | Other, existing skin/eye data in animals ³ No/insufficient data | Yes; existing data that show that substance may cause serious eye damage or eye irritation | Category 1 or Category 2 ² |
| 3: | Existing <i>ex vivo</i> / <i>in vitro</i> data ⁴ No/insufficient data / negative response | Positive: serious eye damage Positive: eye irritant | Category 1 ² Category 2 ² |
| 4: | pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data) ⁵ | pH ≤ 2 or ≥ 11.5 | Category 1 ² |
| Not a pH extreme, no pH data, or extreme pH with low/no buffering capacity | | | |
| 5: | Validated structure/activity relationship (SAR) models No/insufficient data | Severe damage to eyes Eye irritant Skin Corrosive | Category 1 ² Category 2 ² Category 1 ² |
| 6: | Consideration of the total weight of evidence ⁶ No concern based on consideration of the sum of available data | Serious eye damage Eye irritant | Category 1 ² Category 2 ² |
| 7: | | Not Classified | |

Notes to Figure A.3.1:

- ¹ *Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods. At present, there are no internationally accepted test methods for human skin or eye irritation testing.*
- ² *Classify in the appropriate harmonized category, as shown in Tables A.3.1 and A.3.2.*
- ³ *Pre-existing animal data should be carefully reviewed to determine if sufficient skin or eye corrosion/irritation evidence is available through other, similar information.*
- ⁴ *Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, non-tissue-based, though scientifically validated, protocols should be assessed. Examples of, scientifically validated test methods for identifying eye corrosives and severe irritants (i.e., Serious Eye Damage) include OECD TG 437 (Bovine Corneal Opacity and Permeability (BCOP)) and TG 438 (Isolated Chicken Eye). Positive test results from a scientifically validated in vitro test for skin corrosion would likely also lead to a conclusion to classify as causing Serious Eye Damage.*
- ⁵ *Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable.*
- ⁶ *All information that is available on a chemical should be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. The weight of evidence including information on skin irritation could lead to classification of eye irritation. It is recognized that not all skin irritants are eye irritants as well. Professional judgment should be exercised in making such a determination.*

A.3.4 Classification criteria for mixtures

A.3.4.1 Classification of mixtures when data are available for the complete mixture

A.3.4.1.1 The mixture will be classified using the criteria for substances

A.3.4.1.2 Unlike other hazard classes, there are alternative tests available for skin corrosivity of certain types of chemicals that can give an accurate result for classification purposes, as well as being simple and relatively inexpensive to perform. When considering testing of the mixture, chemical manufacturers are encouraged to use a tiered weight of evidence strategy as included in the criteria for classification of substances for skin corrosion and serious eye damage and eye irritation to help ensure an accurate classification, as well as avoid unnecessary animal testing. In the absence of any other information, a mixture is considered to cause serious eye damage (Eye Category 1) if it has a $\text{pH} \leq 2$ or ≥ 11.5 . However, if consideration of acid/alkaline reserve suggests the substance or mixture may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary.

A.3.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.3.4.2.1 Where the mixture itself has not been tested to determine its skin corrosivity or potential to cause serious eye damage or eye irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.3.4.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.3.4.3.1 For purposes of classifying the eye corrosion/irritation hazards of mixtures in the tiered approach: The “relevant ingredients” of a mixture are those which are present in concentrations $>1\%$ (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration $<1\%$ will affect classification of the mixture for eye corrosion/irritation, that ingredient shall also be considered relevant.

A.3.4.3.2 In general, the approach to classification of mixtures as seriously damaging to the eye or eye irritant when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as seriously damaging to the eye or eye irritant when the sum of the concentrations of such ingredients exceeds a threshold cut-off value/concentration limit.

A.3.4.3.3 Table A.3.3 provides the cut-off value/concentration limits to be used to determine if the mixture should be classified as seriously damaging to the eye or an eye irritant.

A.3.4.3.4 Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.3.4.3.1 and A.3.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1 %. For mixtures containing strong acids or bases, the pH should be used as classification criteria (See A.3.4.1) since pH will be a better indicator of serious eye damage than the concentration limits of Table A.3.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach applied in Table A.3.3 due to chemical characteristics that make this approach unworkable, should be classified as Eye Category 1 if it contains $\geq 1\%$ of a corrosive ingredient and as Eye Category 2 when it contains $\geq 3\%$ of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.3.3 does not apply is summarized in Table A.3.4.

A.3.4.3.5 On occasion, reliable data may show that the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic cut-off values/concentration limits mentioned in Tables A.3.3 and A.3.4. In these cases the mixture could be classified according to those data (See also A.0.4.3 *Use of cut-off values/concentration limits*). On occasion, when it is expected that the skin corrosion/irritation or the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic concentration/cut-off levels mentioned in Tables A.3.3 and A.3.4, testing of the mixture may be considered. In those cases, the tiered weight of evidence strategy should be applied as referred to in section A.3.3, Figure A.3.1 and explained in detail in this chapter.

A.3.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture should be classified accordingly (See also paragraph A.0.4.3, *Use of cut-off values/concentration limits*).

Table A.3.3: Concentration of ingredients of a mixture classified as Skin Category 1 and/or Eye Category 1 or 2 that would trigger classification of the mixtures as hazardous to the eye

| Sum of ingredients classified as | Concentration triggering classification of a mixture as | |
|--|---|------------------------|
| | Irreversible eye effects | Reversible eye effects |
| | Category 1 | Category 2 |
| Eye or Skin Category 1 | ≥ 3% | ≥ 1% but < 3% |
| Eye Category 2 | | ≥ 10% |
| (10 × Eye Category 1) + Eye Category 2 | | ≥ 10% |
| Skin Category 1 + Eye Category 1 | ≥ 3% | ≥ 1% but < 3% |
| 10 × (Skin Category 1 + Eye Category 1) + Eye Category 2 | | ≥ 3% |

Note: A mixture may be classified as Eye Category 2B in cases when all relevant ingredients are classified as Eye Category 2B.

Table A.3.4: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to the eye

| Ingredient | Concentration | Mixture classified as: Eye |
|--|---------------|-------------------------------|
| Acid with pH ≤ 2 | ≥ 1% | Category 1 |
| Base with pH ≥ 11.5 | ≥ 1% | Category 1 |
| Other corrosive (Category 1) ingredients for which additivity does not apply | ≥ 1% | Category 1 |
| Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases | ≥ 3% | Category 2 |

A.4 RESPIRATORY OR SKIN SENSITIZATION

A.4.1 Definitions and general considerations

A.4.1.1 *Respiratory sensitizer* means a chemical that will lead to hypersensitivity of the airways following inhalation of the chemical.

Skin sensitizer means a chemical that will lead to an allergic response following skin contact.

A.4.1.2 For the purpose of this chapter, sensitization includes two phases: the first phase is induction of specialized immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e., production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitized individual to an allergen.

A.4.1.3 For respiratory sensitization, the pattern of induction followed by elicitation phases is shared in common with skin sensitization. For skin sensitization, an induction phase is required in which the immune system learns to react; clinical symptoms can then arise when subsequent exposure is sufficient to elicit a visible skin reaction (elicitation phase). As a consequence, predictive tests usually follow this pattern in which there is an induction phase, the response to which is measured by a standardized elicitation phase, typically involving a patch test. The local lymph node assay is the exception, directly measuring the induction response. Evidence of skin sensitization in humans normally is assessed by a diagnostic patch test.

A.4.1.4 Usually, for both skin and respiratory sensitization, lower levels are necessary for elicitation than are required for induction.

A.4.1.5 The hazard class “respiratory or skin sensitization” is differentiated into:

(a) Respiratory sensitization; and

(b) Skin sensitization

A.4.2 Classification criteria for substances

A.4.2.1 Respiratory sensitizers

A.4.2.1.1 Hazard categories

A.4.2.1.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for respiratory sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.1 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals.

A.4.2.1.1.2 Where data are not sufficient for sub-categorization, respiratory sensitizers shall be classified in Category 1.

Table A.4.1: Hazard category and sub-categories for respiratory sensitizers

| | |
|--------------------|-------------------------------|
| Category 1: | Respiratory sensitizer |
|--------------------|-------------------------------|

| | |
|------------------|--|
| | A substance is classified as a respiratory sensitizer (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) if there are positive results from an appropriate animal test. ¹ |
| Sub-category 1A: | Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests. ¹ Severity of reaction may also be considered. |
| Sub-category 1B: | Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests. ¹ Severity of reaction may also be considered. |

A.4.2.1.2 Human evidence

A.4.2.1.2.1 Evidence that a substance can lead to specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

A.4.2.1.2.2 When considering the human evidence, it is necessary that in addition to the evidence from the cases, the following be taken into account:

- (a) The size of the population exposed;
- (b) The extent of exposure.

A.4.2.1.2.3 The evidence referred to above could be:

- (a) Clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:
 - (i) *In vivo* immunological test (e.g., skin prick test);
 - (ii) *In vitro* immunological test (e.g., serological analysis);
 - (iii) Studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g., repeated low-level irritation, pharmacologically mediated effects;

¹ *At this writing, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.*

- (iv) A chemical structure related to substances known to cause respiratory

hypersensitivity;

(b) Data from positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

A.4.2.1.2.4 Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood and smoking history.

A.4.2.1.2.5 The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is, however, recognized that in practice many of the examinations listed above will already have been carried out.

A.4.2.1.3 Animal studies

A.4.2.1.3.1 Data from appropriate animal studies² which may be indicative of the potential of a substance to cause sensitization by inhalation in humans³ may include:

- (a) Measurements of Immunoglobulin E (IgE) and other specific immunological parameters, for example in mice
- (b) Specific pulmonary responses in guinea pigs.

A.4.2.2 Skin sensitizers

A.4.2.2.1 Hazard categories

A.4.2.2.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for skin sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.2 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals according to the guidance values provided in A.4.2.2.2.1 and A.4.2.2.3.2 for sub-category 1A and in A.4.2.2.2.2 and A.4.2.2.3.3 for sub-category 1B.

² At this writing, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.

³ The mechanisms by which substances induce symptoms of asthma are not yet fully known. For preventive measures, these substances are considered respiratory sensitizers. However, if on the basis of the evidence, it can be demonstrated that these substances induce symptoms of asthma by

irritation only in people with bronchial hyperactivity, they should not be considered as respiratory sensitizers.

A.4.2.2.1.2 Where data are not sufficient for sub-categorization, skin sensitizers shall be classified in Category 1.

Table A.4.2: Hazard category and sub-categories for skin sensitizers

| Category 1: | Skin sensitizer |
|--------------------|--|
| | A substance is classified as a skin sensitizer (a) if there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons, or (b) if there are positive results from an appropriate animal test. |
| Sub-category 1A: | Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered. |
| Sub-category 1B: | Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitization in humans. Severity of reaction may also be considered. |

A.4.2.2.2 Human evidence

A.4.2.2.2.1 Human evidence for sub-category 1A may include:

- (a) Positive responses at $\leq 500 \mu\text{g}/\text{cm}^2$ (Human Repeat Insult Patch Test (HRIPT), Human Maximization Test (HMT) – induction threshold);
- (b) Diagnostic patch test data where there is a relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure;
- (c) Other epidemiological evidence where there is a relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.

A.4.2.2.2.2 Human evidence for sub-category 1B may include:

- (a) Positive responses at $> 500 \mu\text{g}/\text{cm}^2$ (HRIPT, HMT – induction threshold);
- (b) Diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;
- (c) Other epidemiological evidence where there is a relatively low but substantial

incidence of allergic contact dermatitis in relation to relatively high exposure.

A.4.2.2.3 Animal studies

A.4.2.2.3.1 For Category 1, when an adjuvant type test method for skin sensitization is used, a response of at least 30% of the animals is considered as positive. For a non-adjuvant Guinea pig test method a response of at least 15% of the animals is considered positive. For Category 1, a stimulation index of three or more is considered a positive response in the local lymph node assay.⁴

A.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in Table A.4.3 below:

Table A.4.3: Animal test results for sub-category 1A

| Assay | Criteria |
|------------------------------|--|
| Local lymph node assay | EC3 value \leq 2% |
| Guinea pig maximization test | \geq 30% responding at \leq 0.1% intradermal induction dose <u>or</u> \geq 60% responding at $>$ 0.1% to \leq 1% intradermal induction dose |
| Buehler assay | \geq 15% responding at \leq 0.2% topical induction dose <u>or</u> \geq 60% responding at $>$ 0.2% to \leq 20% topical induction dose |

Note: EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.

A.4.2.2.3.3 Animal test results for sub-category 1B can include data with values indicated in Table A.4.4 below:

Table A.4.4: Animal test results for sub-category 1B

| Assay | Criteria |
|------------------------------|--|
| Local lymph node assay | EC3 value $>$ 2% |
| Guinea pig maximization test | \geq 30% to $<$ 60% responding at $>$ 0.1% to \leq 1% intradermal induction dose or \geq 30% responding at $>$ 1% intradermal induction dose |
| Buehler assay | \geq 15% to $<$ 60% responding at $>$ 0.2% to \leq 20% topical induction dose or \geq 15% responding at $>$ 20% topical induction dose |

Note: EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.

A.4.2.2.4 Specific considerations

A.4.2.2.4.1 For classification of a substance, evidence shall include one or more of the following using a weight of evidence approach:

⁴ *Test methods for skin sensitization are described in OECD Guideline 406 (the Guinea Pig Maximization test and the Buehler guinea pig test) and Guideline 429 (Local Lymph Node Assay). Other methods may be used provided that they are scientifically validated. The Mouse Ear*

Swelling Test (MEST), appears to be a reliable screening test to detect moderate to strong sensitizers, and can be used, in accordance with professional judgment, as a first stage in the assessment of skin sensitization potential.

- (a) Positive data from patch testing, normally obtained in more than one dermatology clinic;
- (b) Epidemiological studies showing allergic contact dermatitis caused by the substance. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;
- (c) Positive data from appropriate animal studies;
- (d) Positive data from experimental studies in man (See paragraph A.0.2.6 of this Appendix);
- (e) Well documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic;
- (f) Severity of reaction.

A.4.2.2.4.2 Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on skin sensitization are usually derived from case-control or other, less defined studies. Evaluation of human data must, therefore, be carried out with caution as the frequency of cases reflect, in addition to the inherent properties of the substances, factors such as the exposure situation, bioavailability, individual predisposition and preventive measures taken. Negative human data should not normally be used to negate positive results from animal studies. For both animal and human data, consideration should be given to the impact of vehicle.

A.4.2.2.4.3 If none of the above-mentioned conditions are met, the substance need not be classified as a skin sensitizer. However, a combination of two or more indicators of skin sensitization, as listed below, may alter the decision. This shall be considered on a case-by-case basis.

- (a) Isolated episodes of allergic contact dermatitis;
- (b) Epidemiological studies of limited power, e.g., where chance, bias or confounders have not been ruled out fully with reasonable confidence;
- (c) Data from animal tests, performed according to existing guidelines, which do

not meet the criteria for a positive result described in A.4.2.2.3, but which are sufficiently close to the limit to be considered significant;

- (d) Positive data from non-standard methods;
- (e) Positive results from close structural analogues.

A.4.2.2.4.4 Immunological contact urticaria

A.4.2.2.4.4.1 Substances meeting the criteria for classification as respiratory sensitizers may, in addition, cause immunological contact urticaria. Consideration shall be given to classifying these substances as skin sensitizers.

A.4.2.2.4.4.2 Substances which cause immunological contact urticaria without meeting the criteria for respiratory sensitizers shall be considered for classification as skin sensitizers.

A.4.2.2.4.4.3 There is no recognized animal model available to identify substances which cause immunological contact urticaria. Therefore, classification will normally be based on human evidence, similar to that for skin sensitization.

A.4.3 Classification criteria for mixtures

A.4.3.1 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence, as described in the criteria for substances, from human experience or appropriate studies in experimental animals, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care must be exercised in evaluating data on mixtures that the dose used does not render the results inconclusive.

A.4.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.4.3.2.1 Where the mixture itself has not been tested to determine its sensitizing properties, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation, Substantially similar mixtures, and Aerosols.

A.4.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

The mixture shall be classified as a respiratory or skin sensitizer when at least one ingredient has been classified as a respiratory or skin sensitizer and is present at or above the appropriate cut-off value/concentration limit for the specific endpoint as shown in Table A.4.5.

Table A.4.5: Cut-off values/concentration limits of ingredients of a mixture classified as either respiratory sensitizers or skin sensitizers that would trigger classification of the mixture

| Ingredient classified as: | Cut-off values/concentration limits triggering classification of a mixture as: | | |
|--|--|--------|----------------------------|
| | Respiratory Sensitizer Category 1 | | Skin Sensitizer Category 1 |
| | Solid/Liquid | Gas | All physical states |
| Respiratory Sensitizer Category 1 | ≥ 0.1% | ≥ 0.1% | |
| Respiratory Sensitizer Sub-category 1A | ≥ 0.1% | ≥ 0.1% | |
| Respiratory Sensitizer Sub-category 1B | ≥ 1.0% | ≥ 0.2% | |
| Skin Sensitizer Category 1 | | | ≥ 0.1% |
| Skin Sensitizer Sub-category 1A | | | ≥ 0.1% |
| Skin Sensitizer Sub-category 1B | | | ≥ 1.0% |

A.5 GERM CELL MUTAGENICITY

A.5.1 Definitions and general considerations

A.5.1.1 A *mutation* is defined as a permanent change in the amount or structure of the genetic material in a cell. The term *mutation* applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known

(including, for example, specific base pair changes and chromosomal translocations). The term *mutagenic* and *mutagen* will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.

A.5.1.2 The more general terms *genotoxic* and *genotoxicity* apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.

A.5.1.3 This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. However, mutagenicity/genotoxicity tests *in vitro* and in mammalian somatic cells *in vivo* are also considered in classifying substances and mixtures within this hazard class.

A.5.2 Classification criteria for substances

A.5.2.1 The classification system provides for two different categories of germ cell mutagens to accommodate the weight of evidence available. The two-category system is described in the Figure A.5.1.

Figure A.5.1: Hazard categories for germ cell mutagens

| | |
|---------------------------|--|
| <u>CATEGORY 1:</u> | Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans |
| Category 1A: | Substances known to induce heritable mutations in germ cells of humans Positive evidence from human epidemiological studies. |
| Category 1B: | Substances which should be regarded as if they induce heritable mutations in the germ cells of humans <ul style="list-style-type: none"> (a) Positive result(s) from <i>in vivo</i> heritable germ cell mutagenicity tests in mammals; or (b) Positive result(s) from <i>in vivo</i> somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/genotoxicity tests in germ cells <i>in vivo</i>, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or (c) Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people. |
| <u>CATEGORY 2:</u> | Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans Positive evidence obtained from experiments in mammals and/or in some cases from <i>in vitro</i> experiments, obtained from: <ul style="list-style-type: none"> (a) Somatic cell mutagenicity tests <i>in vivo</i>, in mammals; or (b) Other <i>in vivo</i> somatic cell genotoxicity tests which are supported by positive results from <i>in vitro</i> mutagenicity assays. <p><i>Note: Substances which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.</i></p> |

A.5.2.2 Specific considerations for classification of substances as germ cell mutagens:

A.5.2.2.1 To arrive at a classification, test results are considered from experiments determining mutagenic and/or genotoxic effects in germ and/or somatic cells of exposed animals. Mutagenic and/or genotoxic effects determined in *in vitro* tests shall also be considered.

A.5.2.2.2 The system is hazard based, classifying chemicals on the basis of their intrinsic ability to induce mutations in germ cells. The scheme is, therefore, not meant for the (quantitative) risk assessment of chemical substances.

A.5.2.2.3 Classification for heritable effects in human germ cells is made on the basis of scientifically validated tests. Evaluation of the test results shall be done using expert judgment and all the available evidence shall be weighed for classification.

A.5.2.2.4 The classification of substances shall be based on the total weight of evidence available, using expert judgment. In those instances where a single well-conducted test is used for classification, it shall provide clear and unambiguously positive results. The relevance of the route of exposure used in the study of the substance compared to the route of human exposure should also be taken into account.

A.5.3 Classification criteria for mixtures⁵

A.5.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.5.3.1.1 Classification of mixtures shall be based on the available test data for the individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens.

A.5.3.1.2 The mixture will be classified as a mutagen when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 mutagen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.5.1 below for Category 1 and 2 respectively.

Table A.5.1: Cut-off values/concentration limits of ingredients of a mixture classified as germ cell mutagens that would trigger classification of the mixture

| Ingredient classified as: | Cut-off/concentration limits triggering classification of a mixture as: | |
|---------------------------|---|--------------------|
| | Category 1 mutagen | Category 2 mutagen |
| Category 1A/B mutagen | ≥ 0.1 % | - |
| Category 2 mutagen | - | ≥ 1.0 |

Note: The cut-off values/concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).

A.5.3.2 Classification of mixtures when data are available for the mixture itself

The classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of germ cell mutagenicity test systems.

A.5.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.5.3.3.1 Where the mixture itself has not been tested to determine its germ cell mutagenicity hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

⁵ *It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limits or additivity. However, this approach is not used for Germ Cell Mutagenicity. These criteria for Germ Cell Mutagenicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.*

A.5.4 Examples of scientifically validated test methods:

A.5.4.1 Examples of *in vivo* heritable germ cell mutagenicity tests are:

- (a) Rodent dominant lethal mutation test (OECD 478)
- (b) Mouse heritable translocation assay (OECD 485)
- (c) Mouse specific locus test

A.5.4.2 Examples of *in vivo* somatic cell mutagenicity tests are:

- (a) Mammalian bone marrow chromosome aberration test (OECD 475)
- (b) Mouse spot test (OECD 484)
- (c) Mammalian erythrocyte micronucleus test (OECD 474)

A.5.4.3 Examples of mutagenicity/genotoxicity tests in germ cells are:

- (a) Mutagenicity tests:
 - (i) Mammalian spermatogonial chromosome aberration test (OECD 483)
 - (ii) Spermatid micronucleus assay
- (b) Genotoxicity tests:
 - (i) Sister chromatid exchange analysis in spermatogonia

(ii) Unscheduled DNA synthesis test (UDS) in testicular cells

A.5.4.4 Examples of genotoxicity tests in somatic cells are:

(a) Liver Unscheduled DNA Synthesis (UDS) *in vivo* (OECD 486)

(b) Mammalian bone marrow Sister Chromatid Exchanges (SCE)

A.5.4.5 Examples of *in vitro* mutagenicity tests are:

(a) *In vitro* mammalian chromosome aberration test (OECD 473)

(b) *In vitro* mammalian cell gene mutation test (OECD 476)

(c) Bacterial reverse mutation tests (OECD 471)

A.5.4.6 As new, scientifically validated tests arise, these may also be used in the total weight of evidence to be considered.

A.6 CARCINOGENICITY

A.6.1 Definitions

Carcinogen means a substance or a mixture of substances which induce cancer or increase its incidence. Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

Classification of a substance or mixture as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.

A.6.2 Classification criteria for substances⁶

A.6.2.1 For the purpose of classification for carcinogenicity, substances are allocated to one of two categories based on strength of evidence and additional weight of evidence considerations. In certain instances, route-specific classification may be warranted.

⁶ See *Non-mandatory Appendix F Part A for further guidance regarding hazard classification for carcinogenicity. This appendix is consistent with the GHS and is provided as guidance excerpted from the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006).*

Figure A.6.1: Hazard categories for carcinogens

| | |
|------------------------------|--|
| <u>CATEGORY 1:</u> | Known or presumed human carcinogens The classification of a substance as a Category 1 carcinogen is done on the basis of epidemiological and/or animal data. This classification is further distinguished on the basis of whether the evidence for classification is largely from human data (Category 1A) or from animal data (Category 1B): |
| Category 1A: | Known to have carcinogenic potential for humans. Classification in this category is largely based on human evidence. |
| Category 1B: | Presumed to have carcinogenic potential for humans. Classification in this category is largely based on animal evidence. The classification of a substance in Category 1A and 1B is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be derived from: <ul style="list-style-type: none">- human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or- animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case by case basis, scientific judgment may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals. |
| <u>CATEGORY 2:</u> | Suspected human carcinogens The classification of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or B. This classification is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies. |
| Other considerations: | Where the weight of evidence for the carcinogenicity of a substance does not meet the above criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the safety data sheet |

A.6.2.2 Classification as a carcinogen is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for substances which have an intrinsic property to produce such toxic effects. The evaluations are to be based on all existing data, peer-reviewed published studies and additional data accepted by regulatory agencies.

A.6.2.3 *Carcinogen classification* is a one-step, criterion-based process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.

A.6.2.4 *Strength of evidence* involves the enumeration of tumors in human and animal studies and determination of their level of statistical significance. Sufficient human evidence demonstrates causality between human exposure and the development of cancer, whereas sufficient evidence in animals shows a causal relationship between the agent and an increased incidence of tumors. Limited evidence in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. Limited evidence in animals is provided when data suggest a carcinogenic effect, but are less than sufficient. (Guidance on consideration of important factors in the classification of carcinogenicity and a more detailed description of the terms “limited” and “sufficient” have been developed by the International Agency for Research on Cancer (IARC) and are provided in non-mandatory Appendix F.)

A.6.2.5 *Weight of evidence*: Beyond the determination of the strength of evidence for carcinogenicity, a number of other factors should be considered that influence the overall likelihood that an agent may pose a carcinogenic hazard in humans. The full list of factors that influence this determination is very lengthy, but some of the important ones are considered here.

A.6.2.5.1 These factors can be viewed as either increasing or decreasing the level of concern for human carcinogenicity. The relative emphasis accorded to each factor depends upon the amount and coherence of evidence bearing on each. Generally there is a requirement for more complete information to decrease than to increase the level of concern. Additional considerations should be used in evaluating the tumor findings and the other factors in a case-by-case manner.

A.6.2.5.2 Some important factors which may be taken into consideration, when assessing the overall level of concern are:

- (a) Tumor type and background incidence;
- (b) Multisite responses;
- (c) Progression of lesions to malignancy;
- (d) Reduced tumor latency;

Additional factors which may increase or decrease the level of concern include:

- (e) Whether responses are in single or both sexes;
- (f) Whether responses are in a single species or several species;
- (g) Structural similarity or not to a substance(s) for which there is good evidence of

carcinogenicity;

(h) Routes of exposure;

(i) Comparison of absorption, distribution, metabolism and excretion between test animals and humans;

(j) The possibility of a confounding effect of excessive toxicity at test doses; and,

(k) Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression.

Mutagenicity: It is recognized that genetic events are central in the overall process of cancer development. Therefore evidence of mutagenic activity *in vivo* may indicate that a substance has a potential for carcinogenic effects.

A.6.2.5.3 A substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1A, Category 1B, or Category 2 based on tumor data from a structural analogue together with substantial support from consideration of other important factors such as formation of common significant metabolites, e.g., for benzidine congener dyes.

A.6.2.5.4 The classification should also take into consideration whether or not the substance is absorbed by a given route(s); or whether there are only local tumors at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity.

A.6.2.5.5 It is important that whatever is known of the physico-chemical, toxicokinetic and toxicodynamic properties of the substances, as well as any available relevant information on chemical analogues, i.e., structure activity relationship, is taken into consideration when undertaking classification.

A.6.3 Classification criteria for mixtures⁷

A.6.3.1 The mixture shall be classified as a carcinogen when at least one ingredient has been classified as a Category 1 or Category 2 carcinogen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.6.1.

Table A.6.1: Cut-off values/concentration limits of ingredients of a mixture classified as carcinogen that would trigger classification of the mixture

| Ingredient classified as: | Category 1 carcinogen | Category 2 carcinogen |
|----------------------------------|------------------------------|------------------------------|
| Category 1 carcinogen | ≥ 0.1 % | |
| Category 2 carcinogen | | ≥ 0.1% (note 1) |

Note: If a Category 2 carcinogen ingredient is present in the mixture at a concentration

between 0.1% and 1%, information is required on the SDS for a product. However, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of $\geq 1\%$, both an SDS and a label is required and the information must be included on each.

A.6.3.2 Classification of mixtures when data are available for the complete mixture

A mixture may be classified based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of carcinogenicity test systems.

⁷ It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limit or additivity. However, this approach is not used for Carcinogenicity. These criteria for Carcinogenicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.

A.6.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; and Substantially similar mixtures.

A.6.4 Classification of carcinogenicity⁸

A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:

A.6.4.1.1 National Toxicology Program (NTP), “Report on Carcinogens” (latest edition);

A.6.4.1.2 International Agency for Research on Cancer (IARC) “Monographs on the Evaluation of Carcinogenic Risks to Humans” (latest editions)

A.6.4.2 Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

⁸ See *Non-mandatory Appendix F for further guidance regarding hazard classification for*

carcinogenicity and how to relate carcinogenicity classification information from IARC and NTP to GHS.

A.7 REPRODUCTIVE TOXICITY

A.7.1 Definitions and general considerations

A.7.1.1 Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as adverse effects on development of the offspring. Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, chemicals with these effects shall be classified as reproductive toxicants.

For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in Germ cell mutagenicity (See A.5).

A.7.1.2 Adverse effects on sexual function and fertility means any effect of chemicals that interferes with reproductive ability or sexual capacity. This includes, but is not limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, pregnancy outcomes, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

A.7.1.3 Adverse effects on development of the offspring means any effect of chemicals which interferes with normal development of the conceptus either before or after birth, which is induced during pregnancy or results from parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth and functional deficiency.

A.7.1.4 Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes, such effects are treated separately (See A.7.2.1).

A.7.2 Classification criteria for substances

A.7.2.1 For the purpose of classification for reproductive toxicity, substances shall be classified in one of two categories in accordance with Figure A.7.1(a). Effects on sexual function and fertility, and on development, shall be considered. In addition, effects on or via lactation shall be classified in a separate hazard category in accordance with Figure A.7.1(b).

Figure A.7.1(a): Hazard categories for reproductive toxicants

CATEGORY 1:

Known or presumed human reproductive toxicant

Substance shall be classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Category 1A:

Known human reproductive toxicant

The classification of a substance in this category is largely based on evidence from humans.

Category 1B:

Presumed human reproductive toxicant

The classification of a substance in this category is largely based on evidence from experimental animals. Data from animal studies shall provide sufficient evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.

CATEGORY 2:

Suspected human reproductive toxicant

Substances shall be classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this, Category 2 would be the more appropriate classification

Figure A.7.1(b): Hazard category for effects on or via lactation

EFFECTS ON OR VIA LACTATION

Effects on or via lactation shall be classified in a separate single category. Chemicals that are absorbed by women and have been shown to interfere with lactation or that may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, shall be classified to indicate this property hazardous to breastfed babies. This classification shall be assigned on the basis of:

- (a) absorption, metabolism, distribution and excretion studies that indicate the likelihood the substance would be present in potentially toxic levels in breast milk; and/or
- (b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk; and/or
- (c) human evidence indicating a hazard to babies during the lactation period.

A.7.2.2 Basis of classification

A.7.2.2.1 Classification is made on the basis of the criteria, outlined above, an assessment of the total weight of evidence, and the use of expert judgment. Classification as a reproductive toxicant is intended to be used for substances which have an intrinsic, specific property to produce an adverse effect on reproduction and substances should not be so classified if such an effect is produced solely as a non-specific secondary consequence of other toxic effects.

A.7.2.2.2 In the evaluation of toxic effects on the developing offspring, it is important to consider the possible influence of maternal toxicity.

A.7.2.2.3 For human evidence to provide the primary basis for a Category 1A classification there must be reliable evidence of an adverse effect on reproduction in humans. Evidence used for classification shall be from well conducted epidemiological studies, if available, which include the use of appropriate controls, balanced assessment, and due consideration of bias or confounding factors. Less rigorous data from studies in humans may be sufficient for a Category 1A classification if supplemented with adequate data from studies in experimental animals, but classification in Category 1B may also be considered.

A.7.2.3 Weight of evidence

A.7.2.3.1 Classification as a reproductive toxicant is made on the basis of an assessment of the total weight of evidence using expert judgment. This means that all available information that bears on the determination of reproductive toxicity is considered together. Included is information such as epidemiological studies and case reports in humans and specific reproduction studies along with sub-chronic, chronic and special study results in animals that provide relevant information regarding toxicity to reproductive and related endocrine organs. Evaluation of

substances chemically related to the material under study may also be included, particularly when information on the material is scarce. The weight given to the available evidence will be influenced by factors such as the quality of the studies, consistency of results, nature and severity of effects, level of statistical significance for intergroup differences, number of endpoints affected, relevance of route of administration to humans and freedom *from bias*. Both positive and negative results are considered together in a weight of evidence determination. However, a single, positive study performed according to good scientific principles and with statistically or biologically significant positive results may justify classification (See also A.7.2.2.3).

A.7.2.3.2 Toxicokinetic studies in animals and humans, site of action and mechanism or mode of action study results may provide relevant information, which could reduce or increase concerns about the hazard to human health. If it is conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a chemical which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.3.3 In some reproductive toxicity studies in experimental animals the only effects recorded may be considered of low or minimal toxicological significance and classification may not necessarily be the outcome. These effects include, for example, small changes in semen parameters or in the incidence of spontaneous defects in the fetus, small changes in the proportions of common fetal variants such as are observed in skeletal examinations, or in fetal weights, or small differences in postnatal developmental assessments.

A.7.2.3.4 Data from animal studies shall provide sufficient evidence of specific reproductive toxicity in the absence of other systemic toxic effects. However, if developmental toxicity occurs together with other toxic effects in the dam (mother), the potential influence of the generalized adverse effects should be assessed to the extent possible. The preferred approach is to consider adverse effects in the embryo/fetus first, and then evaluate maternal toxicity, along with any other factors which are likely to have influenced these effects, as part of the weight of evidence. In general, developmental effects that are observed at maternally toxic doses should not be automatically discounted. Discounting developmental effects that are observed at maternally toxic doses can only be done on a case-by-case basis when a causal relationship is established or refuted.

A.7.2.3.5 If appropriate information is available it is important to try to determine whether developmental toxicity is due to a specific maternally mediated mechanism or to a non-specific secondary mechanism, like maternal stress and the disruption of homeostasis. Generally, the presence of maternal toxicity should not be used to negate findings of embryo/fetal effects, unless it can be clearly demonstrated that the effects are secondary non-specific effects. This is especially the case when the effects in the offspring are significant, e.g., irreversible effects such as structural malformations. In some situations it is reasonable to assume that reproductive toxicity is due to a secondary consequence of maternal toxicity and discount the effects, for example if the chemical is so toxic that dams fail to thrive and there is severe inanition; they are incapable of nursing pups; or they are prostrate or dying.

A.7.2.4 Maternal toxicity

A.7.2.4.1 Development of the offspring throughout gestation and during the early postnatal stages can be influenced by toxic effects in the mother either through non-specific mechanisms related to stress and the disruption of maternal homeostasis, or by specific maternally-mediated mechanisms. So, in the interpretation of the developmental outcome to decide classification for developmental effects it is important to consider the possible influence of maternal toxicity. This is a complex issue because of uncertainties surrounding the relationship between maternal toxicity and developmental outcome. Expert judgment and a weight of evidence approach, using all available studies, shall be used to determine the degree of influence to be attributed to maternal toxicity when interpreting the criteria for classification for developmental effects. The adverse effects in the embryo/fetus shall be first considered, and then maternal toxicity, along with any other factors which are likely to have influenced these effects, as weight of evidence, to help reach a conclusion about classification.

A.7.2.4.2 Based on pragmatic observation, it is believed that maternal toxicity may, depending on severity, influence development via non-specific secondary mechanisms, producing effects such as depressed fetal weight, retarded ossification, and possibly resorptions and certain malformations in some strains of certain species. However, the limited numbers of studies which have investigated the relationship between developmental effects and general maternal toxicity have failed to demonstrate a consistent, reproducible relationship across species. Developmental effects which occur even in the presence of maternal toxicity are considered to be evidence of developmental toxicity, unless it can be unequivocally demonstrated on a case by case basis that the developmental effects are secondary to maternal toxicity. Moreover, classification shall be considered where there is a significant toxic effect in the offspring, e.g., irreversible effects such as structural malformations, embryo/fetal lethality, or significant post-natal functional deficiencies.

A.7.2.4.3 Classification shall not automatically be discounted for chemicals that produce developmental toxicity only in association with maternal toxicity, even if a specific maternally-mediated mechanism has been demonstrated. In such a case, classification in Category 2 may be considered more appropriate than Category 1. However, when a chemical is so toxic that maternal death or severe inanition results, or the dams (mothers) are prostrate and incapable of nursing the pups, it is reasonable to assume that developmental toxicity is produced solely as a secondary consequence of maternal toxicity and discount the developmental effects. Classification is not necessarily the outcome in the case of minor developmental changes, e.g., a small reduction in fetal/pup body weight or retardation of ossification when seen in association with maternal toxicity.

A.7.2.4.4 Some of the endpoints used to assess maternal toxicity are provided below. Data on these endpoints, if available, shall be evaluated in light of their statistical or biological significance and dose-response relationship.

- (a) Maternal mortality: An increased incidence of mortality among the treated dams over the controls shall be considered evidence of maternal toxicity if

the increase occurs in a dose-related manner and can be attributed to the systemic toxicity of the test material. Maternal mortality greater than 10% is considered excessive and the data for that dose level shall not normally be considered to need further evaluation.

- (b) Mating index (Number of animals with seminal plugs or sperm/Number of mated \times 100)
- (c) Fertility index (Number of animals with implants/Number of matings \times 100)
- (d) Gestation length (If allowed to deliver)
- (e) Body weight and body weight change: Consideration of the maternal body weight change and/or adjusted (corrected) maternal body weight shall be included in the evaluation of maternal toxicity whenever such data are available. The calculation of an adjusted (corrected) mean maternal body weight change, which is the difference between the initial and terminal body weight minus the gravid uterine weight (or alternatively, the sum of the weights of the fetuses), may indicate whether the effect is maternal or intrauterine. In rabbits, the body weight gain may not be a useful indicator of maternal toxicity because of normal fluctuations in body weight during pregnancy.
- (f) Food and water consumption (if relevant): The observation of a significant decrease in the average food or water consumption in treated dams (mothers) compared to the control group may be useful in evaluating maternal toxicity, particularly when the test material is administered in the diet or drinking water. Changes in food or water consumption must be evaluated in conjunction with maternal body weights when determining if the effects noted are reflective of maternal toxicity or more simply, unpalatability of the test material in feed or water.
- (g) Clinical evaluations (including clinical signs, markers, and hematology and clinical chemistry studies): The observation of increased incidence of significant clinical signs of toxicity in treated dams (mothers) relative to the control group is useful in evaluating maternal toxicity. If this is to be used as the basis for the assessment of maternal toxicity, the types, incidence, degree and duration of clinical signs shall be reported in the study. Clinical signs of maternal intoxication include, but are not limited to: coma, prostration, hyperactivity, loss of righting reflex, ataxia, or labored breathing.
- (h) Post-mortem data: Increased incidence and/or severity of post-mortem findings may be indicative of maternal toxicity. This can include gross or microscopic pathological findings or organ weight data, including absolute organ weight, organ-to-body weight ratio, or organ-to-brain weight ratio.

When supported by findings of adverse histopathological effects in the affected organ(s), the observation of a significant change in the average weight of suspected target organ(s) of treated dams (mothers), compared to those in the control group, may be considered evidence of maternal toxicity.

A.7.2.5 Animal and experimental data

A.7.2.5.1 A number of scientifically validated test methods are available, including methods for developmental toxicity testing (e.g., OECD Test Guideline 414, ICH Guideline S5A, 1993), methods for peri- and post-natal toxicity testing (e.g., ICH S5B, 1995), and methods for one or two-generation toxicity testing (e.g., OECD Test Guidelines 415, 416)

A.7.2.5.2 Results obtained from screening tests (e.g., OECD Guidelines 421 - Reproduction/Developmental Toxicity Screening Test, and 422 - Combined Repeated Dose Toxicity Study with Reproduction/Development Toxicity Screening Test) can also be used to justify classification, although the quality of this evidence is less reliable than that obtained through full studies.

A.7.2.5.3 Adverse effects or changes, seen in short- or long-term repeated dose toxicity studies, which are judged likely to impair reproductive function and which occur in the absence of significant generalized toxicity, may be used as a basis for classification, e.g., histopathological changes in the gonads.

A.7.2.5.4 Evidence from in vitro assays, or non-mammalian tests, and from analogous classification. In all cases of this nature, expert judgment must be used to assess the adequacy of the data. Inadequate data shall not be used as a primary support for classification.

A.7.2.5.5 It is preferable that animal studies are conducted using appropriate routes of administration which relate to the potential route of human exposure. However, in practice, reproductive toxicity studies are commonly conducted using the oral route, and such studies will normally be suitable for evaluating the hazardous properties of the substance with respect to reproductive toxicity. However, if it can be conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a substance which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.5.6 Studies involving routes of administration such as intravenous or intraperitoneal injection, which may result in exposure of the reproductive organs to unrealistically high levels of the test substance, or elicit local damage to the reproductive organs, e.g., by irritation, must be interpreted with extreme caution and on their own are not normally the basis for classification.

A.7.2.5.7 There is general agreement about the concept of a limit dose, above which the production of an adverse effect may be considered to be outside the criteria which lead to classification. Some test guidelines specify a limit dose, other test guidelines qualify the limit dose with a statement that higher doses may be necessary if anticipated human exposure is sufficiently

high that an adequate margin of exposure would not be achieved. Also, due to species differences in toxicokinetics, establishing a specific limit dose may not be adequate for situations where humans are more sensitive than the animal model.

A.7.2.5.8 In principle, adverse effects on reproduction seen only at very high dose levels in animal studies (for example doses that induce prostration, severe inappetence, excessive mortality) do not normally lead to classification, unless other information is available, for example, toxicokinetics information indicating that humans may be more susceptible than animals, to suggest that classification is appropriate.

A.7.2.5.9 However, specification of the actual “limit dose” will depend upon the test method that has been employed to provide the test results.

A.7.3 Classification criteria for mixtures⁹

A.7.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.7.3.1.1 The mixture shall be classified as a reproductive toxicant when at least one ingredient has been classified as a Category 1 or Category 2 reproductive toxicant and is present

A.7.3.1.2 The mixture shall be classified for effects on or via lactation when at least one ingredient has been classified for effects on or via lactation and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for the additional category for effects on or via lactation.

⁹ *It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limits or additivity. However, this approach is not used for Reproductive Toxicity. These criteria for Reproductive Toxicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.*

Table A.7.1: Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that trigger classification of the mixture

| Ingredients classified as: | Cut-off values/concentration limits triggering classification of a mixture as: | | |
|---|--|----------------------------------|---|
| | Category 1 reproductive toxicant | Category 2 reproductive toxicant | Additional category for effects on or via lactation |
| Category 1 reproductive toxicant | ≥ 0.1% | | |
| Category 2 reproductive toxicant | | ≥ 0.1 % | |
| Additional category for effects on or via lactation | | | ≥ 0.1 % |

A.7.3.2 Classification of mixtures when data are available for the complete mixture

Available test data for the mixture as a whole may be used for classification on a case-by-case basis. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of reproduction test systems.

A.7.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.7.3.3.1 Where the mixture itself has not been tested to determine its reproductive toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

A.8 SPECIFIC TARGET ORGAN TOXICITY SINGLE EXPOSURE

A.8.1 Definitions and general considerations

A.8.1.1 *Specific target organ toxicity - single exposure, (STOT-SE)* means specific, non-lethal target organ toxicity arising from a single exposure to a chemical. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following repeated exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE* (A.9 of this Appendix) and is therefore not included here.

A.8.1.2 Classification identifies the chemical as being a specific target organ toxicant and, as such, it presents a potential for adverse health effects in people who are exposed to it.

A.8.1.3 The adverse health effects produced by a single exposure include consistent and identifiable toxic effects in humans; or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism, and these changes are relevant for human health. Human data is the primary source of evidence for this hazard class.

A.8.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.8.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, i.e., principally oral, dermal or inhalation.

A.8.1.6 The classification criteria for specific organ systemic toxicity single exposure are organized as criteria for substances Categories 1 and 2 (See A.8.2.1), criteria for substances Category 3 (See A.8.2.2) and criteria for mixtures (See A.8.3). See also Figure A.8.1.

A.8.2 Classification criteria for substances

A.8.2.1 Substances of Category 1 and Category 2

A.8.2.1.1 Substances shall be classified for immediate or delayed effects separately, by the use of expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values (See A.8.2.1.9). Substances shall then be classified in Category 1 or 2, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.8.1.

Figure A.8.1: Hazard categories for specific target organ toxicity following single exposure

CATEGORY 1: Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following single exposure

Substances are classified in Category 1 for STOT-SE on the basis of:

- (a) reliable and good quality evidence from human cases or epidemiological studies; or
- (b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) to be used as part of weight-of-evidence evaluation.

CATEGORY 2: Substances that, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to be harmful to human health following single exposure

Substances are classified in Category 2 for STOT-SE on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) in order to help in classification.

In exceptional cases, human evidence can also be used to place a substance in Category 2 (See A.8.2.1.6).

CATEGORY 3: Transient target organ effects

There are target organ effects for which a substance does not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category only includes narcotic effects and respiratory tract irritation. Substances are classified specifically for these effects as discussed in A.8.2.2.

Note: The primary target organ/system shall be identified where possible, and where this is not possible, the substance shall be identified as a general toxicant. The data shall be evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).

A.8.2.1.2 The relevant route(s) of exposure by which the classified substance produces damage shall be identified.

A.8.2.1.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.8.2.1.4 Weight of evidence of all available data, including human incidents, epidemiology, and studies conducted in experimental animals is used to substantiate specific target organ toxic effects that merit classification.

A.8.2.1.5 The information required to evaluate specific target organ toxicity comes either from single exposure in humans (e.g., exposure at home, in the workplace or environmentally), or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are acute toxicity studies which can include clinical observations and detailed macroscopic and microscopic examination to enable the toxic effects on target 54 tissues/organs to be identified. Results of acute toxicity studies conducted in other species may also provide relevant information.

A.8.2.1.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the chemical shall be classified as Category 1.

A.8.2.1.7 Effects considered to support classification for Category 1 and 2

A.8.2.1.7.1 Classification is supported by evidence associating single exposure to the substance with a consistent and identifiable toxic effect.

A.8.2.1.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.8.2.1.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, and macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently all available evidence, and evidence relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

- (a) Morbidity resulting from single exposure;
- (b) Significant functional changes, more than transient in nature, in the respiratory system, central or peripheral nervous systems, other organs or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);
- (c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;
- (d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

- (e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;
- (f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction; and,55
- (g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.8.2.1.8 Effects considered not to support classification for Category 1 and 2

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

- (a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate “significant” toxicity;
- (b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;
- (c) Changes in organ weights with no evidence of organ dysfunction;
- (d) Adaptive responses that are not considered toxicologically relevant; and,
- (e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.8.2.1.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals for Category 1 and 2

A.8.2.1.9.1 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration “guidance values” are provided for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged.

A.8.2.1.9.2 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the dose/concentration).

A.8.2.1.9.3 The guidance value (C) ranges for single-dose exposure which has produced a significant non-lethal toxic effect are those applicable to acute toxicity testing, as indicated in Table A.8.1.

Table A.8.1: Guidance value ranges for single-dose exposures

| | | Guidance value ranges for: | | |
|---------------------------------|-------------------|----------------------------|------------------------|------------------------------|
| Route of exposure | Units | Category 1 | Category 2 | Category 3 |
| Oral (rat) | mg/kg body weight | $C \leq 300$ | $2000 \geq C > 300$ | Guidance values do not apply |
| Dermal (rat or rabbit) | mg/kg body weight | $C \leq 1000$ | $2000 \geq C > 1000$ | |
| Inhalation (rat) gas | ppmV/4h | $C \leq 2500$ | $20,000 \geq C > 2500$ | |
| Inhalation (rat) vapor | mg/l/4h | $C \leq 10$ | $20 \geq C > 10$ | |
| Inhalation (rat) dust/mist/fume | mg/l/4h | $C \leq 1.0$ | $5.0 \geq C > 1.0$ | |

A.8.2.1.9.4 The guidance values and ranges mentioned in Table A.8.1 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values. Guidance values are not provided for Category 3 since this classification is primarily based on human data; animal data may be included in the weight of evidence evaluation.

A.8.2.1.9.5 Thus, it is feasible that a specific profile of toxicity occurs at a dose/concentration below the guidance value, e.g., < 2000 mg/kg body weight by the oral route, however the nature of the effect may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥ 2000 mg/kg body weight by the oral route, and in addition there is supplementary information from other sources, e.g., other single dose studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is the prudent action to take.

A.8.2.1.10 Other considerations

A.8.2.1.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.8.2.1.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to single exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because specific target organ toxicity observed was considered not relevant or significant to humans, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.8.2.1.10.3 A substance that has not been tested for specific target organ toxicity shall, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important

factors such as formation of common significant metabolites.

A.8.2.2 Substances of Category 3

A.8.2.2.1 Criteria for respiratory tract irritation

The criteria for classifying substances as Category 3 for respiratory tract irritation are:

- (a) Respiratory irritant effects (characterized by localized redness, edema, pruritis and/or pain) that impair function with symptoms such as cough, pain, choking, and breathing difficulties are included. It is recognized that this evaluation is based primarily on human data;
- (b) Subjective human observations supported by objective measurements of clear respiratory tract irritation (RTI) (e.g., electrophysiological responses, biomarkers of inflammation in nasal or bronchoalveolar lavage fluids);
- (c) The symptoms observed in humans shall also be typical of those that would be produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensitive airways. Ambiguous reports simply of “irritation” should be excluded as this term is commonly used to describe a wide range of sensations including those such as smell, unpleasant taste, a tickling sensation, and dryness, which are outside the scope of classification for respiratory tract irritation;
- (d) There are currently no scientifically validated animal tests that deal specifically with RTI; however, useful information may be obtained from the single and repeated inhalation toxicity tests. For example, animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and histopathology (e.g., hyperemia, edema, minimal inflammation, thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above. Such animal studies can be used as part of weight of evidence evaluation; and,
- (e) This special classification will occur only when more severe organ effects including the respiratory system are not observed as those effects would require a higher classification.

A.8.2.2.2 Criteria for narcotic effects

The criteria for classifying substances in Category 3 for narcotic effects are:

- (a) Central nervous system depression including narcotic effects in humans such as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of

coordination, and vertigo are included. These effects can also be manifested as severe headache or nausea, and can lead to reduced judgment, dizziness, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness; and

- (b) (b) Narcotic effects observed in animal studies may include lethargy, lack of coordination righting reflex, narcosis, and ataxia. If these effects are not transient in nature, then they shall be considered for classification as Category 1 or 2.

A.8.3 Classification criteria for mixtures

A.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.8.3.2 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of this data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.8.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.8.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, or Aerosols.

A.8.3.4 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.8.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.8.2 for Categories 1 and 2, respectively.

Table A.8.2: Cut-off values/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2

| Ingredient classified as: | Cut-off values/concentration limits triggering classification of a mixture as: | |
|-------------------------------------|---|-------------------|
| | Category 1 | Category 2 |
| Category 1 Target organ toxicant | ≥ 1.0 % | |
| Category 2 Target organ toxicant | | ≥ 1.0 % |

A.8.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.8.3.4.3 Mixtures shall be classified for either or both single and repeated dose toxicity independently.

A.8.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause target organ toxicity at < 1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.8.3.4.5 Care shall be exercised when extrapolating the toxicity of a mixture that contains Category 3 ingredient(s). A cut-off value/concentration limit of 20%, considered as an additive of all Category 3 ingredients for each hazard endpoint, is appropriate; however, this cut-off value/concentration limit may be higher or lower depending on the Category 3 ingredient(s) involved and the fact that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20% value. Expert judgment shall be exercised. Respiratory tract irritation and narcotic effects are to be evaluated separately in accordance with the criteria given in A.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.

A.9 SPECIFIC TARGET ORGAN TOXICITY REPEATED OR PROLONGED EXPOSURE

A.9.1 Definitions and general considerations

A.9.1.1 *Specific target organ toxicity - repeated exposure (STOT-RE)* means specific target organ toxicity arising from repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following a single-event exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE* (A.8 of this Appendix) and is therefore not included here.

A.9.1.2 Classification identifies the substance or mixture as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

A.9.1.3 These adverse health effects produced by repeated exposure include consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism and these changes are relevant for human health. Human data will be the primary source of evidence for this hazard class.

A.9.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.9.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, e.g., principally oral, dermal or inhalation.

A.9.2 Classification criteria for substances

A.9.2.1 Substances shall be classified as STOT - RE by expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values which take into account the duration of exposure and the dose/concentration which produced the effect(s), (See A.9.2.9). Substances shall be placed in one of two categories, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.9.1.

Figure A.9.1: Hazard categories for specific target organ toxicity following repeated

exposure

CATEGORY 1: Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated or prolonged exposure

Substances are classified in Category 1 for specific target organ toxicity (repeated exposure) on the basis of:

- (a) reliable and good quality evidence from human cases or epidemiological studies; or,
- (b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) to be used as part of weight-of-evidence evaluation.

CATEGORY 2: Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following repeated or prolonged exposure

Substances are classified in Category 2 for specific target organ toxicity (repeated exposure) on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) in order to help in classification.

In exceptional cases human evidence can also be used to place a substance in Category 2 (See A.9.2.6).

Note: The primary target organ/system shall be identified where possible, or the substance shall be identified as a general toxicant. The data shall be carefully evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems)

A.9.2.2 The relevant route of exposure by which the classified substance produces damage shall be identified.

A.9.2.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.9.2.4 Weight of evidence of all data, including human incidents, epidemiology, and studies conducted in experimental animals, is used to substantiate specific target organ toxic effects that merit classification.

A.9.2.5 The information required to evaluate specific target organ toxicity comes either from repeated exposure in humans, e.g., exposure at home, in the workplace or environmentally, or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are 28 day, 90 day or lifetime studies (up to 2 years) that include

hematological, clinico-chemical and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Data from repeat dose studies performed in other species may also be used. Other long-term exposure studies, e.g., for carcinogenicity, neurotoxicity or reproductive toxicity, may also provide evidence of specific target organ toxicity that could be used in the assessment of classification.

A.9.2.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of specific target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the substance shall be classified as Category 1.

A.9.2.7 Effects considered to support classification

A.9.2.7.1 Classification is supported by reliable evidence associating repeated exposure to the substance with a consistent and identifiable toxic effect.

A.9.2.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.9.2.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, hematology, clinical chemistry, macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently all available evidence, and relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

- (a) Morbidity or death resulting from repeated or long-term exposure. Morbidity or death may result from repeated exposure, even to relatively low doses/concentrations, due to bioaccumulation of the substance or its metabolites, or due to the overwhelming of the de-toxification process by repeated exposure;
- (b) Significant functional changes in the central or peripheral nervous systems or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);
- (c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;
- (d) Significant organ damage that may be noted at necropsy and/or subsequently

seen or confirmed at microscopic examination;

- (e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;
- (f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (e.g., severe fatty change in the liver); and,
- (g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.9.2.8 Effects considered not to support classification

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

- (a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate “significant” toxicity;
- (b) Small changes in clinical biochemistry, hematology or urinalysis parameters and /or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;
- (c) Changes in organ weights with no evidence of organ dysfunction;
- (d) Adaptive responses that are not considered toxicologically relevant;
- (e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.9.2.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals

A.9.2.9.1 In studies conducted in experimental animals, reliance on observation of effects alone, without reference to the duration of experimental exposure and dose/concentration, omits a fundamental concept of toxicology, i.e., all substances are potentially toxic, and what determines the toxicity is a function of the dose/concentration and the duration of exposure. In most studies conducted in experimental animals the test guidelines use an upper limit dose value.

A.9.2.9.2 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration “guidance values” are provided in Table A.9.1 for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such

guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged. Also, repeated-dose studies conducted in experimental animals are designed to produce toxicity at the highest dose used in order to optimize the test objective and so most studies will reveal some toxic effect at least at this highest dose. What is therefore to be decided is not only what effects have been produced, but also at what dose/concentration they were produced and how relevant is that for humans.

A.9.2.9.3 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the duration of experimental exposure and the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the duration of exposure and the dose/concentration).

A.9.2.9.4 The decision to classify at all can be influenced by reference to the dose/concentration guidance values at or below which a significant toxic effect has been observed.

A.9.2.9.5 The guidance values refer to effects seen in a standard 90-day toxicity study conducted in rats. They can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Haber’s rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment should be done on a case-by-case basis; for example, for a 28-day study the guidance values below would be increased by a factor of three.

A.9.2.9.6 Thus for Category 1 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur at or below the (suggested) guidance values (C) as indicated in Table A.9.1 would justify **classification:**

**Table A.9.1: Guidance values to assist in Category 1 classification
(applicable to a 90-day study)**

| Route of exposure | Units | Guidance values (dose/concentration) |
|------------------------------------|-----------------------|---|
| Oral (rat) | mg/kg body weight/day | $C \leq 10$ |
| Dermal (rat or rabbit) | mg/kg body weight/day | $C \leq 20$ |
| Inhalation (rat) gas | ppmV/6h/day | $C \leq 50$ |
| Inhalation (rat) vapor | mg/liter/6h/day | $C \leq 0.2$ |
| Inhalation (rat) dust/mist/fume | mg/liter/6h/day | $C \leq 0.02$ |

A.9.2.9.7 For Category 2 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur within the (suggested) guidance value ranges as indicated in Table A.9.2 would justify classification:

Table A.9.2: Guidance values to assist in Category 2 classification

(applicable to a 90-day study)

| Route of exposure | Units | Guidance value range (dose/concentration) |
|--|------------------------------|--|
| Oral (rat) | mg/kg body weight/day | 10 < C ≤ 100 |
| Dermal (rat or rabbit) | mg/kg body weight/day | 20 < C ≤ 200 |
| Inhalation (rat) gas | ppmV/6h/day | 50 < C ≤ 250 |
| Inhalation (rat) vapor | mg/liter/6h/day | 0.2 < C ≤ 1.0 |
| Inhalation (rat) dust/mist/fume | mg/liter/6h/day | 0.02 < C ≤ 0.2 |

A.9.2.9.8 The guidance values and ranges mentioned in A.2.9.9.6 and A.2.9.9.7 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values.

A.9.2.9.9 Thus, it is possible that a specific profile of toxicity occurs in repeat-dose animal studies at a dose/concentration below the guidance value, e.g., < 100 mg/kg body weight/day by the oral route, however the nature of the effect, e.g., nephrotoxicity seen only in male rats of a particular strain known to be susceptible to this effect, may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥ 100 mg/kg body weight/day by the oral route, and in addition there is supplementary information from other sources, e.g., other long-term administration studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is prudent.

A.9.2.10 Other considerations

A.9.2.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.9.2.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to repeated or prolonged exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because no specific target organ toxicity was seen at or below the dose/concentration guidance value for animal testing, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.9.2.10.3 A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.9.3 Classification criteria for mixtures

A.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.9.3.2 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.9.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.9.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one toxicity category; Substantially similar mixtures; and Aerosols.

A.9.3.4 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.9.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.9.3 for Category 1 and 2 respectively.

Table A.9.3: Cut-off value/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2

| Ingredient classified as: | Cut-off values/concentration limits triggering classification of a mixture as: | |
|----------------------------------|---|-------------------|
| | Category 1 | Category 2 |
| Category 1 Target organ toxicant | ≥ 1.0 % | |
| Category 2 Target organ toxicant | | ≥ 1.0 % |

A.9.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.9.3.4.3 Mixtures shall be classified for either or both single- and repeated-dose toxicity independently.

A.9.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause specific target organ toxicity at < 1% concentration when other ingredients in the mixture are known to potentiate its toxic effect. 67

A.10 ASPIRATION HAZARD

A.10.1 Definitions and general and specific considerations

A.10.1.1 *Aspiration* means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

A.10.1.2 Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.

A.10.1.3 Aspiration is initiated at the moment of inspiration, in the time required to take one breath, as the causative material lodges at the crossroad of the upper respiratory and digestive tracts in the laryngopharyngeal region.

A.10.1.4 Aspiration of a substance or mixture can occur as it is vomited following ingestion. This may have consequences for labeling, particularly where, due to acute toxicity, a recommendation may be considered to induce vomiting after ingestion. However, if the substance/mixture also presents an aspiration toxicity hazard, the recommendation to induce vomiting may need to be modified.

A.10.1.5.1 The classification criteria refer to kinematic viscosity. The following provides the conversion between dynamic and kinematic viscosity:

$$\frac{\text{Dynamic viscosity (mPa-s)}}{\text{Density (g/m}^3\text{)}} = \text{Kinematic viscosity (mm}^2\text{/s)}$$

A.10.1.5.2 Although the definition of aspiration in A.10.1.1 includes the entry of solids into the respiratory system, classification according to (b) in table A.10.1 for Category 1 is intended to apply to liquid substances and mixtures only.

A.10.1.5.3 Classification of aerosol/mist products

Aerosol and mist products are usually dispensed in containers such as self-pressurized containers, trigger and pump sprayers. Classification for these products shall be considered if their use may form a pool of product in the mouth, which then may be aspirated. If the mist or aerosol from a pressurized container is fine, a pool may not be formed. On the other hand, if a pressurized container dispenses product in a stream, a pool may be formed that may then be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed that then may be aspirated. When the pump mechanism may be removed and contents are available to be swallowed then the classification of the products should be considered.⁶⁸

A.10.2 Classification criteria for substances

Table A.10.1: Criteria for aspiration toxicity

| Category | Criteria |
|----------|----------|
|----------|----------|

| | |
|--|---|
| Category 1: Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard | A substance shall be classified in Category 1: (a) If reliable and good quality human evidence indicates that it causes aspiration toxicity (See note); or (b) If it is a hydrocarbon and has a kinematic viscosity ≤ 20.5 mm ² /s, measured at 40° C |
|--|---|

Note: Examples of substances included in Category 1 are certain hydrocarbons, turpentine and pine oil.

A.10.3 Classification criteria for mixtures

A.10.3.1 Classification when data are available for the complete mixture

A mixture shall be classified in Category 1 based on reliable and good quality human evidence.

A.10.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.10.3.2.1 Where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazard of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one toxicity category; and Substantially similar mixtures. For application of the dilution bridging principle, the concentration of aspiration toxicants shall not be less than 10%.

A.10.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.10.3.3.1 A mixture which contains $\geq 10\%$ of an ingredient or ingredients classified in Category 1, and has a kinematic viscosity ≤ 20.5 mm²/s, measured at 40 °C, shall be classified in Category 1.

A.10.3.3.2 In the case of a mixture which separates into two or more distinct layers, one of which contains $\geq 10\%$ of an ingredient or ingredients classified in Category 1 and has a kinematic viscosity ≤ 20.5 mm²/s, measured at 40 °C, then the entire mixture shall be classified in Category 1.

Appendix B to 1910.1200 - Hazard Determination (Mandatory)

~~The quality of a hazard communication program is largely dependent upon the adequacy and accuracy of the hazard determination. The hazard determination requirement of this standard is performance oriented. Chemical manufacturers, importers, and employers evaluating chemicals are not required to follow any specific methods for determining hazards, but they must be able to demonstrate that they have adequately ascertained the hazards of the chemicals produced or~~

imported in accordance with the criteria set forth in this Appendix.

Hazard evaluation is a process which relies heavily on the professional judgment of the evaluator, particularly in the area of chronic hazards. The performance orientation of the hazard determination does not diminish the duty of the chemical manufacturer, importer or employer to conduct a thorough evaluation, examining all relevant data and producing a scientifically defensible evaluation. For purposes of this standard, the following criteria shall be used in making hazard determinations that meet the requirements of this standard.

1. Carcinogenicity: As described in paragraph (d)(4) of this section and Appendix A of this section, a determination by the National Toxicology Program, the International Agency for Research on Cancer, or OSHA that a chemical is a carcinogen or potential carcinogen will be considered conclusive evidence for purposes of this section. In addition, however, all available scientific data on carcinogenicity must be evaluated in accordance with the provisions of this Appendix and the requirements of the rule.

2. Human data: Where available, epidemiological studies and case reports of adverse health effects shall be considered in the evaluation.

3. Animal data: Human evidence of health effects in exposed populations is generally not available for the majority of chemicals produced or used in the workplace. Therefore, the available results of toxicological testing in animal populations shall be used to predict the health effects that may be experienced by exposed workers. In particular, the definitions of certain acute hazards refer to specific animal testing results (see Appendix A).

4. Adequacy and reporting of data. The results of any studies which are designed and conducted according to established scientific principles, and which report statistically significant conclusions regarding the health effects of a chemical, shall be a sufficient basis for a hazard determination and reported on any material safety data sheet. In vitro studies alone generally do not form the basis for a definitive finding of hazard under the HCS since they have a positive or negative result rather than a statistically significant finding.

The chemical manufacturer, importer, or employer may also report the results of other scientifically valid studies which tend to refute the findings of hazard.

B.1.1 Definitions and general considerations

B.1.1.1 An *explosive chemical* is a solid or liquid chemical which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic chemicals are included even when they do not evolve gases.

A *pyrotechnic chemical* is a chemical designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.

An *explosive item* is an item containing one or more explosive chemicals.

A *pyrotechnic item* is an item containing one or more pyrotechnic chemicals.

An *unstable explosive* is an explosive which is thermally unstable and/or too sensitive for normal handling, transport, or use.

An *intentional explosive* is a chemical or item which is manufactured with a view to produce a practical explosive or pyrotechnic effect.

B.1.1.2 The class of explosives comprises:

(a) Explosive chemicals;

(b) Explosive items, except devices containing explosive chemicals in such quantity or of such a character that their inadvertent or accidental ignition or initiation shall not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; and

(c) Chemicals and items not included under (a) and (b) above which are manufactured with the view to producing a practical explosive or pyrotechnic effect.

B.1.2 Classification criteria

Chemicals and items of this class shall be classified as unstable explosives or shall be assigned to one of the following six divisions depending on the type of hazard they present:

(a) Division 1.1 - Chemicals and items which have a mass explosion hazard (a mass explosion is one which affects almost the entire quantity present virtually instantaneously);

(b) Division 1.2 - Chemicals and items which have a projection hazard but not a mass explosion hazard;

(c) Division 1.3 - Chemicals and items which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:

(i) Combustion of which gives rise to considerable radiant heat; or

(ii) Which burn one after another, producing minor blast or projection effects or both;

(d) Division 1.4 - Chemicals and items which present no significant hazard: chemicals and items which present only a small hazard in the event of ignition or initiation. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire shall not cause virtually instantaneous explosion

of almost the entire contents of the package;

(e) Division 1.5 - Very insensitive chemicals which have a mass explosion hazard: chemicals which have a mass explosion hazard but are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions;

(f) Division 1.6 - Extremely insensitive items which do not have a mass explosion hazard: items which contain only extremely insensitive detonating chemicals and which demonstrate a negligible probability of accidental initiation or propagation.

B.1.3 Additional classification considerations

B.1.3.1 Explosives shall be classified as unstable explosives or shall be assigned to one of the six divisions identified in B.1.2 in accordance with the three step procedure in Part I of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6). The first step is to ascertain whether the substance or mixture has explosive effects (Test Series 1). The second step is the acceptance procedure (Test Series 2 to 4) and the third step is the assignment to a hazard division (Test Series 5 to 7). The assessment whether a candidate for "ammonium nitrate emulsion or suspension or gel, intermediate for blasting explosives (ANE)" is insensitive enough for inclusion as an oxidizing liquid (See B.13) or an oxidizing solid (See B.14) is determined by Test Series 8 tests.

NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.1.3.2 Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. The screening procedure in B.1.3.1 is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. If the screening procedure identifies the chemical as a potential explosive, the acceptance procedure (See section 10.3 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6)) is necessary for classification.

NOTE: Neither a Series 1 type (a) propagation of detonation test nor a Series 2 type (a) test of sensitivity to detonative shock is necessary if the exothermic decomposition energy of organic materials is less than 800 J/g.

B.1.3.3 If a mixture contains any known explosives, the acceptance procedure is necessary for classification.

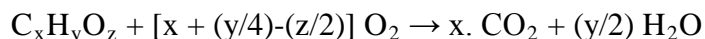
B.1.3.4 A chemical is not classified as explosive if:

(a) There are no chemical groups associated with explosive properties present in the molecule. Examples of groups which may indicate explosive properties are

given in Table A6.1 in Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6); or

(b) The substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200.

The oxygen balance is calculated for the chemical reaction:



using the formula: oxygen balance = $-1600 [2x + (y/2) - z]$ /molecular weight; or

(c) The organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500°C (932°F). The exothermic decomposition energy may be determined using a suitable calorimetric technique; or

d) For mixtures of inorganic oxidizing substances with organic material(s), the concentration of the inorganic oxidizing substance is:

(i) less than 15%, by mass, if the oxidizing substance is assigned to Category 1 or 2;

(ii) less than 30%, by mass, if the oxidizing substance is assigned to Category 3.

B.2 FLAMMABLE GASES

B.2.1 Definition

Flammable gas means a gas having a flammable range with air at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi).

B.2.2 Classification criteria

A flammable gas shall be classified in one of the two categories for this class in accordance with

Table B.2.1: Criteria for flammable gases

| Category | Criteria |
|----------|--|
| 1 | Gases, which at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi): (a) are ignitable when in a mixture of 13% or less by volume in air; or (b) have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit. |
| 2 | Gases, other than those of Category 1, which, at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi), have a flammable range while mixed in air. |

NOTE: Aerosols should not be classified as flammable gases. See B.3.

B.2.3 Additional classification considerations

Flammability shall be determined by tests or by calculation in accordance with ISO 10156 (incorporated by reference; See §1910.6). Where insufficient data are available to use this method, equivalent validated methods may be used.

B.3 FLAMMABLE AEROSOLS

B.3.1 Definition

Aerosol means any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as particles in suspension in a gas, or as a foam, paste, powder, liquid or gas.

B.3.2 Classification criteria

B.3.2.1 Aerosols shall be considered for classification as flammable if they contain any component which is classified as flammable in accordance with this Appendix, i.e.:

Flammable liquids (See B.6);

Flammable gases (See B.2);

Flammable solids (See B.7).

NOTE 1: Flammable components do not include pyrophoric, self-heating or water-reactive chemicals.

NOTE 2: Flammable aerosols do not fall additionally within the scope of flammable gases, flammable liquids, or flammable solids.

B.3.2.2 A flammable aerosol shall be classified in one of the two categories for this class in accordance with Table B.3.1.

Table B.3.1: Criteria for flammable aerosols

| Category | Criteria |
|----------|---|
| 1 | <p>Contains $\geq 85\%$ flammable components and the chemical heat of combustion is ≥ 30 kJ/g; or</p> <p>a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥ 75 cm (29.5 in), or</p> <p>b) For foam aerosols, in the aerosol foam flammability test (i) the flame height is ≥ 20 cm (7.87 in) and the flame duration ≥ 2 s; or (ii) the flame height is ≥ 4 cm (1.57 in) and the flame duration ≥ 7 s</p> |
| 2 | <p>Contains $> 1\%$ flammable components, or the heat of combustion is ≥ 20 kJ/g; and</p> <p>a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥ 15 cm (5.9 in), or</p> <p>in the enclosed space ignition test, the (i) time equivalent is ≥ 300 s/m³; or (ii) Deflagration density is ≥ 300 g/m³</p> <p>b) For foam aerosols, in the aerosol foam flammability test, the flame height is ≥ 4 cm and the flame duration is ≥ 2 s and it does not meet the criteria for Category 1</p> |

NOTE: Aerosols not submitted to the flammability classification procedures in this Appendix shall be classified as extremely flammable (Category 1).

B.3.3 Additional classification considerations

B.3.3.1 To classify a flammable aerosol, data on its flammable components, on its chemical heat of combustion and, if applicable, the results of the aerosol foam flammability test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols) are necessary.

B.3.3.2 The chemical heat of combustion (ΔH_c), in kilojoules per gram (kJ/g), is the product of the theoretical heat of combustion (ΔH_{comb}), and a combustion efficiency, usually less than 1.0 (a typical combustion efficiency is 0.95 or 95%).

For a composite aerosol formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:

$$\Delta H_c (\text{product}) = \sum [w_i\% \times \Delta H_c(i)]$$

where:

ΔH_c = chemical heat of combustion (kJ/g);

$w_i\%$ = mass fraction of component i in the product;

$\Delta H_c(i)$ = specific heat of combustion (kJ/g) of component i in the product;

The chemical heats of combustion shall be found in literature, calculated or determined by tests (See ASTM D240-02, ISO 13943, Sections 86.1 to 86.3, and NFPA 30B (incorporated by reference; See §1910.6)).

B.3.3.3 The Ignition Distance Test, Enclosed Space Ignition Test and Aerosol Foam Flammability Test shall be performed in accordance with sub-sections 31.4, 31.5 and 31.6 of the of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6).

B.4 OXIDIZING GASES

B.4.1 Definition

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

NOTE: "Gases which cause or contribute to the combustion of other material more than air does" means pure gases or gas mixtures with an oxidizing power greater than 23.5% (as determined by a method specified in ISO 10156 or 10156-2 (incorporated by reference, See §1910.6) or an equivalent testing method.)

B.4.2 Classification criteria

An oxidizing gas shall be classified in a single category for this class in accordance with Table B.4.1:

Table B.4.1: Criteria for oxidizing gases

| Category | Criteria |
|----------|---|
| 1 | Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does. |

B.4.3 Additional classification considerations

Classification shall be in accordance with tests or calculation methods as described in ISO 10156 (incorporated by reference; See §1910.6) and ISO 10156-2 (incorporated by reference; See §1910.6).

B.5 GASES UNDER PRESSURE

B.5.1 Definition

Gases under pressure are gases which are contained in a receptacle at a pressure of 200 kPa (29 psi) (gauge) or more, or which are liquefied or liquefied and refrigerated.

They comprise compressed gases, liquefied gases, dissolved gases and refrigerated liquefied gases.

B.5.2 Classification criteria

Gases under pressure shall be classified in one of four groups in accordance with Table B.5.1:

Table B.5.1: Criteria for gases under pressure

| Category | Criteria |
|----------------------------|--|
| Compressed gas | A gas which when under pressure is entirely gaseous at -50°C (-58°F), including all gases with a critical temperature ¹ ≤ 50°C (-58°F). |
| Liquefied gas | A gas which when under pressure is partially liquid at temperatures above -50°C (-58°F). A distinction is made between: (a) High pressure liquefied gas: a gas with a critical temperature ¹ between -50°C (-58°F) and +65°C (149°F); and (b) Low pressure liquefied gas: a gas with a critical temperature ¹ above +65°C (149°F). |
| Refrigerated liquefied gas | A gas which is made partially liquid because of its low temperature. |
| Dissolved gas | A gas which when under pressure is dissolved in a liquid phase solvent. |

(1) *The critical temperature is the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.*

B.6 FLAMMABLE LIQUIDS

B.6.1 Definition

Flammable liquid means a liquid having a flash point of not more than 93°C (199.4°F).

Flash point means the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid, as determined by a method identified in Section B.6.3.

B.6.2 Classification criteria

A flammable liquid shall be classified in one of four categories in accordance with Table B.6.1:

Table B.6.1: Criteria for flammable liquids

| Category | Criteria |
|----------|---|
| 1 | Flash point < 23°C (73.4°F) and initial boiling point ≤ 35°C (95°F) |
| 2 | Flash point < 23°C (73.4°F) and initial boiling point > 35°C (95°F) |
| 3 | Flash point ≥ 23°C (73.4°F) and ≤ 60°C (140°F) |
| 4 | Flash point > 60°C (140°F) and ≤ 93°C (199.4°F) |

B.6.3 Additional classification considerations

The flash point shall be determined in accordance with ASTM D56-05, ASTM D3278, ASTM D3828, ASTM D93-08 (incorporated by reference; See §1910.6), or any other method specified in GHS Revision 3, Chapter 2.6.

The initial boiling point shall be determined in accordance with ASTM D86-07a or ASTM D1078 (incorporated by reference; See §1910.6).

B.7 FLAMMABLE SOLIDS

B.7.1 Definitions

Flammable solid means a solid which is a readily combustible solid, or which may cause or contribute to fire through friction.

Readily combustible solids are powdered, granular, or pasty chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

B.7.2 Classification criteria

B.7.2.1 Powdered, granular or pasty chemicals shall be classified as flammable solids when the time of burning of one or more of the test runs, performed in accordance with the test method described in the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), Part III, sub-section 33.2.1, is less than 45 s or the rate of burning is more than 2.2 mm/s (0.0866 in/s).

B.7.2.2 Powders of metals or metal alloys shall be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample in 10 min or less.

B.7.2.3 Solids which may cause fire through friction shall be classified in this class by analogy with existing entries (e.g., matches) until definitive criteria are established.

B.7.2.4 A flammable solid shall be classified in one of the two categories for this class **using** Method N.1 as described in Part III, sub-section 33.2.1 of the UN ST/SG/AC.10 (incorporated by

reference; See §1910.6), in accordance with Table B.7.1:

Table B.7.1: Criteria for flammable solids

| Category | Criteria |
|-----------------|---|
| 1 | Burning rate test: Chemicals other than metal powders: (a) wetted zone does not stop fire; and (b) burning time < 45 s or burning rate > 2.2 mm/s Metal powders: burning time ≤ 5 min |
| 2 | Burning rate test: Chemicals other than metal powders: (a) wetted zone stops the fire for at least 4 min; and (b) burning time < 45 s or burning rate > 2.2 mm/s Metal powders: burning time > 5 min and ≤ 10 min |

NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.8 SELF-REACTIVE CHEMICALS

B.8.1 Definitions

Self-reactive chemicals are thermally unstable liquid or solid chemicals liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes chemicals classified under this section as explosives, organic peroxides, oxidizing liquids or oxidizing solids.

A self-reactive chemical is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.8.2 Classification criteria

B.8.2.1 A self-reactive chemical shall be considered for classification in this class unless:

- (a) It is classified as an explosive according to B.1 of this appendix;
- (b) It is classified as an oxidizing liquid or an oxidizing solid according to B.13 or B.14 of this appendix, except that a mixture of oxidizing substances which contains 5% or more of combustible organic substances shall be classified as a self-reactive chemical according to the procedure defined in B.8.2.2;
- (c) It is classified as an organic peroxide according to B.15 of this appendix;

(d) Its heat of decomposition is less than 300 J/g; or

(e) Its self-accelerating decomposition temperature (SADT) is greater than 75°C (167°F) for a 50 kg (110 lb) package.

B.8.2.2 Mixtures of oxidizing substances, meeting the criteria for classification as oxidizing liquids or oxidizing solids, which contain 5% or more of combustible organic substances and which do not meet the criteria mentioned in B.8.2.1 (a), (c), (d) or (e), shall be subjected to the self-reactive chemicals classification procedure in B.8.2.3. Such a mixture showing the properties of a self-reactive chemical type B to F shall be classified as a self-reactive chemical.

B.8.2.3 Self-reactive chemicals shall be classified in one of the seven categories of "types A to G" for this class, according to the following principles:

(a) Any self-reactive chemical which can detonate or deflagrate rapidly, as packaged, will be defined as self-reactive chemical TYPE A;

(b) Any self-reactive chemical possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package will be defined as self-reactive chemical TYPE B;

(c) Any self-reactive chemical possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as self-reactive chemical TYPE C;

(d) Any self-reactive chemical which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) will be defined as self-reactive chemical TYPE D:

(i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any self-reactive chemical which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement will be defined as self-reactive chemical TYPE E;

(f) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power will be defined as self-reactive chemical TYPE F;

(g) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C (140°F) to 75°C (167°F) for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point greater than or equal to 150°C (302°F) is used for desensitization will be defined as self-reactive chemical TYPE G. If the mixture is not thermally stable or a diluent having a boiling point less than 150°C (302°F) is used for desensitization, the mixture shall be defined as self-reactive chemical TYPE F.

B.8.3 Additional classification considerations

B.8.3.1 For purposes of classification, the properties of self-reactive chemicals shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6).

B.8.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10, Part II, section 28 (incorporated by reference; See §1910.6).

B.8.3.3 The classification procedures for self-reactive substances and mixtures need not be applied if:

- (a) There are no chemical groups present in the molecule associated with explosive or self-reactive properties; examples of such groups are given in Tables A6.1 and A6.2 in the Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6); or
- (c) For a single organic substance or a homogeneous mixture of organic substances, the estimated SADT is greater than 75°C (167°F) or the exothermic decomposition energy is less than 300 J/g.

The onset temperature and decomposition energy may be estimated using a suitable calorimetric technique (See 20.3.3.3 in Part II of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6)).

B.9 PYROPHORIC LIQUIDS

B.9.1 Definition

Pyrophoric liquid means a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.9.2 Classification criteria

A pyrophoric liquid shall be classified in a single category for this class using test N.3 in Part III, sub-section 33.3.1.5 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in

accordance with Table B.9.1:

Table B.9.1: Criteria for pyrophoric liquids

| Category | Criteria |
|----------|--|
| 1 | The liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min. |

B.9.3 Additional classification considerations

The classification procedure for pyrophoric liquids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the substance is known to be stable at room temperature for prolonged periods of time (days)).

B.10 PYROPHORIC SOLIDS

B.10.1 Definition

Pyrophoric solid means a solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.10.2 Classification criteria

A pyrophoric solid shall be classified in a single category for this class using test N.2 in Part III, sub-section 33.3.1.4 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.10.1:

Table B.10.1: Criteria for pyrophoric solids

| Category | Criteria |
|----------|---|
| 1 | The solid ignites within 5 min of coming into contact with air. |

NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.10.3 Additional classification considerations

The classification procedure for pyrophoric solids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the chemical is known to be stable at room temperature for prolonged periods of time (days)).

B.11 SELF-HEATING CHEMICALS

B.11.1 Definition

A *self-heating chemical* is a solid or liquid chemical, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this chemical differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

NOTE: Self-heating of a substance or mixture is a process where the gradual reaction of that substance or mixture with oxygen (in air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion.

B.11.2 Classification criteria

B.11.2.1 A self-heating chemical shall be classified in one of the two categories for this class if, in tests performed in accordance with test method N.4 in Part III, sub-section 33.3.1.6 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), the result meets the criteria shown in Table B.11.1.

Table B.11.1: Criteria for self-heating chemicals

| Category | Criteria |
|----------|--|
| 1 | A positive result is obtained in a test using a 25 mm sample cube at 140°C (284°F) |
| 2 | A negative result is obtained in a test using a 25 mm cube sample at 140°C (284°F), a positive result is obtained in a test using a 100 mm sample cube at 140°C (284°F), and: (a) The unit volume of the chemical is more than 3 m ³ ; or (b) A positive result is obtained in a test using a 100 mm cube sample at 120°C (248°F) and the unit volume of the chemical is more than 450 liters; or (c) A positive result is obtained in a test using a 100 mm cube sample at 100°C (212°F). |

B.11.2.2 Chemicals with a temperature of spontaneous combustion higher than 50°C (122°F) for a volume of 27 m³ shall not be classified as self-heating chemicals.

B.11.2.3 Chemicals with a spontaneous ignition temperature higher than 50°C (122°F) for a volume of 450 liters shall not be classified in Category 1 of this class.

B.11.3 Additional classification considerations

B.11.3.1 The classification procedure for self-heating chemicals need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied.

B.11.3.2 Examples of screening tests are:

(a) The Grewer Oven test (VDI guideline 2263, part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) with an onset temperature 80°K above the reference temperature for a volume of 1 l;

(b) The Bulk Powder Screening Test (Gibson, N. Harper, D. J. Rogers, R. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181-189, 1985) with an onset temperature 60°K above the reference temperature for a volume of 1 l.

B.12 CHEMICALS WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

B.12.1 Definition

Chemicals which, in contact with water, emit flammable gases are solid or liquid chemicals which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

B.12.2 Classification criteria

B.12.2.1 A chemical which, in contact with water, emits flammable gases shall be classified in one of the three categories for this class, using test N.5 in Part III, sub-section 33.4.1.4 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.12.1:

Table B.12.1: Criteria for chemicals which, in contact with water, emit flammable gases

| Category | Criteria |
|-----------------|---|
| 1 | Any chemical which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 liters per kilogram of chemical over any one minute. |
| 2 | Any chemical which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 liters per kilogram of chemical per hour, and which does not meet the criteria for Category 1. |
| 3 | Any chemical which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 1 liter per kilogram of chemical per hour, and which does not meet the criteria for Categories 1 and 2. |

NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.12.2.2 A chemical is classified as a chemical which, in contact with water, emits flammable gases if spontaneous ignition takes place in any step of the test procedure.

B.12.3 Additional classification considerations

The classification procedure for this class need not be applied if:

- (a) The chemical structure of the chemical does not contain metals or metalloids;
- (b) Experience in production or handling shows that the chemical does not react with water, (e.g., the chemical is manufactured with water or washed with water); or
- (c) The chemical is known to be soluble in water to form a stable mixture.

B.13 OXIDIZING LIQUIDS

B.13.1 Definition

Oxidizing liquid means a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.13.2 Classification criteria

An oxidizing liquid shall be classified in one of the three categories for this class using test O.2 in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.13.1:

Table B.13.1: Criteria for oxidizing liquids

| Category | Criteria |
|----------|--|
| 1 | Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of chemical and cellulose is less than that of a 1:1 mixture, by mass, of 50% perchloric acid and cellulose; |
| 2 | Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met; |
| 3 | Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65% aqueous nitric acid and cellulose; and the criteria for Categories 1 and 2 are not met. |

B.13.3 Additional classification considerations

B.13.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

- (a) The chemical does not contain oxygen, fluorine or chlorine; or
- (b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically

bonded only to carbon or hydrogen.

B.13.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.13.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgments based on known experience shall take precedence over test results.

B.13.3.4 In cases where chemicals generate a pressure rise (too high or too low), caused by chemical reactions not characterizing the oxidizing properties of the chemical, the test described in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6) shall be repeated with an inert substance (e.g., diatomite (kieselguhr)) in place of the cellulose in order to clarify the nature of the reaction.

B.14 OXIDIZING SOLIDS

B.14.1 Definition

Oxidizing solid means a solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.14.2 Classification criteria

An oxidizing solid shall be classified in one of the three categories for this class using test O.1 in Part III, sub-section 34.4.1 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.14.1:

Table B.14.1: Criteria for oxidizing solids

| Category | Criteria |
|----------|---|
| 1 | Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, by mass, of potassium bromate and cellulose. |
| 2 | Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 2:3 mixture (by mass) of potassium bromate and cellulose and the criteria for Category 1 are not met. |
| 3 | Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 mixture (by mass) of potassium bromate and cellulose and the criteria for Categories 1 and 2 are not met. |

NOTE 1: Some oxidizing solids may present explosion hazards under certain conditions (e.g., when stored in large quantities). For example, some types of ammonium nitrate may give rise to an explosion hazard under extreme conditions and the "Resistance to detonation test" (IMO: Code of Safe Practice for Solid Bulk Cargoes, 2005, Annex 3, Test 5) may be used to assess this hazard.

When information indicates that an oxidizing solid may present an explosion hazard, it shall be indicated on the Safety Data Sheet.

NOTE 2: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.14.3 Additional classification considerations

B.14.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

- (a) The chemical does not contain oxygen, fluorine or chlorine; or
- (b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.14.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.14.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgements based on known experience shall take precedence over test results.

B.15 ORGANIC PEROXIDES

B.15.1 Definition

B.15.1.1 *Organic peroxide* means a liquid or solid organic chemical which contains the bivalent -O-O- structure and as such is considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures containing at least one organic peroxide. Organic peroxides are thermally unstable chemicals, which may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:

- (a) Be liable to explosive decomposition;
- (b) Burn rapidly;
- (c) Be sensitive to impact or friction;
- (d) React dangerously with other substances.

B.15.1.2 An organic peroxide is regarded as possessing explosive properties when in laboratory

testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.15.2 Classification criteria

B.15.2.1 Any organic peroxide shall be considered for classification in this class, unless it contains:

(a) Not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or

(b) Not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.

NOTE: The available oxygen content (%) of an organic peroxide mixture is given by the

formula:

where:

n_i = number of peroxygen groups per molecule of organic peroxide i ;

c_i = concentration (mass %) of organic peroxide i ;

m_i = molecular mass of organic peroxide i .

B.15.2.2 Organic peroxides shall be classified in one of the seven categories of "Types A to G" for this class, according to the following principles:

(a) Any organic peroxide which, as packaged, can detonate or deflagrate rapidly shall be defined as organic peroxide TYPE A;

(b) Any organic peroxide possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package shall be defined as organic peroxide TYPE B;

(c) Any organic peroxide possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion shall be defined as organic peroxide TYPE C;

(d) Any organic peroxide which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) shall be defined as organic peroxide TYPE D:

(i) detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) does not detonate at all, deflagrates slowly and shows no violent effect when heated

under confinement; or

(iii) does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any organic peroxide which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement shall be defined as organic peroxide TYPE E;

(f) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power shall be defined as organic peroxide TYPE F;

(g) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C (140°F) or higher for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point of not less than 150°C (302°F) is used for desensitization, shall be defined as organic peroxide TYPE G. If the organic peroxide is not thermally stable or a diluent having a boiling point less than 150°C (302°F) is used for desensitization, it shall be defined as organic peroxide TYPE F.

B.15.3 Additional classification considerations

B.15.3.1 For purposes of classification, the properties of organic peroxides shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6).

B.15.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), Part II, section 28.

B.15.3.3 Mixtures of organic peroxides may be classified as the same type of organic peroxide as that of the most dangerous ingredient. However, as two stable ingredients can form a thermally less stable mixture, the SADT of the mixture shall be determined.

B.16 CORROSIVE TO METALS

B.16.1 Definition

A chemical which is corrosive to metals means a chemical which by chemical action will materially damage, or even destroy, metals.

B.16.2 Classification criteria

A chemical which is corrosive to metals shall be classified in a single category for this class,

using the test in Part III, sub-section 37.4 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.16.1:

Table B.16.1: Criteria for chemicals corrosive to metal

| Category | Criteria |
|----------|--|
| 1 | Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm per year at a test temperature of 55°C (131°F) when tested on both materials. |

NOTE: Where an initial test on either steel or aluminium indicates the chemical being tested is corrosive the follow-up test on the other metal is not necessary.

B.16.3 Additional classification considerations

The specimen to be used for the test shall be made of the following materials:

- (a) For the purposes of testing steel, steel types S235JR+CR (1.0037 resp.St 37-2), S275J2G3+CR (1.0144 resp.St 44-3), ISO 3574, Unified Numbering System (UNS) G 10200, or SAE 1020;
- (b) For the purposes of testing aluminium: non-clad types 7075-T6 or AZ5GU-T6.

Appendix C to 1910.1200 - ~~Information Sources (Advisory) is removed.~~

ALLOCATION OF LABEL ELEMENTS (MANDATORY)

C.1 The label for each hazardous chemical shall include the product identifier used on the safety data sheet.

C.1.1 The labels on shipped containers shall also include the name, address, and telephone number of the chemical manufacturer, importer, or responsible party.

C.2 The label for each hazardous chemical that is classified shall include the signal word, hazard statement(s), pictogram(s), and precautionary statement(s) specified in C.4 for each hazard class and associated hazard category, except as provided for in C.2.1 through C.2.4.

C.2.1 Precedence of hazard information

C.2.1.1 If the signal word "Danger" is included, the signal word "Warning" shall not appear;

C.2.1.2 If the skull and crossbones pictogram is included, the exclamation mark pictogram shall not appear where it is used for acute toxicity;

C.2.1.3 If the corrosive pictogram is included, the exclamation mark pictogram shall not appear

where it is used for skin or eye irritation;

C.2.1.4 If the health hazard pictogram is included for respiratory sensitization, the exclamation mark pictogram shall not appear where it is used for skin sensitization or for skin or eye irritation.

C.2.2 Hazard statement text

C.2.2.1 The text of all applicable hazard statements shall appear on the label, except as otherwise specified. The information in italics shall be included as part of the hazard statement as provided. For example: "causes damage to organs (*state all organs affected*) through prolonged or repeated exposure (*state route of exposure if no other routes of exposure cause the hazard*)". Hazard statements may be combined where appropriate to reduce the information on the label and improve readability, as long as all of the hazards are conveyed as required.

C.2.2.2 If the chemical manufacturer, importer, or responsible party can demonstrate that all or part of the hazard statement is inappropriate to a specific substance or mixture, the corresponding statement may be omitted from the label.

C.2.3 Pictograms

C.2.3.1 Pictograms shall be in the shape of a square set at a point and shall include a black hazard symbol on a white background with a red frame sufficiently wide to be clearly visible. A square red frame set at a point without a hazard symbol is not a pictogram and is not permitted on the label.

C.2.3.2 One of eight standard hazard symbols shall be used in each pictogram. The eight hazard symbols are depicted in Figure C.1. A pictogram using the exclamation mark symbol is presented in Figure C.2, for the purpose of illustration.

Figure C.1 – Hazard Symbols and Classes









| Flame | Flame Over Circle | Exclamation Mark | Exploding Bomb |
|---|---|--|--|
|  Flammables Self Reactives Pyrophorics Self-heating Emits Flammable Gas Organic Peroxides |  Oxidizers |  Irritant Dermal Sensitizer Acute Toxicity (harmful) Narcotic Effects Respiratory Tract Irritation |  Explosives Self Reactives Organic Peroxides |
| Corrosion | Gas Cylinder | Health Hazard | Skull and Crossbones |
|  Corrosives |  Gases Under Pressure |  Carcinogen Respiratory Sensitizer Reproductive Toxicity Target Organ Toxicity Mutagenicity Aspiration Toxicity |  Acute Toxicity (severe) |

Figure C.2 – Exclamation Mark Pictogram



C.2.3.3 Where a pictogram required by the Department of Transportation under Title 49 of the Code of Federal Regulations appears on a shipped container, the pictogram specified in C.4 for the same hazard shall not appear.

C.2.4 Precautionary statement text

C.2.4.1 There are four types of precautionary statements presented, "prevention," "response," "storage," and "disposal." The core part of the precautionary statement is presented in bold print. This is the text, except as otherwise specified, that shall appear on the label. Where additional

information is required, it is indicated in plain text.

C.2.4.2 When a backslash or diagonal mark (/) appears in the precautionary statement text, it indicates that a choice has to be made between the separated phrases. In such cases, the chemical manufacturer, importer, or responsible party can choose the most appropriate phrase(s). For example, "Wear protective gloves/protective clothing/eye protection/face protection" could read "wear eye protection".

C.2.4.3 When three full stops (...) appear in the precautionary statement text, they indicate that all applicable conditions are not listed. For example, in "Use explosion-proof electrical/ventilating/lighting/.../equipment", the use of "..." indicates that other equipment may need to be specified. In such cases, the chemical manufacturer, importer, or responsible party can choose the other conditions to be specified.

C.2.4.4 When text in *italics* is used in a precautionary statement, this indicates specific conditions applying to the use or allocation of the precautionary statement. For example, "Use explosion-proof electrical/ventilating/lighting/.../equipment" is only required for flammable solids "*if dust clouds can occur*". Text in italics is intended to be an explanatory, conditional note and is not intended to appear on the label.

C.2.4.5 Where square brackets ([]) appear around text in a precautionary statement, this indicates that the text in square brackets is not appropriate in every case and should be used only in certain circumstances. In these cases, conditions for use explaining when the text should be used are provided. For example, one precautionary statement states: "[In case of inadequate ventilation] wear respiratory protection." This statement is given with the condition for use "– text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use". This means that, if additional information is provided with the chemical explaining what type of ventilation would be adequate for safe use, the text in square brackets should be used and the statement would read: "In case of inadequate ventilation wear respiratory protection." However, if the chemical is supplied without such ventilation information, the text in square brackets should not be used, and the precautionary statement should read: "Wear respiratory protection."

C.2.4.6 Precautionary statements may be combined or consolidated to save label space and improve readability. For example, "Keep away from heat, sparks and open flame," "Store in a well-ventilated place" and "Keep cool" can be combined to read "Keep away from heat, sparks and open flame and store in a cool, well-ventilated place."

C.2.4.7 In most cases, the precautionary statements are independent (e.g., the phrases for explosive hazards do not modify those related to certain health hazards, and products that are classified for both hazard classes shall bear appropriate precautionary statements for both). Where a chemical is classified for a number of hazards, and the precautionary statements are similar, the most stringent shall be included on the label (this will be applicable mainly to preventive measures). An order of precedence may be imposed by the chemical manufacturer, importer or responsible party in situations where phrases concern "Response." Rapid action may be crucial. For example, if a chemical is carcinogenic and acutely toxic, rapid action may be

crucial, and first aid measures for acute toxicity will take precedence over those for long-term effects. In addition, medical attention to delayed health effects may be required in cases of incidental exposure, even if not associated with immediate symptoms of intoxication.

C.2.4.8 If the chemical manufacturer, importer, or responsible party can demonstrate that a precautionary statement is inappropriate to a specific substance or mixture, the precautionary statement may be omitted from the label.

C.3 Supplementary hazard information


C.3.1 To ensure that non-standardized information does not lead to unnecessarily wide variation or undermine the required information, supplementary information on the label is limited to when it provides further detail and does not contradict or cast doubt on the validity of the standardized hazard information.

C.3.2 Where the chemical manufacturer, importer, or distributor chooses to add supplementary information on the label, the placement of supplemental information shall not impede identification of information required by this section.

C.3.3 Where an ingredient with unknown acute toxicity is used in a mixture at a concentration \geq 1%, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label.


C.4 REQUIREMENTS FOR SIGNAL WORDS, HAZARD STATEMENTS, PICTOGRAMS, AND PRECAUTIONARY STATEMENTS

C.4.1 ACUTE TOXICITY – ORAL (Classified in Accordance with Appendix A.1)

| | | | Pictogram Skull and crossbones |
|--------------------------|--------------------|-------------------------|---|
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Fatal if swallowed | |
| 2 | Danger | Fatal if swallowed | |
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |

| | | | |
|---|---|--------------------------------|---|
| <p>Wash ...thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Do not eat, drink or smoke when using this product.</p> | <p>If swallowed: Immediately call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- if immediate administration of antidote is required.</i> Rinse mouth.</p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|---|--------------------------------|---|


C.4.1 ACUTE TOXICITY – ORAL (CONTINUED)
(Classified in Accordance with Appendix A.1)

| | | | |
|------------------------|--------------------|-------------------------|--|
| | | | <p>Pictogram Skull and crossbones</p> |
| Hazard category | Signal word | Hazard statement |  |
| 3 | Danger | Toxic if swallowed | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|--|---|--------------------------------|---|
| <p>Wash ... thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Do not eat, drink or smoke when using this product.</p> | <p>If swallowed: Immediately call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- if immediate administration of antidote is required.</i> Rinse mouth.</p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |


C.4.1 ACUTE TOXICITY – ORAL (CONTINUED)
(Classified in Accordance with Appendix A.1)

| | | | |
|------------------------|--------------------|-------------------------|--|
| | | | Pictogram Exclamation mark |
| Hazard category | Signal word | Hazard statement |  |
| 4 | Warning | Harmful if swallowed | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|---|--|----------------|---|
| Wash ... thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Do not eat, drink or smoke when using this product. | If swallowed: Call a poison center/doctor/.../ if you feel unwell. ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Rinse mouth. | | Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified). |

C.4.2 ACUTE TOXICITY - DERMAL
(Classified in Accordance with Appendix A.1)


| | | | |
|------------------------|--------------------|----------------------------|---|
| | | | Pictogram Skull and crossbones |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Fatal in contact with skin | |
| 2 | Danger | Fatal in contact with skin | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|-------------------|-----------------|----------------|-----------------|
|-------------------|-----------------|----------------|-----------------|

| | | | |
|--|--|--------------------------------|--|
| <p>Do not get in eyes, on skin, or on clothing. Wash ... thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing. Chemical manufacturer, importer, or distributor to specify type of equipment. If on skin:</p> | <p>Wash with plenty of water/... ... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. Immediately call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- if immediate measures such as specific cleansing agent is advised.</i></p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
| <p>Take off immediately all contaminated clothing and wash it before reuse.</p> | | | |


C.4.2 ACUTE TOXICITY - DERMAL (CONTINUED)
(Classified in Accordance with Appendix A.1)

| | | | |
|-------------------------------|---------------------------|-----------------------------------|---|
| | | | <p>Pictogram Skull and crossbones</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |
| <p>3</p> | <p>Danger</p> | <p>Toxic in contact with skin</p> | |

| | | | |
|---------------------------------|------------------------|-----------------------|------------------------|
| <p>Precautionary statements</p> | | | |
| <p>Prevention</p> | <p>Response</p> | <p>Storage</p> | <p>Disposal</p> |


| | | | |
|---|--|--------------------------------|---|
| <p>Wear protective gloves/protective clothing. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If on skin: Wash with plenty of water/... ... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. Call a poison center/doctor/.../if you feel unwell. ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- if measures such as specific cleansing agent is advised.</i> Take off immediately all contaminated clothing and wash it before reuse.</p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|--|--------------------------------|---|

C.4.2 ACUTE TOXICITY – DERMAL (CONTINUED)
(Classified in Accordance with Appendix A.1)

| | | | |
|---------------------------------|---------------------------|-------------------------------------|---|
| | | | <p>Pictogram Exclamation mark</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |
| <p>4</p> | <p>Warning</p> | <p>Harmful in contact with skin</p> | |
| <p>Precautionary statements</p> | | | |
| <p>Prevention</p> | <p>Response</p> | <p>Storage</p> | <p>Disposal</p> |

| | | |
|--|--|---|
| <p>Wear protective gloves/protective clothing Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If on skin: Wash with plenty of water/... ... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. Call a poison center/doctor/.../if you feel unwell. ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- if measures such as specific cleansing agent is advised.</i> Take off contaminated clothing and wash it before reuse.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|--|---|

C.4.3 ACUTE TOXICITY - INHALATION
(Classified in Accordance with Appendix A.1)


| | | | |
|-------------------------------|---------------------------|--------------------------------|---|
| | | | <p>Pictogram Skull and crossbones</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |
| <p>1</p> | <p>Danger</p> | <p>Fatal if inhaled</p> | |
| <p>2</p> | <p>Danger</p> | <p>Fatal if inhaled</p> | |

Precautionary statements

| | | | |
|--------------------------|------------------------|-----------------------|------------------------|
| <p>Prevention</p> | <p>Response</p> | <p>Storage</p> | <p>Disposal</p> |
|--------------------------|------------------------|-----------------------|------------------------|

| | | | |
|--|--|---|---|
| <p>Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. Use only outdoors or in a well-ventilated area. [In case of inadequate ventilation] wear respiratory protection. Chemical manufacturer, importer, or distributor to specify equipment. <i>- Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.</i></p> | <p>If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Specific treatment is urgent (see ... on this label) ... Reference to supplemental first aid instruction. <i>- if immediate administration of antidote is required.</i></p> | <p>Store in a well-ventilated place. Keep container tightly closed. <i>- if product is volatile as to generate hazardous atmosphere.</i> Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|--|---|---|

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)
(Classified in Accordance with Appendix A.1)


| | | | |
|-------------------------------|---------------------------|--------------------------------|---|
| | | | <p>Pictogram Skull and crossbones</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |
| <p>3</p> | <p>Danger</p> | <p>Toxic if inhaled</p> | |

Precautionary statements

| | | | |
|------------------------|------------------------|-----------------------|--|
| <p>Disposal</p> | <p>Response</p> | <p>Storage</p> | |
|------------------------|------------------------|-----------------------|--|

| | | | |
|---|--|--|--|
| <p>Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. Use only outdoors or in a well-ventilated area.</p> | <p>If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- if immediate specific measures are required.</i></p> | <p>Store in a well-ventilated place. Keep container tightly closed. <i>- if product is volatile so as to generate hazardous atmosphere.</i> Store locked up.</p> | <p>Dispose of content/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|--|--|--|


C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)
(Classified in Accordance with Appendix A.1)

| | | | |
|-------------------------------|---------------------------|--------------------------------|--|
| | | | <p>Pictogram Exclamation mark</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |
| <p>4</p> | <p>Warning</p> | <p>Harmful if inhaled</p> | |


Precautionary statements

| Prevention | Response | Storage | Disposal |
|---|---|---------|----------|
| <p>Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. Use only outdoors or in a well-ventilated area.</p> | <p>If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor/.../if you feel unwell. ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.</p> | | |

C.4.4 SKIN CORROSION/IRRITATION
(Classified in Accordance with Appendix A.2)


| | | | |
|--------------------------|--------------------|---|---|
| | | | Pictogram Corrosion |
| Hazard category | Signal word | Hazard statement |  |
| 1A to 1C | Danger | Causes severe skin burns and eye damage | |
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |

| | | | |
|--|---|--------------------------------|--|
| <p>Do not breathe dusts or mists. <i>- if inhalable particles of dusts or mists may occur during use.</i></p> <p>Wash ...thoroughly after handling. ...Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.</p> <p>Wear protective gloves/protective clothing/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If swallowed: Rinse mouth. Do NOT induce vomiting.</p> <p>If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse.</p> <p>If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.</p> <p>Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.</i></p> <p>If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|---|--------------------------------|--|

| | | | |
|--|---------------------------|--------------------------------|---|
| <p>C.4.4 SKIN CORROSION/IRRITATION (CONTINUED)</p> | | | |
| <p>(Classified in Accordance with Appendix A.2)</p> | | | |
| | | | <p>Pictogram Exclamation mark</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |
| <p>2</p> | <p>Warning</p> | <p>Causes skin irritation</p> | |
| <p>Precautionary statements</p> | | | |

| Prevention | Response | Storage | Disposal |
|---|--|---------|----------|
| <p>Wash ... thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.</p> <p>Wear protective gloves. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If on skin: Wash with plenty of water/... ... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.</p> <p>Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.</i></p> <p>If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.</p> | | |

C.4.5 EYE DAMAGE/IRRITATION
(Classified in Accordance with Appendix A.3)


| | | | Pictogram Corrosion |
|-----------------|-------------|---------------------------|---|
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Causes serious eye damage | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|------------|----------|---------|----------|
| | | | |

| | | | |
|--|---|--|--|
| <p>Wear eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.</p> | | |
|--|---|--|--|

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.3)

| | | | |
|------------------------|--------------------|-------------------------------|---|
| | | | <p>Pictogram Exclamation mark</p> |
| Hazard category | Signal word | Hazard statement |  |
| 2A | Warning | Causes serious eye irritation | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|---|--|----------------|-----------------|
| <p>Wash ... thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Wear eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.</p> | | |

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.3)


| | | | |
|--|--|--|---|
| | | | <p>Pictogram <i>No Pictogram</i></p> |
|--|--|--|---|

| Hazard category | Signal word | Hazard statement | |
|-----------------|-------------|-----------------------|--|
| 2B | Warning | Causes eye irritation | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|---|---|---------|----------|
| Wash ... thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. | If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. | | |

C.4.6 SENSITIZATION - RESPIRATORY
 (Classified in Accordance with Appendix A.4)


| | | | Pictogram Health hazard |
|---|--------------------|---|--|
| Hazard category | Signal word | Hazard statement |  |
| 1 (including both sub-categories 1A and 1B) | Danger | May cause allergy or asthma symptoms or breathing difficulties if inhaled | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|------------|----------|---------|----------|
| | | | |

| | | | |
|---|---|--|--|
| <p>Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. [In case of inadequate ventilation] wear respiratory protection. Chemical manufacturer, importer, or distributor to specify equipment <i>- Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.</i></p> | <p>If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.</p> | | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|---|--|--|


C.4.7 SENSITIZATION - SKIN
(Classified in Accordance with Appendix A.4)

| | | | |
|---|--------------------|-------------------------------------|---|
| | | | <p>Pictogram Exclamation mark</p> |
| Hazard category | Signal word | Hazard statement |  |
| 1 (including both sub-categories 1A and 1B) | Warning | May cause an allergic skin reaction | |

| | | | |
|--------------------------|-----------------|----------------|-----------------|
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |

| | | | |
|---|---|--|---|
| <p>Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions.</p> <p>Contaminated work clothing must not be allowed out of the workplace.</p> <p>Wear protective gloves. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If on skin: Wash with plenty of water/... ... Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.</p> <p>If skin irritation or rash occurs: Get medical advice/attention.</p> <p>Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.</i></p> <p>Wash contaminated clothing before reuse.</p> | | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|---|--|---|

C.4.8 GERM CELL MUTAGENICITY
(Classified in Accordance with Appendix A.5)

| | | | |
|------------------------|--------------------|--|---|
| | | | <p>Pictogram Health hazard</p> |
| Hazard category | Signal word | Hazard statement |  |
| 1A and 1B | Danger | May cause genetic defects <...> | |
| 2 | Warning | Suspected of causing genetic defects <...> | |
| | | <i>(state route of exposure if no other routes of exposure cause the hazard)</i> | |

Precautionary statements

| | | | |
|-------------------|-----------------|----------------|-----------------|
| Prevention | Response | Storage | Disposal |
|-------------------|-----------------|----------------|-----------------|

| | | | |
|--|--|--------------------------------|--|
| <p>Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment, as required.</p> | <p>If exposed or concerned: Get medical advice/attention.</p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|--|--------------------------------|--|


C.4.9 CARCINOGENICITY
(Classified in Accordance with Appendix A.6)

| | | | |
|------------------------|--------------------|--|---|
| | | | <p>Pictogram Health hazard</p> |
| Hazard category | Signal word | Hazard statement | |
| 1A and 1B | Danger | May cause cancer <...> | |
| 2 | Warning | Suspected of causing cancer <...> | |
| | | <i>(state route of exposure if no other routes of exposure cause the hazard)</i> | |

Precautionary statements


| Prevention | Response | Storage | Disposal |
|--|--|--------------------------------|--|
| <p>Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment, as required.</p> | <p>If exposed or concerned: Get medical advice/attention.</p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |

Note: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product; however, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ³ 1%, both an SDS and a label is required and the information must be included on each.

| C.4.10 TOXIC TO REPRODUCTION (Classified in Accordance with Appendix A.7) | | | |
|--|--|--|--|
| | | | Pictogram Health hazard |
| Hazard category | Signal word | Hazard statement |  |
| 1A and 1B | Danger | May damage fertility or the unborn child <...> <<...>> | |
| 2 | Warning | Suspected of damaging fertility or the unborn child <...> <<...>> | |
| | | <i>(state specific effect if known)</i> | |
| | | <i>(state route of exposure if no other routes of exposure cause the hazard)</i> | |
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |
| Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment, as required. | If exposed or concerned: Get medical advice/attention. | Store locked up. | Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified). |
| C.4.10 TOXIC TO REPRODUCTION (CONTINUED) (Classified in Accordance with Appendix A.7) (EFFECTS ON OR VIA LACTATION) | | | |
| | | | Pictogram <i>No Pictogram</i> |
| Hazard category | Signal word | Hazard statement | |
| <i>No designated number</i> (See Table A.7.1 in Appendix A.7) | <i>No signal word</i> | May cause harm to breast-fed children | |
| Precautionary statements | | | |

| Prevention | Response | Storage | Disposal |
|--|---|---------|----------|
| Obtain special instructions before use. Do not breathe dusts or mists. <i>- if inhalable particles of dusts or mists may occur during use.</i> Avoid contact during pregnancy/while nursing. Wash ... thoroughly after handling. ...Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Do not eat, drink or smoke when using this product. | If exposed or concerned: Get medical advice/attention. | | |


C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure)
(Classified in Accordance with Appendix A.8)

| | | | Pictogram Health hazard |
|-----------------|-------------|---|---|
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Causes damage to organs <...> <<...>> | |
| | | <...> (or state all organs affected if known) | |
| | | <<...>> (state route of exposure if no other routes of exposure cause the hazard) | |

| Precautionary statements | | | |
|--------------------------|----------|---------|----------|
| Prevention | Response | Storage | Disposal |

| | | | |
|--|--|--------------------------------|---|
| <p>Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. Wash ...thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Do not eat, drink or smoke when using this product.</p> | <p>If exposed: Call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction. <i>- if immediate measures are required.</i></p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|--|--------------------------------|---|

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.8)


| | | | |
|------------------------|--------------------|---|--|
| | | | <p>Pictogram Health hazard</p> |
| Hazard category | Signal word | Hazard statement |  |
| 2 | Warning | May cause damage to organs <...> <<...>> | |
| | | <...> (or state all organs affected, if known) | |
| | | <<...>> (state route of exposure if no other routes of exposure cause the hazard) | |

Precautionary statements

| | | | |
|-------------------|-----------------|----------------|-----------------|
| Prevention | Response | Storage | Disposal |
|-------------------|-----------------|----------------|-----------------|

| | | | |
|---|---|--------------------------------|---|
| <p>Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. Wash ... thoroughly after handling. ... Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Do not eat, drink or smoke when using this product.</p> | <p>If exposed or concerned: Call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.</p> | <p>Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|---|--------------------------------|---|

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.8)


| | | | |
|------------------------|--------------------|--------------------------------------|--|
| | | | <p>Pictogram Exclamation mark</p> |
| Hazard category | Signal word | Hazard statement |  |
| 3 | Warning | May cause respiratory irritation; or | |
| | | May cause drowsiness or dizziness | |

Precautionary statements

| | | | |
|---|---|--|---|
| Prevention | Response | Storage | Disposal |
| <p>Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. Use only outdoors or in a well-ventilated area.</p> | <p>If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor/.../if you feel unwell. ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.</p> | <p>Store in a well-ventilated place. Keep container tightly closed. <i>- if product is volatile so as to generate hazardous atmosphere.</i> Store locked up.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |


4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure)
(Classified in Accordance with Appendix A.9)

| | | | |
|--|--|--|---|
| | | | <p>Pictogram Health hazard</p> |
|--|--|--|---|

| | | | | |
|--------------------------|-------------|---|---|---|
| Hazard category | Signal word | Hazard statement | |  |
| | 1 | Danger | Causes damage to organs <...> through prolonged or repeated exposure <<...>> | |
| | | <...> (state all organs affected, if known) | | |
| | | | <<...>> (state route of exposure if no other routes of exposure cause the hazard) | |
| Precautionary statements | | | | |
| Prevention | Response | Storage | Disposal | |

| | | | |
|--|--|--|---|
| <p>Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. Wash ... thoroughly after handling. ...Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. Do not eat, drink or smoke when using this product.</p> | <p>Get medical advice/attention if you feel unwell.</p> | | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|--|--|---|

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.9)


| | | | |
|-------------------------------|---------------------------|--|--|
| | | | <p>Pictogram Health hazard</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |
| <p>2</p> | <p>Warning</p> | <p>May cause damage to organs <...> through prolonged or repeated exposure <<...>></p> | |
| | | <p><...> (state all organs affected, if known)</p> | |
| | | <p><<...>> (state route of exposure if no other routes of exposure cause the hazard)</p> | |

Precautionary statements

| | | | |
|---|--|-----------------------|---|
| <p>Prevention</p> | <p>Response</p> | <p>Storage</p> | <p>Disposal</p> |
| <p>Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions.</p> | <p>Get medical advice/attention if you feel unwell.</p> | | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |

C.4.13 ASPIRATION HAZARD
(Classified in Accordance with Appendix A.10)


| | | | |
|--|--|--|---|
| | | | <p>Pictogram Health hazard</p> |
|--|--|--|---|

| Hazard category | Signal word | Hazard statement |  |
|-----------------|-------------|--|---|
| 1 | Danger | May be fatal if swallowed and enters airways | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|------------|--|-------------------------|---|
| | If swallowed: Immediately call a poison center/doctor/... ... Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. Do NOT induce vomiting. | Store locked up. | Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified). |

C.4.14 EXPLOSIVES
(Classified in Accordance with Appendix B.1)


| | | | Pictogram Exploding bomb |
|--------------------|-------------|--------------------|---|
| Hazard category | Signal word | Hazard statement |  |
| Unstable explosive | Danger | Unstable explosive | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|------------|----------|---------|----------|
|------------|----------|---------|----------|

| | | | |
|---|--|---|--|
| <p>Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear personal protective equipment/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment, as required.</p> | <p>Explosion risk in case of fire. Do NOT fight fire when fire reaches explosives. Evacuate area.</p> | <p>Storein accordance with local/regional/national/international regulations (to be specified).</p> | <p>Dispose of contents/container toin accordance with local/regional/national/international regulations (to be specified).</p> |
|---|--|---|--|

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1)

| | | | |
|------------------------|--------------------|--------------------------------------|--|
| | | | <p>Pictogram Exploding bomb</p> |
| Hazard category | Signal word | Hazard statement |  |
| Division 1.1 | Danger | Explosive; mass explosion hazard | |
| Division 1.2 | Danger | Explosive; severe projection hazard | |
| Division 1.3 | Danger | Explosive; fire, blast or projection | |

Precautionary statements

| | | | |
|-------------------|-----------------|----------------|-----------------|
| Prevention | Response | Storage | Disposal |
|-------------------|-----------------|----------------|-----------------|


| | | | |
|---|---|--|--|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep wetted with... ... Chemical manufacturer, importer, or distributor to specify appropriate material. <i>- if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).</i></p> <p>Ground/bond container and receiving equipment. <i>- if the explosive is electrostatically sensitive.</i></p> <p>Do not subject to grinding/shock/.../friction. ...Chemical manufacturer, importer, or distributor to specify applicable rough handling.</p> <p>Wear face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: evacuate area. Explosion risk in case of fire. Do NOT fight fire when fire reaches explosives.</p> | <p>Storein accordance with local/regional/national/international regulations (to be specified).</p> | <p>Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|---|--|--|

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.14 EXPLOSIVES (CONTINUED)

(Classified in Accordance with Appendix B.1)

| | | | |
|--|--|--|--|
| | | | <p>Pictogram Exploding bomb¹</p> |
|--|--|--|--|

| | | | |
|------------------------|--------------------|---------------------------|--|
| Hazard category | Signal word | Hazard statement |  |
| Division 1.4 | Warning | Fire or projection hazard | |

Precautionary statements¹

| Prevention | Response | Storage | Disposal |
|--|--|--|---|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Ground/bond container and receiving equipment. <i>- if the explosive is electrostatically sensitive.</i></p> <p>Do not subject to grinding/shock/.../friction. Chemical manufacturer, importer, or distributor to specify applicable rough handling.</p> <p>Wear face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Evacuate area. Explosion risk in case of fire. <i>- except if explosives are 1.4S ammunition and components thereof.</i></p> <p>Do NOT fight fire when fire reaches explosives. Fight fire with normal precautions from a reasonable distance <i>- if explosives are 1.4S ammunition and components thereof.</i></p> | <p>Storein accordance with local/regional/national/international regulations (to be specified).</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.¹

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1)

| | | | |
|------------------------|--------------------|--------------------------|---|
| | | | Pictogram <i>No Pictogram</i> |
| Hazard category | Signal word | Hazard statement | |
| Division 1.5 | Danger | May mass explode in fire | |


| Precautionary statements | | | |
|--|---|--|--|
| Prevention | Response | Storage | Disposal |
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep wetted with... ... Chemical manufacturer, importer, or distributor to specify appropriate material. <i>- if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).</i></p> <p>Ground/bond container and receiving equipment <i>- if the explosive is electrostatically sensitive.</i></p> <p>Do not subject to grinding/shock/.../friction. ...Chemical manufacturer, importer, or distributor to specify applicable rough handling.</p> <p>Wear face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Evacuate area. Explosion risk in case of fire. Do NOT fight fire when fire reaches explosives.</p> | <p>Storein accordance with local/regional/national/international regulations (to be specified).</p> | <p>Dispose of contents/container to in accordance with local/regional/national/international regulations (to be specified).</p> |

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

| C.4.14 EXPLOSIVES (CONTINUED) (Classified in Accordance with Appendix B.1) | | | |
|---|--------------------|-------------------------|---|
| | | | Pictogram <i>No Pictogram</i> |
| Hazard category | Signal word | Hazard statement | |
| | | | |

| | | | |
|--------------------------|-----------------------|----------------------------|-----------------|
| Division 1.6 | <i>No signal word</i> | <i>No hazard statement</i> | |
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |
| None assigned | None assigned | None assigned | None assigned |

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

| | | | |
|---|--------------------|-------------------------|---|
| C.4.15 FLAMMABLE GASES (Classified in Accordance with Appendix B.2) | | | |
| | | | Pictogram Flame |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Extremely flammable gas | |


| | | | |
|--|---|--|-----------------|
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |
| Keep away from heat/sparks/open flames/hot surfaces. -No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). | Leaking gas fire: Do not extinguish, unless leak can be stopped safely. Eliminate all ignition sources if safe to do so. | Store in well-ventilated place. | |

| | | | |
|---|--------------------|-------------------------|---|
| C.4.15 FLAMMABLE GASES (CONTINUED) (Classified in Accordance with Appendix B.2) | | | |
| | | | Pictogram <i>No Pictogram</i> |
| Hazard category | Signal word | Hazard statement | |
| 2 | Warning | Flammable gas | |

| | | | |
|--------------------------|-----------------|----------------|-----------------|
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |

| | | | |
|--|---|---|--|
| <p>Keep away from heat/sparks/open flames/hot surfaces. -No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).</p> | <p>Leaking gas fire: Do not extinguish, unless leak can be stopped safely. Eliminate all ignition sources if safe to do so.</p> | <p>Store in well-ventilated place.</p> | |
|--|---|---|--|


C.4.16 FLAMMABLE AEROSOLS
(Classified in Accordance with Appendix B.3)

| | | | |
|------------------------|--------------------|-----------------------------|---|
| | | | Pictogram Flame |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Extremely flammable aerosol | |
| 2 | Warning | Flammable aerosol | |

Precautionary statements

| | | | |
|---|-----------------|---|-----------------|
| Prevention | Response | Storage | Disposal |
| <p>Keep away from heat/sparks/open flames/hot surfaces. -No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s). Do not spray on an open flame or other ignition source. Pressurized container: Do not shake or burn, even after use.</p> | | <p>Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.</p> | |


C.4.17 OXIDIZING GASES
(Classified in Accordance with Appendix B.4)

| | | | |
|------------------------|--------------------|---------------------------------------|---|
| | | | Pictogram Flame over circle |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | May cause or intensify fire; oxidizer | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|--|---|--|----------|
| Keep/Store away from clothing/.../combustible materials. ...Chemical manufacturer, importer, or distributor to specify other incompatible materials. Keep reduction valves/valves and fittings free from oil and grease. | In case of fire: Stop leak if safe to do so. | Store in well-ventilated place. | |


**C.4.18 GASES UNDER PRESSURE
(Classified in Accordance with Appendix B.5)**

| | | | Pictogram Gas cylinder |
|-----------------|-------------|--|--|
| Hazard category | Signal word | Hazard statement |  |
| Compressed gas | Warning | Contains gas under pressure; may explode if heated | |
| Liquefied gas | Warning | Contains gas under pressure; may explode if heated | |
| Dissolved gas | Warning | Contains gas under pressure; may explode if heated | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|------------|----------|---|----------|
| | | Protect from sunlight. Store in a well-ventilated place. | |


**C.4.18 GASES UNDER PRESSURE (CONTINUED)
(Classified in Accordance with Appendix B.5)**

| | | | Pictogram Gas cylinder |
|----------------------------|-------------|--|---|
| Hazard category | Signal word | Hazard statement |  |
| Refrigerated liquefied gas | Warning | Contains refrigerated gas; may cause cryogenic burns or injury | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|--|--|--|-----------------|
| Wear cold insulating gloves/face shield/eye protection. | Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention. | Store in well-ventilated place. | |

**C.4.19 FLAMMABLE LIQUIDS
(Classified in Accordance with Appendix B.6)**

| | | | Pictogram Flame |
|------------------------|--------------------|--------------------------------------|---|
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Extremely flammable liquid and vapor | |
| 2 | Danger | Highly flammable liquid and vapor | |
| 3 | Warning | Flammable liquid and vapor | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|-------------------|-----------------|----------------|-----------------|
| | | | |

| | | | |
|---|--|--|---|
| <p>Keep away from heat/sparks/open flames/hot surfaces.– No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep container tightly closed. Ground/Bond container and receiving equipment - <i>if electrostatically sensitive material is for reloading.</i> - <i>if product is volatile so as to generate hazardous atmosphere.</i></p> <p>Use explosion-proof electrical/ventilating/lighting/.../equipment. ... Chemical manufacturer, importer, or distributor to specify other equipment.</p> <p>Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. In case of fire: Use ... to extinguish. ... Chemical manufacturer, importer, or distributor to specify appropriate media. - <i>if water increases risk.</i></p> | <p>Store in a well-ventilated place. Keep cool.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|--|--|---|


| | | | |
|---|---------------------------|--------------------------------|---|
| <p>C.4.19 FLAMMABLE LIQUIDS (CONTINUED) (Classified in Accordance with Appendix B.6)</p> | | | |
| | | | <p>Pictogram <i>No Pictogram</i></p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> | |
| <p>4</p> | <p>Warning</p> | <p>Combustible liquid</p> | |

Cautionary statements

| | | | |
|--------------------------|------------------------|-----------------------|------------------------|
| <p>Prevention</p> | <p>Response</p> | <p>Storage</p> | <p>Disposal</p> |
|--------------------------|------------------------|-----------------------|------------------------|

| | | | |
|---|--|---|---|
| Keep away from flames and hot surfaces. – No smoking. Wear protective gloves/eye protection/face protection Chemical manufacturer, importer, or distributor to specify type of equipment. | In case of fire: Use ... to extinguish. ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i> | Store in a well-ventilated place. Keep cool. | Dispose of contents/container to... in accordance with local/regional/national/international regulations (to be specified). |
|---|--|---|---|

C.4.20 FLAMMABLE SOLIDS
(Classified in Accordance with Appendix B.7)


| | | | |
|------------------------|--------------------|-------------------------|---|
| | | | Pictogram Flame |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Flammable solid | |
| 2 | Warning | Flammable solid | |

Precautionary statements

| | | | |
|-------------------|-----------------|----------------|-----------------|
| Prevention | Response | Storage | Disposal |
|-------------------|-----------------|----------------|-----------------|



| | | | |
|---|--|--|--|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Ground/Bond container and receiving equipment. <i>- if electrostatically sensitive material is for reloading.</i></p> <p>Use explosion-proof electrical/ventilating/lighting/... /equipment. ... Chemical manufacturer, importer, or distributor to specify other equipment. <i>- if dust clouds can occur.</i></p> <p>Wear protective gloves/eye protection/face protection Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Use ... to extinguish ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> | | |
|---|--|--|--|

**C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES
(Classified in Accordance with Appendix B.8)**

| | | | |
|---------------------------------|---------------------------|---------------------------------------|---|
| | | | <p>Pictogram Flame</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> | <p>Exploding bomb</p> |
| <p>Type A</p> | <p>Danger</p> | <p>Heating may cause an explosion</p> |  |
| <p>Precautionary statements</p> | | | |
| <p>Prevention</p> | <p>Response</p> | <p>Storage</p> | <p>Disposal</p> |


| | | | |
|--|--|--|---|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep/Store away from clothing/.../combustible materials. ... Chemical manufacturer, importer, or distributor to specify other incompatible materials.</p> <p>Keep only in original container.</p> <p>Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Use ... to extinguish ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> <p>In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.</p> | <p>Store in a well-ventilated place. Keep cool. Store at temperatures not exceeding ...°C/...°F. ... Chemical manufacturer, importer, or distributor to specify temperature.</p> <p>Store away from other materials.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|--|--|---|

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (CONTINUED)
(Classified in Accordance with Appendix B.8)

| | | | | |
|--------------------------|--------------------|---------------------------------------|---|---|
| | | | <p>Pictogram Exploding bomb and flame</p> | |
| Hazard category | Signal word | Hazard statement |  |  |
| Type B | Danger | Heating may cause a fire or explosion | | |
| Precautionary statements | | | | |
| Prevention | Response | Storage | Disposal | |


| | | | |
|--|---|--|--|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep/Store away from clothing/.../combustible materials. ... Chemical manufacturer, importer, or distributor to specify other incompatible materials.</p> <p>Keep only in original container.</p> <p>Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Use ... to extinguish. ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> <p>In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.</p> | <p>Store in a well-ventilated place. Keep cool. Store at temperatures not exceeding ...°C/...°F. ... Chemical manufacturer, importer, or distributor to specify temperature.</p> <p>Store away from other materials.</p> | <p>Dispose of contents/container to... ...in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|---|--|--|

**C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES(CONTINUED)
(Classified in Accordance with Appendix B.8)**

| | | | Pictogram |
|--------------------------|-----------------|--------------------------|--|
| Hazard category | Signal word | Hazard statement |  |
| Type C | Danger | Heating may cause a fire | |
| Type D | Danger | Heating may cause a fire | |
| Type E | Warning | Heating may cause a fire | |
| Type F | Warning | Heating may cause a fire | |
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |


| | | | |
|---|--|---|--|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep/Store away from clothing/.../combustible materials. ...Chemical manufacturer, importer, or distributor to specify other incompatible materials.</p> <p>Keep only in original container.</p> <p>Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Use ... to extinguish ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> | <p>Store in a well-ventilated place. Keep cool. Store at temperatures not exceeding ...°C/...°F. ...Chemical manufacturer, importer, or distributor to specify temperature.</p> <p>Store away from other materials.</p> | <p>Dispose of contents/container to... ...in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|--|---|--|

**C.4.22 PYROPHORIC LIQUIDS
(Classified in Accordance with Appendix B.9)**

| | | | |
|--------------------------|--------------------|--|---|
| | | | <p>Pictogram Flame</p> |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Catches fire spontaneously if exposed to air | |
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |

| | | | |
|--|--|--|--|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).</p> <p>Do not allow contact with air. Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>If on skin: Immerse in cool water/wrap with wet bandages In case of fire: Use ... to extinguish ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> | <p>Store contents under Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.</p> | |
|--|--|--|--|


C.4.23 PYROPHORIC SOLIDS
(Classified in Accordance with Appendix B.10)

| | | | |
|------------------------|--------------------|--|--|
| | | | Pictogram Flame |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | Catches fire spontaneously if exposed to air | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|--|--|--|-----------------|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Do not allow contact with air. Wear protective gloves/eye protection/face protection Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>Brush off loose particles from skin. Immerse in cool water/wrap in wet bandages. In case of fire: Use ... to extinguish ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> | <p>Store contents under Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.</p> | |

C.4.24 SELF-HEATING SUBSTANCES AND MIXTURES
(Classified in Accordance with Appendix B.11)


| | | | |
|------------------------|--------------------|-------------------------|---|
| | | | Pictogram Flame |
| Hazard category | Signal word | Hazard statement |  |

| | | | |
|---|---------|--|------------------------------|
| 1 | | Danger | Self-heating; may catch fire |
| 2 | Warning | Self-heating in large quantities; may catch fire | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|---|----------|---|----------|
| <p>Keep cool. Protect from sunlight. Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | | <p>Maintain air gap between stacks/pallets. Store bulk masses greater than ... kg/...lbs at temperatures not exceeding ...°C/...°F. ... Chemical manufacturer, importer, or distributor to specify mass and temperature. Store away from other materials.</p> | |

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES (Classified in Accordance with Appendix B.12)


| | | | |
|------------------------|--------------------|--|---|
| | | | Pictogram Flame |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | In contact with water releases flammable gases, which may ignite spontaneously | |

| | | | |
|---|--------|--|--|
| 2 | Danger | In contact with water releases flammable gas | |
|---|--------|--|--|

Precautionary statements

| Prevention | Response | Storage | Disposal |
|---|--|--|---|
| <p>Do not allow contact with water. Handle under inert gas. Protect from moisture. Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>Brush off loose particles from skin and immerse in cool water/wrap in wet bandages. In case of fire: Use ... to extinguish ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> | <p>Store in a dry place. Store in a closed container.</p> | <p>Dispose of contents/container to... ...in accordance with local/regional/national/international regulations (to be specified).</p> |

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.12)

| Hazard category | Signal word | Hazard statement | Pictogram |
|-----------------|-------------|--|---|
| | | | Flame |
| | | |  |
| 3 | Warning | In contact with water releases flammable gas | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|--|---|--|---|
| <p>Handle under inert gas. Protect from moisture. Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Use ... to extinguish. ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> | <p>Store in a dry place. Store in a closed container.</p> | <p>Dispose of contents/container to... ...in accordance with local/regional/national/international regulations (to be specified).</p> |


C.4.26 OXIDIZING LIQUIDS
 (Classified in Accordance with Appendix B.13)

| | | | |
|------------------------|--------------------|--|---|
| | | | Pictogram Flame over circle |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | May cause fire or explosion; strong oxidizer | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|--|---|---------|---|
| <p>Keep away from heat. Keep/Store away from clothing and other combustible materials. Take any precaution to avoid mixing with combustibles/...</p> <p>... Chemical manufacturer, importer, or distributor to specify other incompatible materials.</p> <p>Wear protective gloves /eye protection/face protection.</p> <p>Chemical manufacturer, importer, or distributor to specify type of equipment.</p> <p>Wear fire/flame resistant/retardant clothing.</p> | <p>If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.</p> <p>In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.</p> <p>In case of fire: Use ... to extinguish.</p> <p>... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> | | <p>Dispose of contents/container to...</p> <p>...in accordance with local/regional/national/international regulations (to be specified).</p> |


C.4.26 OXIDIZING LIQUIDS (CONTINUED)
 (Classified in Accordance with Appendix B.13)

| | | | |
|------------------------|--------------------|------------------------------|---|
| | | | Pictogram Flame over circle |
| Hazard category | Signal word | Hazard statement |  |
| 2 | Danger | May intensify fire; oxidizer | |
| 3 | Warning | May intensify fire; oxidizer | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|--|---|---------|---|
| <p>Keep away from heat. Keep/Store away from clothing/.../combustible materials. ...Chemical manufacturer, importer, or distributor to specify other incompatible materials.</p> <p>Take any precaution to avoid mixing with combustibles/... ... Chemical manufacturer, importer, or distributor to specify other incompatible materials.</p> <p>Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Use ... to extinguish. ... Chemical manufacturer, importer, or distributor to specify appropriate media. - <i>if water increases risk.</i></p> | | <p>Dispose of contents/container to... ...in accordance with local/regional/national/international regulations (to be specified).</p> |

C.4.27 OXIDIZING SOLIDS
(Classified in Accordance with Appendix B.14)


| | | | Pictogram Flame over circle |
|-----------------|-------------|--|---|
| Hazard category | Signal word | Hazard statement |  |
| 1 | Danger | May cause fire or explosion; strong oxidizer | |

Precautionary statements

| Prevention | Response | Storage | Disposal |
|------------|----------|---------|----------|
|------------|----------|---------|----------|

| | | |
|--|---|---|
| <p>Keep away from heat. Keep away from clothing and other combustible materials. Take any precaution to avoid mixing with combustibles/... ...Chemical manufacturer, importer, or distributor to specify other incompatible materials. Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment. Wear fire/flame resistant/retardant clothing.</p> | <p>If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion. In case of fire: Use ... to extinguish. ... Chemical manufacturer, importer, or distributor to specify appropriate media. <i>- if water increases risk.</i></p> | <p>Dispose of contents/container to... ...in accordance with local/regional/national/international regulations (to be specified).</p> |
|--|---|---|


C.4.27 OXIDIZING SOLIDS (CONTINUED)
(Classified in Accordance with Appendix B.14)

| | | | |
|------------------------|--------------------|------------------------------|---|
| | | | <p>Pictogram Flame over circle</p> |
| Hazard category | Signal word | Hazard statement |  |
| 2 | Danger | May intensify fire; oxidizer | |
| 3 | Warning | May intensify fire; oxidizer | |

| | | | |
|--------------------------|-----------------|----------------|-----------------|
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |

| | | | |
|---|---|--|--|
| <p>Keep away from heat. Keep/Store away from clothing/.../ combustible materials. ... Chemical manufacturer, importer, or distributor to specify incompatible materials.</p> <p>Take any precaution to avoid mixing with combustibles/... ...Chemical manufacturer, importer, or distributor to specify other incompatible materials.</p> <p>Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | <p>In case of fire: Use ... to extinguish. ... Chemical manufacturer, importer, or distributor to specify appropriate media. - <i>if water increases risk.</i></p> | | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|---|--|--|

C.4.28 ORGANIC PEROXIDES
(Classified in Accordance with Appendix B.15)



| | | | |
|-------------------------------|---------------------------|---------------------------------------|---|
| | | | <p>Pictogram Exploding bomb</p> |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |
| <p>Type A</p> | <p>Danger</p> | <p>Heating may cause an explosion</p> | |

Precautionary statements

| | | | |
|--------------------------|------------------------|-----------------------|------------------------|
| <p>Prevention</p> | <p>Response</p> | <p>Storage</p> | <p>Disposal</p> |
|--------------------------|------------------------|-----------------------|------------------------|


| | | | |
|---|--|---|---|
| <p>Keep away from heat/sparks/open flames/hot surfaces.- No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep/Store away from clothing/.../combustible materials. ... Chemical manufacturer, importer, or distributor to specify incompatible materials.</p> <p>Keep only in original container.</p> <p>Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | | <p>Store at temperatures not exceeding ... °C/... °F. Keep cool. ... Chemical manufacturer, importer, or distributor to specify temperature.</p> <p>Protect from sunlight.</p> <p>Store away from other materials.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|--|---|---|

C.4.28 ORGANIC PEROXIDES (CONTINUED)
(Classified in Accordance with Appendix B.15)

| | | | | |
|---------------------------------|---------------------------|---------------------------------------|--|---|
| | | | <p>Pictogram Exploding bomb and flame</p> | |
| <p>Hazard category</p> | <p>Signal word</p> | <p>Hazard statement</p> |  |  |
| <p>Type B</p> | <p>Danger</p> | <p>Heating may cause an explosion</p> | | |
| <p>Precautionary statements</p> | | | | |
| <p>Prevention</p> | <p>Response</p> | <p>Storage</p> | <p>Disposal</p> | |

| | | | |
|---|--|---|---|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep /Store away from clothing/.../combustible materials. ... Chemical manufacturer, importer, or distributor to specify incompatible materials.</p> <p>Keep only in original container.</p> <p>Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | | <p>Store at temperatures not exceeding ...°C/...°F. Keep cool. Chemical manufacturer, importer, or distributor to specify temperature.</p> <p>Protect from sunlight.</p> <p>Store away from other materials.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|--|---|---|

C.4.28 ORGANIC PEROXIDES (CONTINUED)
(Classified in Accordance with Appendix B.15)


| | | | Pictogram Flame |
|------------------------|--------------------|--------------------------|---|
| Hazard category | Signal word | Hazard statement |  |
| Type C | Danger | Heating may cause a fire | |
| Type D | Danger | Heating may cause a fire | |
| Type E | Warning | Heating may cause a fire | |
| Type F | Warning | Heating may cause a fire | |

Precautionary statements

| | | | |
|-------------------|-----------------|----------------|-----------------|
| Prevention | Response | Storage | Disposal |
|-------------------|-----------------|----------------|-----------------|


| | | | |
|---|--|---|---|
| <p>Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).</p> <p>Keep /Store away from clothing/.../combustible materials. ... Chemical manufacturer, importer, or distributor to specify incompatible materials.</p> <p>Keep only in original container.</p> <p>Wear protective gloves/eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.</p> | | <p>Store at temperatures not exceeding ...°C/...°F. Keep cool. Chemical manufacturer, importer, or distributor to specify temperature.</p> <p>Protect from sunlight.</p> <p>Store away from other materials.</p> | <p>Dispose of contents/container to... ... in accordance with local/regional/national/international regulations (to be specified).</p> |
|---|--|---|---|

**C.4.29 CORROSIVE TO METALS
(Classified in Accordance with Appendix B.16)**

| | | | |
|--------------------------|--------------------|----------------------------|---|
| | | | <p>Pictogram Corrosion</p> |
| Hazard category | Signal word | Hazard statement |  |
| 1 | Warning | May be corrosive to metals | |
| Precautionary statements | | | |
| Prevention | Response | Storage | Disposal |

| | | | |
|---|--|---|--|
| Keep only in original container. | Absorb spillage to prevent material damage. | Store in corrosive resistant/... container with a resistant inner liner. ... Chemical manufacturer, importer, or distributor to specify other compatible materials. | |
|---|--|---|--|

C.4.30 Label elements for OSHA defined hazards

| | | | |
|-------------------------------|--------------------|---|---|
| | | | Pictogram Flame |
| Hazard category | Signal word | Hazard statement |  |
| Pyrophoric Gas | Danger | Catches fire spontaneously if exposed to air | |
| | | | Pictogram No Pictogram |
| Hazard category | Signal word | Hazard statement | |
| Simple Asphyxiant | Warning | May displace oxygen and cause rapid suffocation | |
| | | | Pictogram No Pictogram |
| Hazard category | Signal word | Hazard statement | |
| Combustible Dust ² | Warning | May form combustible dust concentrations in air | |

1 Except no pictogram is required for explosives that are 1.4S small arms ammunition and components thereof. Labels for 1.4S small arms ammunition and components shall include appropriate precautionary statements.

2 The chemical manufacturer or importer shall label chemicals that are shipped in dust form, and present a combustible dust hazard in that form when used downstream, under paragraph (f)(1); 2) the chemical manufacturer or importer shipping chemicals that are in a form that is not yet a dust must provide a label to customers under paragraph (f)(4) if, under normal conditions of use, the chemicals are processed in a downstream workplace in such a way that they present a combustible dust hazard; and 3) the employer shall follow the workplace labeling requirements under paragraph (f)(6) where combustible dust hazards are present.

Appendix D to 1910.1200 - Definition of "Trade Secret" _____
—(Mandatory)

The following is a reprint of the Restatement of Torts section 757, comment b (1939):

b. Definition of trade secret.

~~A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.~~

~~It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.~~

~~It differs from other secret information in a business (see s759 of the Restatement of Torts which is not included in this Appendix) in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like.~~

~~A trade secret is a process or device for continuous use in the operations of the business.~~

~~Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article.~~

~~It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.~~

~~Secrecy.~~

~~The subject matter of a trade secret must be secret.~~

~~Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret.~~

~~Matters which are completely disclosed by the goods which one markets cannot be his secret.~~

~~Substantially, a trade secret is known only in the particular business in which it is used.~~

~~It is not requisite that only the proprietor of the business know it.~~

~~He may, without losing his protection, communicate it to employees involved in its use.~~

~~He may likewise communicate it to others pledged to secrecy.~~

~~Others may also know of it independently, as, for example, when they have discovered the process or formula by independent invention and are keeping it secret.~~

~~Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information.~~

~~An exact definition of a trade secret is not possible.~~

~~Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.~~

~~Novelty and prior art.~~

~~A trade secret may be a device or process which is patentable; but it need not be that.~~

~~It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make.~~

~~Novelty and invention are not requisite for a trade secret as they are for patentability.~~

~~These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research.~~

~~The patent monopoly is a reward to the inventor.~~

~~But such is not the case with a trade secret.~~

~~Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices.~~

~~The protection is merely against breach of faith and reprehensible means of learning another's secret.~~

~~For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability.~~

~~The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this Section.~~

~~Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use.~~

~~If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.~~

APPENDIX D TO §1910.1200 - SAFETY DATA SHEETS (MANDATORY)

A safety data sheet (SDS) shall include the information specified in Table D.1 under the section number and heading indicated for sections 1-11 and 16. If no relevant information is found for any given subheading within a section, the SDS shall clearly indicate that no applicable information is available. Sections 12-15 may be included in the SDS, but are not mandatory.

Table D.1. Minimum Information for an SDS

| | Heading | Subheading |
|----|---------------------------------|---|
| 1. | Identification | (a) Product identifier used on the label; (b) Other means of identification; (c) Recommended use of the chemical and restrictions on use; (d) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party; (e) Emergency phone number. |
| 2. | Hazard(s) identification | (a) Classification of the chemical in accordance with paragraph (d) of §1910.1200; (b) Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200. (Hazard symbols may be provided as graphical reproductions in black and white or the name of the symbol, e.g., flame, skull and crossbones); (c) Describe any hazards not otherwise classified that have been identified during the classification process; (d) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration = 1% and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required. |

| | | |
|----|--|--|
| 3. | Composition/ information on ingredients | <p>Except as provided for in paragraph (i) of §1910.1200 on trade secrets:</p> <p style="text-align: center;">For Substances</p> <p style="text-align: center;">(a) Chemical name; (b) Common name and synonyms; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.</p> <p style="text-align: center;">For Mixtures</p> <p style="text-align: center;">In addition to the information required for substances:</p> <p style="text-align: center;">(a) The chemical name and concentration (exact percentage) or concentration ranges of all ingredients which are classified as health hazards in accordance with paragraph (d) of §1910.1200 and (1) are present above their cut-off/concentration limits; or (2) present a health risk below the cut-off/concentration limits. (b) The concentration (exact percentage) shall be specified unless a trade secret claim is made in accordance with paragraph (i) of §1910.1200, when there is batch-to-batch variability in the production of a mixture, or for a group of substantially similar mixtures (See A.0.5.1.2) with similar chemical composition. In these cases, concentration ranges may be used.</p> <p style="text-align: center;">For All Chemicals Where a Trade Secret is Claimed</p> <p>Where a trade secret is claimed in accordance with paragraph (i) of §1910.1200, a statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.</p> |
| 4. | First-aid measures | <p>(a) Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion; (b) Most important symptoms/effects, acute and delayed. (c) Indication of immediate medical attention and special treatment needed, if necessary.</p> |
| 5. | Fire-fighting measures | <p>(a) Suitable (and unsuitable) extinguishing media. (b) Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products). (c) Special protective equipment and precautions for fire-fighters.</p> |
| 6. | Accidental release measures | <p>(a) Personal precautions, protective equipment, and emergency procedures. (b) Methods and materials for containment and cleaning up.</p> |
| 7. | Handling and storage | <p>(a) Precautions for safe handling. (b) Conditions for safe storage, including any incompatibilities.</p> |
| 8. | Exposure controls/personal protection | <p>(a) OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available. (b) Appropriate engineering controls. (c) Individual protection measures, such as personal protective equipment.</p> |

| | | |
|-----|--|---|
| 9. | Physical and chemical properties | <ul style="list-style-type: none"> (a) Appearance (physical state, color, etc.); (b) Odor; (c) Odor threshold; (d) pH; (e) Melting point/freezing point; (f) Initial boiling point and boiling range; (g) Flash point; (h) Evaporation rate; (i) Flammability (solid, gas); (j) Upper/lower flammability or explosive limits; (k) Vapor pressure; (l) Vapor density; (m) Relative density; (n) Solubility(ies); (o) Partition coefficient: n-octanol/water; (p) Auto-ignition temperature; (q) Decomposition temperature; (r) Viscosity. |
| 10. | Stability and reactivity | <ul style="list-style-type: none"> (a) Reactivity; (b) Chemical stability; (c) Possibility of hazardous reactions; (d) Conditions to avoid (e.g., static discharge, shock, or vibration); (e) Incompatible materials; (f) Hazardous decomposition products. |
| 11. | Toxicological information | <p>Description of the various toxicological (health) effects and the available data used to identify those effects, including:</p> <ul style="list-style-type: none"> (a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); (b) Symptoms related to the physical, chemical and toxicological characteristics; (c) Delayed and immediate effects and also chronic effects from short- and long-term exposure; (d) Numerical measures of toxicity (such as acute toxicity estimates). (e) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA. |
| 12. | Ecological information (Non-mandatory) | <ul style="list-style-type: none"> (a) Ecotoxicity (aquatic and terrestrial, where available); (b) Persistence and degradability; (c) Bioaccumulative potential; (d) Mobility in soil; (e) Other adverse effects (such as hazardous to the ozone layer). |
| 13. | Disposal considerations (Non-mandatory) | <p>Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.</p> |
| 14. | Transport information (Non-mandatory) | <ul style="list-style-type: none"> (a) UN number; (b) UN proper shipping name; (c) Transport hazard class(es); (d) Packing group, if applicable; (e) Environmental hazards (e.g., Marine pollutant (Yes/No)); (f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code); (g) Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises. |
| 15. | Regulatory information (Non-mandatory) | <p>Safety, health and environmental regulations specific for the product in question.</p> |

| | |
|---|--|
| 16. Other information, including date of preparation or last revision | The date of preparation of the SDS or the last change to it. |
|---|--|

Appendix E to 1910.1200 (Advisory) - Guidelines for Employer Compliance

The Hazard Communication Standard (HCS) is based on a simple concept—that employees have both a need and a right to know the hazards and identities of the chemicals they are exposed to when working. They also need to know what protective measures are available to prevent adverse effects from occurring. The HCS is designed to provide employees with the information they need. Knowledge acquired under the HCS will help employers provide safer workplaces for their employees. When employers have information about the chemicals being used, they can take steps to reduce exposures, substitute less hazardous materials, and establish proper work practices. These efforts will help prevent the occurrence of work-related illnesses and injuries caused by chemicals. The HCS addresses the issues of evaluating and communicating hazards to workers. Evaluation of chemical hazards involves a number of technical concepts, and is a process that requires the professional judgment of experienced experts. That's why the HCS is designed so that employers who simply use chemicals, rather than produce or import them, are not required to evaluate the hazards of those chemicals. Hazard determination is the responsibility of the producers and importers of the materials. Producers and importers of chemicals are then required to provide the hazard information to employers that purchase their products. Employers that don't produce or import chemicals need only focus on those parts of the rule that deal with establishing a workplace program and communicating information to their workers. This appendix is a general guide for such employers to help them determine what's required under the rule. It does not supplant or substitute for the regulatory provisions, but rather provides a simplified outline of the steps an average employer would follow to meet those requirements.

1. **Becoming Familiar With The Rule.** OSHA has provided a simple summary of the HCS in a pamphlet entitled "Chemical Hazard Communication," OSHA Publication Number 3084. Some employers prefer to begin to become familiar with the rule's requirements by reading this pamphlet. A copy may be obtained from your local OSHA Area Office, or by contacting the OSHA Publications Office at (202) 523-9667. The standard is long, and some parts of it are technical, but the basic concepts are simple. In fact, the requirements reflect what many employers have been doing for years. You may find that you are already largely in compliance with many of the provisions, and will simply have to modify your existing programs somewhat. If you are operating in an OSHA-approved State Plan State, you must comply with the State's requirements, which may be different than those of the Federal rule. Many of the State Plan States had hazard communication or "right-to-know" laws prior to promulgation of the Federal rule. Employers in State Plan States should contact their State OSHA offices for more information regarding applicable requirements. The HCS requires information to be prepared and transmitted regarding all hazardous chemicals. The HCS covers both physical hazards (such as flammability), and health hazards (such as irritation, lung damage, and cancer). Most chemicals used in the workplace have some hazard potential, and thus will be covered by the rule. One difference between this rule and many others adopted by OSHA is that this one is performance-oriented. That means that you have the flexibility to adapt the rule to the needs of your workplace, rather than having to follow specific, rigid requirements. It also means that you

have to exercise more judgment to implement an appropriate and effective program. The standard's design is simple. Chemical manufacturers and importers must evaluate the hazards of the chemicals they produce or import. Using that information, they must then prepare labels for containers, and more detailed technical bulletins called material safety data sheets (MSDS). Chemical manufacturers, importers, and distributors of hazardous chemicals are all required to provide the appropriate labels and material safety data sheets to the employers to which they ship the chemicals. The information is to be provided automatically. Every container of hazardous chemicals you receive must be labeled, tagged, or marked with the required information. Your suppliers must also send you a properly completed material safety data sheet (MSDS) at the time of the first shipment of the chemical, and with the next shipment after the MSDS is updated with new and significant information about the hazards. You can rely on the information received from your suppliers. You have no independent duty to analyze the chemical or evaluate the hazards of it. Employers that "use" hazardous chemicals must have a program to ensure the information is provided to exposed employees. "Use" means to package, handle, react, or transfer. This is an intentionally broad scope, and includes any situation where a chemical is present in such a way that employees may be exposed under normal conditions of use or in a foreseeable emergency. The requirements of the rule that deal specifically with the hazard communication program are found in this section in paragraphs (e), written hazard communication program; (f), labels and other forms of warning; (g), material safety data sheets; and (h), employee information and training. The requirements of these paragraphs should be the focus of your attention. Concentrate on becoming familiar with them, using paragraphs (b), scope and application, and (c), definitions, as references when needed to help explain the provisions. There are two types of work operations where the coverage of the rule is limited. These are laboratories and operations where chemicals are only handled in sealed containers (e.g., a warehouse). The limited provisions for these workplaces can be found in paragraph (b) of this section, scope and application. Basically, employers having these types of work operations need only keep labels on containers as they are received; maintain material safety data sheets that are received, and give employees access to them; and provide information and training for employees. Employers do not have to have written hazard communication programs and lists of chemicals for these types of operations. The limited coverage of laboratories and sealed container operations addresses the obligation of an employer to the workers in the operations involved, and does not affect the employer's duties as a distributor of chemicals. For example, a distributor may have warehouse operations where employees would be protected under the limited sealed container provisions. In this situation, requirements for obtaining and maintaining MSDSs are limited to providing access to those received with containers while the substance is in the workplace, and requesting MSDSs when employees request access for those not received with the containers. However, as a distributor of hazardous chemicals, that employer will still have responsibilities for providing MSDSs to downstream customers at the time of the first shipment and when the MSDS is updated. Therefore, although they may not be required for the employees in the work operation, the distributor may, nevertheless, have to have MSDSs to satisfy other requirements of the rule.

2. Identify Responsible Staff Hazard communication is going to be a continuing program in your facility. Compliance with the HCS is not a "one shot deal." In order to have a successful program, it will be necessary to assign responsibility for both the initial and ongoing activities that have to be undertaken to comply with the rule. In some cases, these activities may already be part of current job assignments. For example, site supervisors are

frequently responsible for on-the-job training sessions. Early identification of the responsible employees, and involvement of them in the development of your plan of action, will result in a more effective program design. Evaluation of the effectiveness of your program will also be enhanced by involvement of affected employees. For any safety and health program, success depends on commitment at every level of the organization. This is particularly true for hazard communication, where success requires a change in behavior. This will only occur if employers understand the program, and are committed to its success, and if employees are motivated by the people presenting the information to them.

3. Identify Hazardous Chemicals in the Workplace.

The standard requires a list of hazardous chemicals in the workplace as part of the written hazard communication program. The list will eventually serve as an inventory of everything for which an MSDS must be maintained. At this point, however, preparing the list will help you complete the rest of the program since it will give you some idea of the scope of the program required for compliance in your facility. The best way to prepare a comprehensive list is to survey the workplace. Purchasing records may also help, and certainly employers should establish procedures to ensure that in the future purchasing procedures result in MSDSs being received before a material is used in the workplace. The broadest possible perspective should be taken when doing the survey. Sometimes people think of "chemicals" as being only liquids in containers. The HCS covers chemicals in all physical forms—liquids, solids, gases, vapors, fumes, and mists—whether they are "contained" or not. The hazardous nature of the chemical and the potential for exposure are the factors which determine whether a chemical is covered. If it's not hazardous, it's not covered. If there is no potential for exposure (e.g., the chemical is inextricably bound and cannot be released), the rule does not cover the chemical. Look around. Identify chemicals in containers, including pipes, but also think about chemicals generated in the work operations. For example, welding fumes, dusts, and exhaust fumes are all sources of chemical exposures. Read labels provided by suppliers for hazard information. Make a list of all chemicals in the workplace that are potentially hazardous. For your own information and planning, you may also want to note on the list the location(s) of the products within the workplace, and an indication of the hazards as found on the label. This will help you as you prepare the rest of your program. Paragraph (b) of this section, scope and application, includes exemptions for various chemicals or workplace situations. After compiling the complete list of chemicals, you should review paragraph (b) of this section to determine if any of the items can be eliminated from the list because they are exempted materials. For example, food, drugs, and cosmetics brought into the workplace for employee consumption are exempt. So rubbing alcohol in the first aid kit would not be covered. Once you have compiled as complete a list as possible of the potentially hazardous chemicals in the workplace, the next is to determine if you have received material safety data sheets for all of them. Check your files against the inventory you have just compiled. If any are missing, contact your supplier and request one. It is a good idea to document these requests, either by copy of a letter or a note regarding telephone conversations. If you have MSDSs for chemicals that are not on your list, figure out why. Maybe you don't use the chemical anymore. Or maybe you missed it in your survey. Some suppliers do provide MSDSs for products that are not hazardous. These do not have to be maintained by you. You should not allow employees to use any chemicals for which you have not received an MSDS. The MSDS provides information you need to ensure proper protective measures are implemented prior to exposure.

4. Preparing and Implementing a Hazard Communication Program

All workplaces where employees are exposed to hazardous chemicals must have a written plan which describes

how the standard will be implemented in that facility. Preparation of a plan is not just a paper exercise—all of the elements must be implemented in the workplace in order to be in compliance with the rule. See paragraph (e) of this section for the specific requirements regarding written hazard communication programs. The only work operations which do not have to comply with the written plan requirements are laboratories and work operations where employees only handle chemicals in sealed containers. See paragraph (b) of this section, scope and application, for the specific requirements for these two types of workplaces. The plan does not have to be lengthy or complicated. It is intended to be a blueprint for implementation of your program—an assurance that all aspects of the requirements have been addressed. Many trade associations and other professional groups have provided sample programs and other assistance materials to affected employers. These have been very helpful to many employers since they tend to be tailored to the particular industry involved. You may wish to investigate whether your industry trade groups have developed such materials. Although such general guidance may be helpful, you must remember that the written program has to reflect what you are doing in your workplace. Therefore, if you use a generic program it must be adapted to address the facility it covers. For example, the written plan must list the chemicals present at the site, indicate who is to be responsible for the various aspects of the program in your facility, and indicate where written materials will be made available to employees. If OSHA inspects your workplace for compliance with the HCS, the OSHA compliance officer will ask to see your written plan at the outset of the inspection. In general, the following items will be considered in evaluating your program. The written program must describe how the requirements for labels and other forms of warning, material safety data sheets, and employee information and training, are going to be met in your facility. The following discussion provides the type of information compliance officers will be looking for to decide whether these elements of the hazard communication program have been properly addressed:

A. Labels and Other Forms of Warning

In-plant containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings. Chemical manufacturers, importers, and distributors are required to ensure that every container of hazardous chemicals they ship is appropriately labeled with such information and with the name and address of the producer or other responsible party. Employers purchasing chemicals can rely on the labels provided by their suppliers. If the material is subsequently transferred by the employer from a labeled container to another container, the employer will have to label that container unless it is subject to the portable container exemption. See paragraph (f) of this section for specific labeling requirements. The primary information to be obtained from an OSHA-required label is an identity for the material, and appropriate hazard warnings. The identity is any term which appears on the label, the MSDS, and the list of chemicals, and thus links these three sources of information. The identity used by supplier may be a common or trade name ("Black Magic Formula"), or a chemical name (1,1,1,-trichloroethane). The hazard warning is a brief statement of the hazardous effects of the chemical ("flammable," "causes lung damage"). Labels frequently contain other information, such as precautionary measures ("do not use near open flame"), but this information is provided voluntarily and is not required by the rule. Labels must be legible, and prominently displayed. There are no specific requirements for size or color, or any specified text. With these requirements in mind, the compliance officer will be looking for the following types of information to ensure that labeling will be properly implemented in your facility:

1. Designation of person(s) responsible for ensuring labeling of in-plant containers;
2. Designation of person(s) responsible for ensuring labeling of any shipped

containers; 3. Description of labeling system(s) used; 4. Description of written alternatives to labeling of in-plant containers (if used); and, 5. Procedures to review and update label information when necessary. Employers that are purchasing and using hazardous chemicals-rather than producing or distributing them-will primarily be concerned with ensuring that every purchased container is labeled. If materials are transferred into other containers, the employer must ensure that these are labeled as well, unless they fall under the portable container exemption (paragraph (f)(7) of this section). In terms of labeling systems, you can simply choose to use the labels provided by your suppliers on the containers. These will generally be verbal text labels, and do not usually include numerical rating systems or symbols that require special training. The most important thing to remember is that this is a continuing duty-all in-plant containers of hazardous chemicals must always be labeled. Therefore, it is important to designate someone to be responsible for ensuring that the labels are maintained as required on the containers in your facility, and that newly purchased materials are checked for labels prior to use.

B. Material Safety Data Sheets Chemical manufacturers and importers are required to obtain or develop a material safety data sheet for each hazardous chemical they produce or import. Distributors are responsible for ensuring that their customers are provided a copy of these MSDSs. Employers must have an MSDS for each hazardous chemical which they use. Employers may rely on the information received from their suppliers. The specific requirements for material safety data sheets are in paragraph (g) of this section. There is no specified format for the MSDS under the rule, although there are specific information requirements. OSHA has developed a non-mandatory format, OSHA Form 174, which may be used by chemical manufacturers and importers to comply with the rule. The MSDS must be in English. You are entitled to receive from your supplier a data sheet which includes all of the information required under the rule. If you do not receive one automatically, you should request one. If you receive one that is obviously inadequate, with, for example, blank spaces that are not completed, you should request an appropriately completed one. If your request for a data sheet or for a corrected data sheet does not produce the information needed, you should contact your local OSHA Area Office for assistance in obtaining the MSDS. The role of MSDSs under the rule is to provide detailed information on each hazardous chemical, including its potential hazardous effects, its physical and chemical characteristics, and recommendations for appropriate protective measures. This information should be useful to you as the employer responsible for designing protective programs, as well as to the workers. If you are not familiar with material safety data sheets and with chemical terminology, you may need to learn to use them yourself. A glossary of MSDS terms may be helpful in this regard. Generally speaking, most employers using hazardous chemicals will primarily be concerned with MSDS information regarding hazardous effects and recommended protective measures. Focus on the sections of the MSDS that are applicable to your situation. MSDSs must be readily accessible to employees when they are in their work areas during their workshifts. This may be accomplished in many different ways. You must decide what is appropriate for your particular workplace. Some employers keep the MSDSs in a binder in a central location (e.g., in the pick-up truck on a construction site). Others, particularly in workplaces with large numbers of chemicals, computerize the information and provide access through terminals. As long as employees can get the information when they need it, any approach may be used. The employees must have access to the MSDSs themselves-simply having a system where the information can be read to them over the phone is only permitted under the mobile worksite provision, paragraph (g)(9) of this section, when employees must travel between

workplaces during the shift. In this situation, they have access to the MSDSs prior to leaving the primary worksite, and when they return, so the telephone system is simply an emergency arrangement. In order to ensure that you have a current MSDS for each chemical in the plant as required, and that employee access is provided, the compliance officers will be looking for the following types of information in your written program: 1. Designation of person(s) responsible for obtaining and maintaining the MSDSs; 2. How such sheets are to be maintained in the workplace (e.g., in notebooks in the work area(s) or in a computer with terminal access), and how employees can obtain access to them when they are in their work area during the work shift; 3. Procedures to follow when the MSDS is not received at the time of the first shipment; 4. For producers, procedures to update the MSDS when new and significant health information is found; and, 5. Description of alternatives to actual data sheets in the workplace, if used. For employers using hazardous chemicals, the most important aspect of the written program in terms of MSDSs is to ensure that someone is responsible for obtaining and maintaining the MSDSs for every hazardous chemical in the workplace. The list of hazardous chemicals required to be maintained as part of the written program will serve as an inventory. As new chemicals are purchased, the list should be updated. Many companies have found it convenient to include on their purchase orders the name and address of the person designated in their company to receive MSDSs.

C. Employee Information and Training Each employee who may be "exposed" to hazardous chemicals when working must be provided information and trained prior to initial assignment to work with a hazardous chemical, and whenever the hazard changes. "Exposure" or "exposed" under the rule means that "an employee is subjected to a hazardous chemical in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.) and includes potential (e.g., accidental or possible) exposure." See paragraph (h) of this section for specific requirements. Information and training may be done either by individual chemical, or by categories of hazards (such as flammability or carcinogenicity). If there are only a few chemicals in the workplace, then you may want to discuss each one individually. Where there are large numbers of chemicals, or the chemicals change frequently, you will probably want to train generally based on the hazard categories (e.g., flammable liquids, corrosive materials, carcinogens). Employees will have access to the substance-specific information on the labels and MSDSs. Information and training is a critical part of the hazard communication program. Information regarding hazards and protective measures are provided to workers through written labels and material safety data sheets. However, through effective information and training, workers will learn to read and understand such information, determine how it can be obtained and used in their own workplaces, and understand the risks of exposure to the chemicals in their workplaces as well as the ways to protect themselves. A properly conducted training program will ensure comprehension and understanding. It is not sufficient to either just read material to the workers, or simply hand them material to read. You want to create a climate where workers feel free to ask questions. This will help you to ensure that the information is understood. You must always remember that the underlying purpose of the HCS is to reduce the incidence of chemical source illnesses and injuries. This will be accomplished by modifying behavior through the provision of hazard information and information about protective measures. If your program works, you and your workers will better understand the chemical hazards within the workplace. The procedures you establish regarding, for example, purchasing, storage, and handling of these chemicals will improve, and thereby reduce the risks posed to employees exposed to the chemical hazards involved. Furthermore, your workers'

comprehension will also be increased, and proper work practices will be followed in your workplace.

If you are going to do the training yourself, you will have to understand the material and be prepared to motivate the workers to learn. This is not always an easy task, but the benefits are worth the effort. More information regarding appropriate training can be found in OSHA Publication No. 2254 which contains voluntary training guidelines prepared by OSHA's Training Institute. A copy of this document is available from OSHA's Publications Office at (202) 219-4667. In reviewing your written program with regard to information and training, the following items need to be considered:

1. Designation of person(s) responsible for conducting training;
2. Format of the program to be used (audiovisuals, classroom instruction, etc.);
3. Elements of the training program (should be consistent with the elements in paragraph (h) of this section); and,
4. Procedure to train new employees at the time of their initial assignment to work with a hazardous chemical, and to train employees when a new hazard is introduced into the workplace. The written program should provide enough details about the employer's plans in this area to assess whether or not a good faith effort is being made to train employees. OSHA does not expect that every worker will be able to recite all of the information about each chemical in the workplace. In general, the most important aspects of training under the HCS are to ensure that employees are aware that they are exposed to hazardous chemicals, that they know how to read and use labels and material safety data sheets, and that, as a consequence of learning this information, they are following the appropriate protective measures established by the employer. OSHA compliance officers will be talking to employees to determine if they have received training, if they know they are exposed to hazardous chemicals, and if they know where to obtain substance-specific information on labels and MSDSs. The rule does not require employers to maintain records of employee training, but many employers choose to do so. This may help you monitor your own program to ensure that all employees are appropriately trained. If you already have a training program, you may simply have to supplement it with whatever additional information is required under the HCS. For example, construction employers that are already in compliance with the construction training standard (29 CFR 1926.21) will have little extra training to do. An employer can provide employees information and training through whatever means are found appropriate and protective. Although there would always have to be some training on-site (such as informing employees of the location and availability of the written program and MSDSs), employee training may be satisfied in part by general training about the requirements of the HCS and about chemical hazards on the job which is provided by, for example, trade associations, unions, colleges, and professional schools. In addition, previous training, education and experience of a worker may relieve the employer of some of the burdens of informing and training that worker. Regardless of the method relied upon, however, the employer is always ultimately responsible for ensuring that employees are adequately trained. If the compliance officer finds that the training is deficient, the employer will be cited for the deficiency regardless of who actually provided the training on behalf of the employer. D. Other

Requirements In addition to these specific items, compliance officers will also be asking the following questions in assessing the adequacy of the program: Does a list of the hazardous chemicals exist in each work area or at a central location? Are methods the employer will use to inform employees of the hazards of non-routine tasks outlined? Are employees informed of the hazards associated with chemicals contained in unlabeled pipes in their work areas? On multi-employer worksites, has the employer provided other employers with information about labeling systems and precautionary measures where the other employers have employees exposed to the initial employer's chemicals? Is the written program made available to employees and their designated representatives? If your program adequately addresses the means of communicating information to employees in your workplace, and provides answers to the basic questions outlined above, it will be found to be in compliance with the rule.

5. Checklist for Compliance The following checklist will help to ensure you are in compliance with the rule:

- Obtained a copy of the rule. _____
- Read and understood the requirements. _____
- Assigned responsibility for tasks. _____
- Prepared an inventory of chemicals. _____
- Ensured containers are labeled. _____
- Obtained MSDS for each chemical. _____
- Prepared written program. _____
- Made MSDSs available to workers. _____
- Conducted training of workers. _____
- Established procedures to maintain current program. _____
- Established procedures to evaluate effectiveness. _____

6. Further Assistance If you have a question regarding compliance with the HCS, you should contact your local OSHA Area Office for assistance. In addition, each OSHA Regional Office has a Hazard Communication Coordinator who can answer your questions. Free consultation services are also available to assist employers, and information regarding these services can be obtained through the Area and Regional offices as well. The telephone number for the OSHA office closest to you should be listed in your local telephone directory. If you are not able to obtain this information, you may contact OSHA's Office of Information and Consumer Affairs at (202) 219-8151 for further assistance in identifying the appropriate contacts.

[59 FR 65947, December 22, 1994]

**APPENDIX F TO §1910.1200 – GUIDANCE FOR HAZARD
CLASSIFICATIONS
RE: CARCINOGENICITY (NON-MANDATORY)**

The mandatory criteria for classification of a chemical for carcinogenicity under HCS are found in Appendix A.6. This non-mandatory Appendix provides additional guidance on hazard classification for carcinogenicity. Part A of Appendix F includes background guidance provided by GHS based on the Preamble of the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006). Part B provides IARC classification information. Part C provides background guidance from the National Toxicology Program (NTP) "Report on Carcinogens" (RoC), and Part D is a table that compares GHS carcinogen hazard categories to carcinogen classifications under IARC and NTP, allowing classifiers to be able to use information from IARC and NTP RoC carcinogen classifications to complete their classifications under the GHS, and thus the HCS.

Part A: Background Guidance¹

As noted in Footnote 6 of Appendix A.6., the GHS includes as guidance for classifiers information taken from the Preamble of the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006), providing guidance on the evaluation of the strength and evidence of carcinogenic risks to humans. This guidance also discusses some additional considerations in classification and an approach to analysis, rather than hard-and-fast rules. Part A is consistent with Appendix A.6, and should help in evaluating information to determine carcinogenicity.

Carcinogenicity in humans:

The evidence relevant to carcinogenicity from studies in humans is classified into one of the following categories:

- (a) ***Sufficient evidence of carcinogenicity:*** A causal relationship has been established between exposure to the agent and human cancer. That is, a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence.

- (b) ***Limited evidence of carcinogenicity:*** A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.

In some instances, the above categories may be used to classify the degree of evidence related to carcinogenicity in specific organs or tissues.

Carcinogenicity in experimental animals:

The evidence relevant to carcinogenicity in experimental animals is classified into one of the following categories:

(a) **Sufficient evidence of carcinogenicity:** A causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (i) two or more species of animals or (ii) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumors in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide sufficient evidence.

Exceptionally, a single study in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumor or age at onset, or when there are strong findings of tumors at multiple sites.

(a) **Limited evidence of carcinogenicity:** The data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g. (i) the evidence of carcinogenicity is restricted to a single experiment; (ii) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; (iii) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or (iv) the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.

Guidance on how to consider important factors in classification of carcinogenicity (See Reference Section)

The weight of evidence analysis called for in GHS and the HCS is an integrative approach that considers important factors in determining carcinogenic potential along with the strength of evidence analysis. The IPCS "**Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis**" (2001), International Life Sciences Institute (ILSI) "**Framework for Human Relevance Analysis of Information on Carcinogenic Modes of Action**" (Meek, et al., 2003; Cohen et al., 2003, 2004), and Preamble to the IARC Monographs (2006; Section B.6. (Scientific Review and Evaluation; Evaluation and Rationale)) provide a basis for systematic assessments that may be performed in a consistent fashion. The IPCS also convened a panel in 2004 to further develop and clarify the human relevance framework. However, the above documents are not intended to dictate answers, nor provide lists of criteria to be checked off.

Mode of action

Various documents on carcinogen assessment all note that mode of action in and of itself, or consideration of comparative metabolism, should be evaluated on a case-by-case basis and are part of an analytic evaluative approach. One must look closely at any mode of action in animal

experiments, taking into consideration comparative toxicokinetics / toxicodynamics between the animal test species and humans to determine the relevance of the results to humans. This may lead to the possibility of discounting very specific effects of certain types of substances. Life stage-dependent effects on cellular differentiation may also lead to qualitative differences between animals and humans. Only if a mode of action of tumor development is conclusively determined not to be operative in humans may the carcinogenic evidence for that tumor be discounted. However, a weight of evidence evaluation for a substance calls for any other tumorigenic activity to be evaluated, as well.

Responses in multiple animal experiments

Positive responses in several species add to the weight of evidence that a substance is a carcinogen. Taking into account all of the factors listed in A.6.2.5.2 and more, such chemicals with positive outcomes in two or more species would be provisionally considered to be classified in GHS Category 1B until human relevance of animal results are assessed in their entirety. It should be noted, however, that positive results for one species in at least two independent studies, or a single positive study showing unusually strong evidence of malignancy may also lead to Category 1B.

Responses are in one sex or both sexes

Any case of gender-specific tumors should be evaluated in light of the total tumorigenic response to the substance observed at other sites (multi-site responses or incidence above background) in determining the carcinogenic potential of the substance. If tumors are seen only in one sex of an animal species, the mode of action should be carefully evaluated to see if the response is consistent with the postulated mode of action. Effects seen only in one sex in a test species may be less convincing than effects seen in both sexes, unless there is a clear patho-physiological difference consistent with the mode of action to explain the single sex response.

Confounding effects of excessive toxicity or localized effects

Tumors occurring only at excessive doses associated with severe toxicity generally have doubtful potential for carcinogenicity in humans. In addition, tumors occurring only at sites of contact and/or only at excessive doses need to be carefully evaluated for human relevance for carcinogenic hazard. For example, forestomach tumors, following administration by gavage of an irritating or corrosive, non-mutagenic chemical, may be of questionable relevance. However, such determinations must be evaluated carefully in justifying the carcinogenic potential for humans; any occurrence of other tumors at distant sites must also be considered.

Tumor type, reduced tumor latency

Unusual tumor types or tumors occurring with reduced latency may add to the weight of evidence for the carcinogenic potential of a substance, even if the tumors are not statistically significant.

Toxicokinetic behavior is normally assumed to be similar in animals and humans, at least from a qualitative perspective. On the other hand, certain tumor types in animals may be associated with toxicokinetics or toxicodynamics that are unique to the animal species tested and may not be predictive of carcinogenicity in humans. Very few such examples have been agreed internationally. However, one example is the lack of human relevance of kidney tumors in male rats associated with compounds causing α_2 -globulin nephropathy (IARC, Scientific Publication N° 147²). Even when a particular tumor type may be discounted, expert judgment must be used in assessing the total tumor profile in any animal experiment.

Part B: International Agency for Research on Cancer (IARC)³

IARC Carcinogen Classification Categories:

Group 1: The agent is *carcinogenic to humans*.

This category is used when there is *sufficient evidence of carcinogenicity* in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than *sufficient* but there is *sufficient evidence of carcinogenicity* in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Group 2:

This category includes agents for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost *sufficient*, as well as those for which, at the other extreme, there are no human data but for which there is evidence of carcinogenicity in experimental animals. Agents are assigned to either Group 2A (*probably carcinogenic to humans*) or Group 2B (*possibly carcinogenic to humans*) on the basis of epidemiological and experimental evidence of carcinogenicity and mechanistic and other relevant data. The terms *probably carcinogenic* and *possibly carcinogenic* have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with *probably carcinogenic* signifying a higher level of evidence than possibly carcinogenic.

Group 2A: The agent is *probably carcinogenic to humans*.

This category is used when there is *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals. In some cases, an agent may be classified in this category when there is *inadequate evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, an agent may be classified in this category solely on the basis of *limited evidence of carcinogenicity* in humans. An agent may be assigned to this category if it clearly belongs, based on mechanistic considerations, to a class of agents for which one or more members have been classified in Group 1 or Group 2A.

Group 2B: The agent is *possibly carcinogenic to humans*.

This category is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than **sufficient evidence of carcinogenicity** in experimental animals. It may also be used when there is *inadequate evidence of carcinogenicity* in humans but there is *sufficient evidence of carcinogenicity* in experimental animals. In some instances, an agent for which there is *inadequate evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data.

Part C: National Toxicology Program (NTP), "Report on Carcinogens", Background Guidance

NTP Listing Criteria⁴:

The criteria for listing an agent, substance, mixture, or exposure circumstance in the Report on Carcinogens (RoC) are as follows:

Known To Be A Human Carcinogen: There is sufficient evidence of carcinogenicity from studies in humans⁵ that indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

Reasonably Anticipated To Be A Human Carcinogen: There is limited evidence of carcinogenicity from studies in humans that indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,

or

there is sufficient evidence of carcinogenicity from studies in experimental animals that indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site, or type of tumor, or age at onset,

or

there is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms that do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

Part D. Table Relating Approximate Equivalences among IARC, NTP RoC, and GHS Carcinogenicity Classifications

The following table may be used to perform hazard classifications for carcinogenicity under the HCS. It relates the approximated GHS hazard categories for carcinogenicity to the classifications provided by IARC and NTP, as described in Parts B and C of this Appendix.

| Approximate Equivalences Among Carcinogen Classification Schemes | | |
|---|-------------|--|
| IARC | GHS | NTP RoC |
| Group 1 | Category 1A | Known |
| Group 2A | Category 1B | Reasonably Anticipated (See Note 1) |
| Group 2B | Category 2 | |

Note 1:

1. *Limited evidence of carcinogenicity from studies in humans (corresponding to IARC 2A / GHS 1B);*
2. *Sufficient evidence of carcinogenicity from studies in experimental animals (again, essentially corresponding to IARC 2A / GHS 1B);*
3. *Less than sufficient evidence of carcinogenicity in humans or laboratory animals; however:*
 - a. *The agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous RoC as either "Known" or "Reasonably Anticipated" to be a human carcinogen, or*
 - b. *There is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.*

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Footnote 1 The text of Appendix F, Part A, on the IARC Monographs, is paraphrased from the 2006 Preamble to the "Monographs on the Evaluation of Carcinogenic Risks to Humans" the Classifier is referred to the full IARC Preamble for the complete text. The text is not part of the agreed GHS text on the harmonized system developed by the OECD Task Force-HCL.

Footnote 2 While most international agencies do not consider kidney tumors coincident with a2u-globulin nephropathy to be a predictor of risk in humans, this view is not universally held. (See: Doi et al., 2007)

Footnote 3 Preamble of the International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (2006)

Footnote 4 See: <http://ntp.niehs.nih.gov/go/15209>

Footnote 5 This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues or cells from humans exposed to the substance in question that can be useful for evaluating whether a relevant cancer mechanism is

operating in people.

1910.1201 Retention of DOT markings, placards and labels.

(a) Any employer who receives a package of hazardous material which is required to be marked, labeled or placarded in accordance with the U. S. Department of Transportation's Hazardous Materials Regulations (49 CFR Parts 171 through 180) shall retain those markings, labels and placards on the package until the packaging is sufficiently cleaned of residue and purged of vapors to remove any potential hazards.

(b) Any employer who receives a freight container, rail freight car, motor vehicle, or transport vehicle that is required to be marked or placarded in accordance with the Hazardous Materials Regulations shall retain those markings and placards on the freight container, rail freight car, motor vehicle or transport vehicle until the hazardous materials which require the marking or placarding are sufficiently removed to prevent any potential hazards.

(c) Markings, placards and labels shall be maintained in a manner that ensures that they are readily visible.

(d) For non-bulk packages which will not be reshipped, the provisions of this section are met if a label or other acceptable marking is affixed in accordance with the Hazard Communication Standard (29 CFR 1910.1200).

(e) For the purposes of this section, the term "hazardous material" and any other terms not defined in this section have the same definition as in the Hazardous Materials Regulations (49 CFR Parts 171 through 180).

1910.1450 Occupational exposure to hazardous chemicals in laboratories.

* (Section 1910.1450 was added by 55 FR 3327, Jan. 31, 1990)

(a) Scope and application.

(1) This section shall apply to all employers engaged in the laboratory use of hazardous chemicals as defined below.

(2) Where this section applies, it shall supersede, for laboratories, the requirements of all other OSHA health standards in 29 CFR part 1910, subpart Z, except as follows:

(i) For any OSHA health standard, only the requirement to limit employee exposure to the specific permissible exposure limit shall apply for laboratories, unless that particular standard states otherwise or unless the conditions of paragraph (a)(2)(iii) of this section apply.

(ii) Prohibition of eye and skin contact where specified by any OSHA health standard shall be observed.

(iii) Where the action level (or in the absence of an action level, the permissible exposure limit) is routinely exceeded for an OSHA regulated substance with exposure monitoring and medical surveillance requirements paragraphs (d) and (g)(1)(ii) of this section shall apply.

(3) This section shall not apply to:

(i) Uses of hazardous chemicals which do not meet the definition of laboratory use, and in such cases, the employer shall comply with the relevant standard in 29 CFR part 1910, subpart 2, even if such use occurs in a laboratory.

(ii) Laboratory uses of hazardous chemicals which provide no potential for employee exposure. Examples of such conditions might include:

(A) Procedures using chemically-impregnated test media such as Dip-and-Read tests where a reagent strip is dipped into the specimen to be tested and the results are interpreted by comparing the color reaction to a color chart supplied by the manufacturer of the test strip; and

(B) Commercially prepared kits such as those used in performing pregnancy tests in which all of the reagents needed to conduct the test are contained in the kit.

(b) Definitions -

"Action level" means a concentration designated in 29 CFR part 1910 for a specific substance, calculated as an eight (8)-hour time-weighted average, which initiates certain required activities such as exposure monitoring and medical surveillance.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Carcinogen" (see "select carcinogen").

"Chemical Hygiene Officer" means an employee who is designated by the employer, and who is qualified by training or experience, to provide technical guidance in the development and implementation of the provisions of the Chemical Hygiene Plan. This definition is not intended to place limitations on the position description or job classification that the designated individual shall hold within the employer's organizational structure.

"Chemical Hygiene Plan" means a written program developed and implemented by the

employer which sets forth procedures, equipment, personal protective equipment and work practices that (i) are capable of protecting employees from the health hazards presented by hazardous chemicals used in that particular workplace and (ii) meets the requirements of paragraph (e) of this section.

"Combustible liquid" means any liquid having a flashpoint at or above 100 deg. F (37.8 deg. C), but below 200 deg. F (93.3 deg. C), except any mixture having components with flashpoints of 200 deg. F (93.3 deg. C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.

"Compressed gas" means:

(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70 deg. F (21.1 deg. C); or

(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130 deg. F (54.4 deg. C) regardless of the pressure at 70 deg. F (21.1 deg. C); or

(iii) A liquid having a vapor pressure exceeding 40 psi at 100 deg. F (37.8 C) as determined by ASTM D-323-72.

"Designated area" means an area which may be used for work with "select carcinogens," reproductive toxins or substances which have a high degree of acute toxicity. A designated area may be the entire laboratory, such as a laboratory hood.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers or failure of control equipment which results in an uncontrolled release of a hazardous chemical into the workplace.

"Employee" means an individual employed in a laboratory workplace who may be exposed to hazardous chemicals in the course of his or her assignments.

"Explosive" means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

"Flammable" means a chemical that falls into one of the following categories:

(i) "Aerosol, flammable" means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame protection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening;

(ii) "Gas, flammable" means:

(A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of 13 percent by volume or less; or

(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than 12 percent by volume, regardless of the lower limit.

(iii) "Liquid, flammable" means any liquid having a flashpoint below 100 deg F (37.8 deg. C), except any mixture having components with flashpoints of 100 deg. C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

(iv) "Solid, flammable" means a solid, other than a blasting agent or explosive as defined in 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

"Flashpoint" means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24 - 1979 (ASTM D 56-79)) - for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100 deg. F (37.8 deg. C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (See American National Standard Method of Test for Flashpoint by Pensky-Martens Closed Tester, Z11.7 - 1979 (ASTM D 93-79)) - for liquids with a viscosity equal to or greater than 45 SUS at 100 deg. F (37.8 deg. C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of test for Flash Point by Setaflash Closed Tester (ASTM D 3278-78)).

Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flashpoint determination methods specified above.

"Hazardous chemical" means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that

acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic systems, and agents which damage the lungs, skin, eyes, or mucous membranes.

Appendices A and B of the Hazard Communication Standard (29 CFR 1910.1200) provide further guidance in defining the scope of health hazards and determining whether or not a chemical is to be considered hazardous for purposes of this standard.

"Laboratory" means a facility where the "laboratory use of hazardous chemicals" occurs. It is a workplace where relatively small quantities of hazardous chemicals are used on a non-production basis.

"Laboratory scale" means work with substances in which the containers used for reactions, transfers, and other handling of substances are designed to be easily and safely manipulated by one person. "Laboratory scale" excludes those workplaces whose function is to produce commercial quantities of materials.

"Laboratory-type hood" means a device located in a laboratory, enclosure on five sides with a movable sash or fixed partial enclosed on the remaining side; constructed and maintained to draw air from the laboratory and to prevent or minimize the escape of air contaminants into the laboratory; and allows chemical manipulations to be conducted in the enclosure without insertion of any portion of the employee's body other than hands and arms.

Walk-in hoods with adjustable sashes meet the above definition provided that the sashes are adjusted during use so that the airflow and the exhaust of air contaminants are not compromised and employees do not work inside the enclosure during the release of airborne hazardous chemicals.

"Laboratory use of hazardous chemicals" means handling or use of such chemicals in which all of the following conditions are met:

- (i) Chemical manipulations are carried out on a "laboratory scale;"
- (ii) Multiple chemical procedures or chemicals are used;
- (iii) The procedures involved are not part of a production process, nor in any way simulate a production process; and
- (iv) "Protective laboratory practices and equipment" are available and in common use to minimize the potential for employee exposure to hazardous chemicals.

"Medical consultation" means a consultation which takes place between an employee and a licensed physician for the purpose of determining what medical examinations or procedures, if any, are appropriate in cases where a significant exposure to a hazardous chemical may have taken place.

"Organic peroxide" means an organic compound that contains the bivalent -O-O- structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

"Oxidizer" means a chemical other than a blasting agent or explosive as defined in 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

"Physical hazard" means a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.

"Protective laboratory practices and equipment" means those laboratory procedures, practices and equipment accepted by laboratory health and safety experts as effective, or that the employer can show to be effective, in minimizing the potential for employee exposure to hazardous chemicals.

"Reproductive toxins" means chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis).

"Select carcinogen" means any substance which meets one of the following criteria:

- (i) It is regulated by OSHA as a carcinogen; or
- (ii) It is listed under the category, "known to be carcinogens," in the Annual Report on Carcinogens published by the National Toxicology Program (NTP)(latest edition); or
- (iii) It is listed under Group 1 ("carcinogenic to humans") by the International Agency for research on Cancer Monographs (IARC)(latest editions); or
- (iv) It is listed in either Group 2A or 2B by IARC or under the category, "reasonably anticipated to be carcinogens" by NTP, and causes statistically significant tumor incidence in experimental animals in accordance with any of the following criteria:
 - (A) After inhalation exposure of 6 - 7 hours per day, 5 days per week, for a significant portion

of a lifetime to dosages of less than 10 mg/m(3);

(B) After repeated skin application of less than 300 (mg/kg of body weight) per week; or

(C) After oral dosages of less than 50 mg/kg of body weight per day.

"Unstable (reactive)" means a chemical which is the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shocks, pressure or temperature.

"Water-reactive" means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

(c) Permissible exposure limits. For laboratory uses of OSHA regulated substances, the employer shall assure that laboratory employees' exposures to such substances do not exceed the permissible exposure limits specified in 29 CFR part 1910, subpart Z.

(d) Employee exposure determination

(1) Initial monitoring. The employer shall measure the employee's exposure to any substance regulated by a standard which requires monitoring if there is reason to believe that exposure levels for that substance routinely exceed the action level (or in the absence of an action level, the PEL).

(2) Periodic monitoring. If the initial monitoring prescribed by paragraph (d)(1) of this section discloses employee exposure over the action level (or in the absence of an action level, the PEL), the employer shall immediately comply with the exposure monitoring provisions of the relevant standard.

(3) Termination of monitoring. Monitoring may be terminated in accordance with the relevant standard.

(4) Employee notification of monitoring results. The employer shall, within 15 working days after the receipt of any monitoring results, notify the employee of these results in writing either individually or by posting results in an appropriate location that is accessible to employees.

(e) Chemical hygiene plan - General. (Appendix A of this section is non-mandatory but provides guidance to assist employers in the development of the Chemical Hygiene Plan.)

(1) Where hazardous chemicals as defined by this standard are used in the workplace, the employer shall develop and carry out the provisions of a written Chemical Hygiene Plan which is:

(i) Capable of protecting employees from health hazards associated with hazardous chemicals in that laboratory and

(ii) Capable of keeping exposures below the limits specified in paragraph (c) of this section.

(2) The Chemical Hygiene Plan shall be readily available to employees, employee representatives and, upon request, to the Assistant Secretary.

(3) The Chemical Hygiene Plan shall include each of the following elements and shall indicate specific measures that the employer will take to ensure laboratory employee protection;

(i) Standard operating procedures relevant to safety and health considerations to be followed when laboratory work involves the use of hazardous chemicals;

(ii) Criteria that the employer will use to determine and implement control measures to reduce employee exposure to hazardous chemicals including engineering controls, the use of personal protective equipment and hygiene practices; particular attention shall be given to the selection of control measures for chemicals that are known to be extremely hazardous;

(iii) A requirement that fume hoods and other protective equipment are functioning properly and specific measures that shall be taken to ensure proper and adequate performance of such equipment;

(iv) Provisions for employee information and training as prescribed in paragraph (f) of this section;

(v) The circumstances under which a particular laboratory operation, procedure or activity shall require prior approval from the employer or the employer's designee before implementation;

(vi) Provisions for medical consultation and medical examinations in accordance with paragraph (g) of this section;

(vii) Designation of personnel responsible for implementation of the Chemical Hygiene Plan including the assignment of a Chemical Hygiene Officer, and, if appropriate, establishment of a Chemical Hygiene Committee; and

(viii) Provisions for additional employee protection for work with particularly hazardous substances. These include "select carcinogens," reproductive toxins and substances which have a high degree of acute toxicity. Specific consideration shall be given to the following provisions which shall be included where appropriate:

- (A) Establishment of a designated area;
- (B) Use of containment devices such as fume hoods or glove boxes;
- (C) Procedures for safe removal of contaminated waste; and
- (D) Decontamination procedures.

(4) The employer shall review and evaluate the effectiveness of the Chemical Hygiene Plan at least annually and update it as necessary.

(f) Employee information and training.

(1) The employer shall provide employees with information and training to ensure that they are apprised of the hazards of chemicals present in their work area.

(2) Such information shall be provided at the time of an employee's initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. The frequency of refresher information and training shall be determined by the employer.

(3) Information. Employees shall be informed of:

(i) The contents of this standard and its appendices which shall be made available to employees;

(ii) the location and availability of the employer's Chemical Hygiene Plan;

(iii) The permissible exposure limits for OSHA regulated substances or recommended exposure limits for other hazardous chemicals where there is no applicable OSHA standard;

(iv) Signs and symptoms associated with exposures to hazardous chemicals used in the laboratory; and

(v) The location and availability of known reference material on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, Material Safety Data Sheets received from the chemical supplier.

(4) Training.

(i) Employee training shall include:

(A) Methods and observations that may be used to detect the presence or release of a hazardous chemical (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(B) The physical and health hazards of chemicals in the work area; and

(C) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

(ii) The employee shall be trained on the applicable details of the employer's written Chemical Hygiene Plan.

(g) Medical consultation and medical examinations.

(1) The employer shall provide all employees who work with hazardous chemicals an opportunity to receive medical attention, including any follow-up examinations which the examining physician determines to be necessary, under the following circumstances:

(i) Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory, the employee shall be provided an opportunity to receive an appropriate medical examination.

(ii) Where exposure monitoring reveals an exposure level routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring and medical surveillance requirements, medical surveillance shall be established for the affected employee as prescribed by the particular standard.

(iii) Whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure, the affected employee shall be provided an opportunity for a medical consultation. Such consultation shall be for the purpose of determining the need for a medical examination.

(2) All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

(3) Information provided to the physician. The employer shall provide the following information to the physician:

(i) The identity of the hazardous chemical(s) to which the employee may have been exposed;

(ii) A description of the conditions under which the exposure occurred including quantitative exposure data, if available; and

(iii) A description of the signs and symptoms of exposure that the employee is experiencing, if any.

(4) Physician's written opinion.

(i) For examination or consultation required under this standard, the employer shall obtain a written opinion from the examining physician which shall include the following:

(A) Any recommendation for further medical follow-up;

(B) The results of the medical examination and any associated tests;

(C) Any medical condition which may be revealed in the course of the examination which may place the employee at increased risk as a result of exposure to a hazardous workplace; and

(D) A statement that the employee has been informed by the physician of the results of the consultation or medical examination and any medical condition that may require further examination or treatment.

(ii) The written opinion shall not reveal specific findings of diagnoses unrelated to occupational exposure.

(h) Hazard identification.

(1) With respect to labels and material safety data sheets:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.

(ii) Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees.

(2) The following provisions shall apply to chemical substances developed in the laboratory:

(i) If the composition of the chemical substance which is produced exclusively for the laboratory's use is known, the employer shall determine if it is a hazardous chemical as defined in paragraph (b) of this section. If the chemical is determined to be hazardous, the employer shall provide appropriate training as required under paragraph (f) of this section.

(ii) If the chemical produced is a byproduct whose composition is not known, the employer shall assume that the substance is hazardous and shall implement paragraph (e) of this section.

(iii) If the chemical substance is produced for another user outside of the laboratory, the employer shall comply with the Hazard Communication Standard (29 CFR 1910.120) including the requirements for preparation of material safety data sheets and labeling.

(i) Use of respirators. Where the use of respirators is necessary to maintain exposure below permissible exposure limits, the employer shall provide, at no cost to the employee, the proper respiratory equipment. Respirators shall be selected and used in accordance with the requirements of 29 CFR 1910.134.

(j) Recordkeeping.

(1) The employer shall establish and maintain for each employee an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations including tests or written opinions required by this standard.

(2) The employer shall assure that such records are kept, transferred, and made available in accordance with 29 CFR 1910.1020.

(k) [Reserved]

(l) Appendices. The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

Appendix A to 1910.1450 - National Research Council Recommendations Concerning Chemical Hygiene in Laboratories (Non-Mandatory)

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Foreword

As guidance for each employer's development of an appropriate laboratory Chemical Hygiene Plan, the following non-mandatory recommendations are provided. They were extracted from "Prudent Practices" for Handling Hazardous Chemicals in Laboratories" (referred to below as "Prudent Practices"), which was published in 1981 by the National Research Council and is available from the National Academy Press, 2101 Constitution Ave., NW, Washington DC 20418.

"Prudent Practices" is cited because of its wide distribution and acceptance and because of its preparation by members of the laboratory community through the sponsorship of the National Research Council. However, none of the recommendations given here will modify any requirements of the laboratory standard. This Appendix merely presents pertinent recommendations from "Prudent Practices", organized into a form convenient for quick reference during operation of a laboratory facility and during development and application of a Chemical Hygiene Plan. Users of this appendix should consult "Prudent Practices" for a more extended presentation and justification for each recommendation.

"Prudent Practices" deal with both safety and chemical hazards while the laboratory standard is concerned primarily with chemical hazards. Therefore, only those recommendations directed primarily toward control of toxic exposures are cited in this appendix, with the term "chemical Hygiene" being substituted for the word "safety". However, since conditions producing or threatening physical injury often pose toxic risks as well, page references concerning major categories of safety hazards in the laboratory are given in section F.

The recommendations from "Prudent Practices" have been paraphrased, combined, or otherwise reorganized, and headings have been added. However, their sense has not been changed.

Corresponding Sections of the Standard and this Appendix

The following table is given for the convenience of those who are developing a Chemical Hygiene Plan which will satisfy the requirements of paragraph (e) of the standard. It indicates those sections of this appendix which are most pertinent to each of the sections of paragraph (e) and related paragraphs.

| | | |
|-----------------------------------|------------|------------|
| | : Relevant | |
| Paragraph and topic in laboratory | | : appendix |

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| standard | : | section | : |
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| | : | | |
| (e)(3)(i) Standard operating procedures for handling toxic chemicals. | : | | C, D, E |
| (e)(3)(ii) Criteria to be used for implementation of measures to reduce exposures. | : | | D |
| (e)(3)(iii) Fume hood performance | : | | C4b |
| (e)(3)(iv) Employee information and training (including emergency procedures). | : | | D10, D9 |
| (e)(3)(v) Requirements for prior approval of laboratory activities. | : | | E2b, E4b |
| (e)(3)(vi) Medical consultation and medical examinations. | : | | D5, E4f |
| (e)(3)(vii) Chemical hygiene responsibilities. | : | | B |
| (e)(3)(viii) Special precautions for work with particularly hazardous substances. | : | | E2, E3, E4 |
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| | : | | |

In this appendix, those recommendations directed primarily at administrators and supervisors are given in sections A - D. Those recommendations of primary concern to employees who are actually handling laboratory chemicals are given in section E. (Reference to page numbers in "Prudent Practices" are given in parentheses.)

A. General Principles for Work with Laboratory Chemicals

In addition to the more detailed recommendations listed below in sections B-E, "Prudent Practices" expresses certain general principles, including the following:

1. It is prudent to minimize all chemical exposures. Because few laboratory chemicals are without hazards, general precautions for handling all laboratory chemicals should be adopted, rather than specific guidelines for particular chemicals (2,10). Skin contact with chemicals should be avoided as a cardinal rule (198).

2. Avoid underestimation of risk. Even for substances of no known significant hazard, exposure should be minimized; for work with substances which present special hazards, special precautions should be taken (10, 37, 38). One should assume that any mixture will be more toxic than its most toxic component (30, 103) and that all substances of unknown toxicity are toxic (3, 34).

3. Provide adequate ventilation. The best way to prevent exposure to airborne substances is to prevent their escape into the working atmosphere by use of hoods and other ventilation devices (32, 198).

4. Institute a chemical hygiene program. A mandatory chemical hygiene program designed to minimize exposures is needed; it should be a regular, continuing effort, not merely a standby or short-term activity (6,11). Its recommendations should be followed in academic teaching laboratories as well as by full-time laboratory workers (13).

5. Observe the PELs, TLVs. The Permissible Exposure Limits of OSHA and the Threshold Limit Values of the American Conference of Governmental Industrial Hygienists should not be exceeded (13).

B. Chemical Hygiene Responsibilities

Responsibility for chemical hygiene rests at all levels (6, 11, 21) including the:

1. Chief executive officer, who has ultimate responsibility for chemical hygiene within the institution and must, with other administrators, provide continuing support for institutional chemical hygiene (7, 11).

2. Supervisor of the department or other administrative unit, who is responsible for chemical hygiene in that unit (7).

3. chemical hygiene officer(s), whose appointment is essential (7) and who must:

(a) Work with administrators and other employees to develop and implement appropriate chemical hygiene policies and practices (7);

(b) Monitor procurement, use, and disposal of chemicals used in the lab (8);

(c) See that appropriate audits are maintained (8);

(d) Help project directors develop precautions and adequate facilities (10);

(e) Know the current legal requirements concerning regulated substances (50); and

(f) Seek ways to improve the chemical hygiene program (8, 11).

4. Laboratory supervisor, who has overall responsibility for chemical hygiene in the laboratory (21) including responsibility to:

(a) Ensure that workers know and follow the chemical hygiene rules, that protective equipment is available and in working order, and that appropriate training has been provided (21, 22);

(b) Provide regular, formal chemical hygiene and housekeeping inspections including routine inspections of emergency equipment (21, 171);

(c) Know the current legal requirements concerning regulated substances (50, 231);

(d) Determine the required levels of protective apparel and equipment (156, 160, 162); and

(e) Ensure that facilities and training for use of any material being ordered are adequate (215).

5. Project director or director of other specific operation, who has primary responsibility for chemical hygiene procedures for that operation (7).

6. Laboratory worker, who is responsible for:

(a) Planning and conducting each operation in accordance with the institutional chemical hygiene procedures (7, 21, 22, 230); and

(b) Developing good personal chemical hygiene habits (22).

C. The Laboratory Facility

1. Design. The laboratory facility should have:

(a) An appropriate general ventilation system (see C4 below) with air intakes and exhausts located so as to avoid intake of contaminated air (194);

(b) Adequate, well-ventilated stockrooms/storerrooms (218, 219).

(c) Laboratory hoods and sinks (12, 162);

(d) Other safety equipment including eyewash fountains and drench showers (162, 169); and

(e) Arrangements for waste disposal (12, 240).

2. Maintenance. Chemical-hygiene-related equipment (hoods, incinerator, etc.) should undergo continual appraisal and be modified if inadequate (11, 12).

3. Usage. The work conducted (10) and its scale (12) must be appropriate to the physical facilities available and, especially, to the quality of ventilation (13).

4. Ventilation - (a) General laboratory ventilation. This system should: Provide a source of air for breathing and for input to local ventilation devices (199); it should not be relied on for protection from toxic substances released into the laboratory (198); ensure that laboratory air is continually replaced, preventing increase of air concentrations of toxic substances during the working day (194); direct air flow into the laboratory from non-laboratory areas and out to the exterior of the building (194).

(b) Hoods. A laboratory hood with 2.5 linear feet of hood space per person should be provided for every 2 workers if they spend most of their time working with chemicals (199); each hood should have a continuous monitoring device to allow convenient confirmation of adequate hood performance before use (200, 209). If this is not possible, work with substances of unknown toxicity should be avoided (13) or other types of local ventilation devices should be provided (199). See pp. 201-206 for a discussion of hood design, construction, and evaluation.

(c) Other local ventilation devices. Ventilated storage cabinets, canopy hoods, snorkels, etc. should be provided as needed (199). Each canopy hood and snorkel should have a separate exhaust duct (207).

(d) Special ventilation areas. Exhaust air from glove boxes and isolation rooms should be passed through scrubbers or other treatment before release into the regular exhaust system (208). Cold rooms and warm rooms should have provisions for rapid escape and for escape in the event of electrical failure (209).

(e) Modifications. Any alteration of the ventilation system should be made only if thorough testing indicates that worker protection from airborne toxic substances will continue to be adequate (12, 193, 204).

(f) Performance. Rate: 4-12 room air changes/hour is normally adequate general ventilation if local exhaust systems such as hoods are used as the primary method of control (194).

(g) Quality. General air flow should not be turbulent and should be relatively uniform throughout the laboratory, with no high velocity or static areas (194, 195); airflow into and within the hood should not be excessively turbulent (200); hood face velocity should be adequate (typically 60-100 lfm) (200, 204).

(h) Evaluation. Quality and quantity of ventilation should be evaluated on installation (202), regularly monitored (at least every 3 months) (6, 12, 14, 195), and reevaluated whenever a change in local ventilation devices is made (12, 195, 207). See pp 195-198 for methods of

evaluation and for calculation of estimated airborne contaminant concentrations.

D. Components of the Chemical Hygiene Plan

1. Basic Rules and Procedures (Recommendations for these are given in section E, below)

2. Chemical Procurement, Distribution, and Storage

(a) Procurement. Before a substance is received, information on proper handling, storage, and disposal should be known to those who will be involved (215, 216). No container should be accepted without an adequate identifying label (216). Preferably, all substances should be received in a central location (216).

(b) Stockrooms/storerooms. Toxic substances should be segregated in a well-identified area with local exhaust ventilation (221). Chemicals which are highly toxic (227) or other chemicals whose containers have been opened should be in unbreakable secondary containers (219). Stored chemicals should be examined periodically (at least annually) for replacement, deterioration, and container integrity (218-19).

Stockrooms/storerooms should not be used as preparation or repackaging areas, should be open during normal working hours, and should be controlled by one person (219).

(c) Distribution. When chemicals are hand carried, the container should be placed in an outside container or bucket. Freight-only elevators should be used if possible (223).

(d) Laboratory storage. Amounts permitted should be as small as practical. Storage on bench tops and in hoods is inadvisable. Exposure to heat or direct sunlight should be avoided. Periodic inventories should be conducted, with unneeded items being discarded or returned to the storeroom/stockroom (225-6, 229).

3. Environmental Monitoring

Regular instrumental monitoring of airborne concentrations is not usually justified or practical in laboratories but may be appropriate when testing or redesigning hoods or other ventilation devices (12) or when a highly toxic substance is stored or used regularly (e.g., 3 times/week) (13).

4. Housekeeping, Maintenance, and Inspections

(a) Cleaning. Floors should be cleaned regularly (24).

(b) Inspections. Formal housekeeping and chemical hygiene inspections should be held at least quarterly (6, 21) for units which have frequent personnel changes and semiannually for others; informal inspections should be continual (21).

(c) Maintenance. Eye wash fountains should be inspected at intervals of not less than 3 months (6). Respirators for routine use should be inspected periodically by the laboratory supervisor (169). Other safety equipment should be inspected regularly. (e.g., every 3-6 months) (6, 24, 171). Procedures to prevent restarting of out-of-service equipment should be established (25).

(d) Passageways. Stairways and hallways should not be used as storage areas (24). Access to exits, emergency equipment, and utility controls should never be blocked (24).

5. Medical Program

(a) Compliance with regulations. Regular medical surveillance should be established to the extent required by regulations (12).

(b) Routine surveillance. Anyone whose work involves regular and frequent handling of toxicologically significant quantities of a chemical should consult a qualified physician to determine on an individual basis whether a regular schedule of medical surveillance is desirable (11, 50).

(c) First aid. Personnel trained in first aid should be available during working hours and an emergency room with medical personnel should be nearby (173). See pp. 176-178 for description of some emergency first aid procedures.

6. Protective Apparel and Equipment

These should include for each laboratory:

(a) Protective apparel compatible with the required degree of protection for substances being handled (158-161);

(b) An easily accessible drench-type safety shower (162, 169);

(c) An eyewash fountain (162)

(d) A fire extinguisher (162-164);

(e) Respiratory protection (164-9), fire alarm and telephone for emergency use (162) should be available nearby; and

(f) Other items designated by the laboratory supervisor (156, 160).

7. Records

(a) Accident records should be written and retained (174).

(b) Chemical Hygiene Plan records should document that the facilities and precautions were compatible with current knowledge and regulations (7).

(c) Inventory and usage records for high-risk substances should be kept as specified in sections E3e below.

(d) Medical records should be retained by the institution in accordance with the requirements of state and federal regulations (12).

8. Signs and Labels

Prominent signs and labels of the following types should be posted:

(a) Emergency telephone numbers of emergency personnel/facilities, supervisors, and laboratory workers (28);

(b) Identity labels, showing contents of containers (including waste receptacles) and associated hazards (27, 48);

(c) Location signs for safety showers, eyewash stations, other safety and first aid equipment, exits (27) and areas where food and beverage consumption and storage are permitted (24); and

(d) Warnings at areas or equipment where special or unusual hazards exist (27).

9. Spills and Accidents

(a) A written emergency plan should be established and communicated to all personnel; it should include procedures for ventilation failure (200), evacuation, medical care, reporting, and

drills (172).

(b) There should be an alarm system to alert people in all parts of the facility including isolation areas such as cold rooms (172).

(c) A spill control policy should be developed and should include consideration of prevention, containment, cleanup, and reporting (175).

(d) All accidents or near accidents should be carefully analyzed with the results distributed to all who might benefit (8, 28).

10. Information and Training Program

(a) Aim: To assure that all individuals at risk are adequately informed about the work in the laboratory, its risks, and what to do if an accident occurs (5, 15).

(b) Emergency and Personal Protection Training: Every laboratory worker should know the location and proper use of available protective apparel and equipment (154, 169).

Some of the full-time personnel of the laboratory should be trained in the proper use of emergency equipment and procedures (6).

Such training as well as first aid instruction should be available to (154) and encouraged for (176) everyone who might need it.

(c) Receiving and stockroom/storeroom personnel should know about hazards, handling equipment, protective apparel, and relevant regulations (217).

(d) Frequency of Training: The training and education program should be a regular, continuing activity - not simply an annual presentation (15).

(e) Literature/Consultation: Literature and consulting advice concerning chemical hygiene should be readily available to laboratory personnel, who should be encouraged to use these information resources (14).

11. Waste Disposal Program.

(a) Aim: To assure that minimal harm to people, other organisms, and the environment will result from the disposal of waste laboratory chemicals (5).

(b) Content (14, 232, 233, 240): The waste disposal program should specify how waste is to be collected, segregated, stored, and transported and include consideration of what materials can be incinerated. Transport from the institution must be in accordance with DOT regulations (244).

(c) Discarding Chemical Stocks: Unlabeled containers of chemicals and solutions should undergo prompt disposal; if partially used, they should not be opened (24, 27).

Before a worker's employment in the laboratory ends, chemicals for which that person was responsible should be discarded or returned to storage (226).

(d) Frequency of Disposal: Waste should be removed from laboratories to a central waste storage area at least once per week and from the central waste storage area at regular intervals (14).

(e) Method of Disposal: Incineration in an environmentally acceptable manner is the most practical disposal method for combustible laboratory waste (14, 238, 241).

Indiscriminate disposal by pouring waste chemicals down the drain (14, 231, 242) or adding them to mixed refuse for landfill burial is unacceptable (14).

Hoods should not be used as a means of disposal for volatile chemicals (40, 200).

Disposal by recycling (233, 243) or chemical decontamination (40, 230) should be used when possible.

E. Basic Rules and Procedures for Working with Chemicals

The Chemical Hygiene Plan should require that laboratory workers know and follow its rules and procedures. In addition to the procedures of the sub programs mentioned above, these should include the rules listed below.

1. General Rules

The following should be used for essentially all laboratory work with chemicals:

(a) Accidents and spills - Eye Contact: Promptly flush eyes with water for a prolonged period (15 minutes) and seek medical attention (33, 172).

Ingestion: This is one route of entry for which treatment depends on the type and amount of

chemical involved. Seek medical attention immediately.

Skin Contact: Promptly flush the affected area with water (33, 172, 178) and remove any contaminated clothing (172, 178). If symptoms persist after washing, seek medical attention (33).

Clean-up. Promptly clean up spills, using appropriate protective apparel and equipment and proper disposal (24, 33). See pp. 233-237 for specific clean-up recommendations.

(b) **Avoidance of "routine" exposure:** Develop and encourage safe habits (23); avoid unnecessary exposure to chemicals by any route (23);

Do not smell or taste chemicals (32). Vent apparatus which may discharge toxic chemicals (vacuum pumps, distillation columns, etc.) into local exhaust devices (199).

Inspect gloves (157) and test glove boxes (208) before use.

Do not allow release of toxic substances in cold rooms and warm rooms, since these have contained recirculated atmospheres (209).

(c) **Choice of chemicals:** Use only those chemicals for which the quality of the available ventilation system is appropriate (13).

(d) **Eating, smoking, etc.:** Avoid eating, drinking, smoking, gum chewing, or application of cosmetics in areas where laboratory chemicals are present (22, 24, 32, 40); wash hands before conducting these activities (23, 24).

Avoid storage, handling, or consumption of food or beverages in storage areas, refrigerators, glassware or utensils which are also used for laboratory operations (23, 24, 226).

(e) **Equipment and glassware:** Handle and store laboratory glassware with care to avoid damage; do not use damaged glassware (25). Use extra care with Dewar flasks and other evacuated glass apparatus; shield or wrap them to contain chemicals and fragments should implosion occur (25). Use equipment only for its designed purpose (23, 26).

(f) **Exiting:** Wash areas of exposed skin well before leaving the laboratory (23).

(g) **Horseplay:** Avoid practical jokes or other behavior which might confuse, startle or distract another worker (23).

(h) **Mouth suction:** Do not use mouth suction for pipeting or starting a siphon (23, 32).

(i) Personal apparel: Confine long hair and loose clothing (23, 158). Wear shoes at all times in the laboratory but do not wear sandals, perforated shoes, or sneakers (158).

(j) Personal housekeeping: Keep the work area clean and uncluttered, with chemicals and equipment being properly labeled and stored; clean up the work area on completion of an operation or at the end of each day (24).

(k) Personal protection: Assure that appropriate eye protection (154-156) is worn by all persons, including visitors, where chemicals are stored or handled (22, 23, 33, 154).

Wear appropriate gloves when the potential for contact with toxic materials exists (157); inspect the gloves before each use, wash them before removal, and replace them periodically (157). (A table of resistance to chemicals of common glove materials is given p. 159).

Use appropriate (164-168) respiratory equipment when air contaminant concentrations are not sufficiently restricted by engineering controls (164-5), inspecting the respirator before use (169).

Use any other protective and emergency apparel and equipment as appropriate (22, 157-162).

Avoid use of contact lenses in the laboratory unless necessary; if they are used, inform supervisor so special precautions can be taken (155).

Remove laboratory coats immediately on significant contamination (161).

(l) Planning: Seek information and advice about hazards (7), plan appropriate protective procedures, and plan positioning of equipment before beginning any new operation (22, 23).

(m) Unattended operations: Leave lights on, place an appropriate sign on the door, and provide for containment of toxic substances in the event of failure of a utility service (such as cooling water) to an unattended operation (27, 128).

(n) Use of hood: Use the hood for operations which might result in release of toxic chemical vapors or dust (198-9).

As a rule of thumb, use a hood or other local ventilation device when working with any appreciably volatile substance with a TLV of less than 50 ppm (13).

Confirm adequate hood performance before use; keep hood closed at all times except when adjustments within the hood are being made (200); keep materials stored in hoods to a minimum and do not allow them to block vents or air flow (200).

Leave the hood "on" when it is not in active use if toxic substances are stored in it or if it is uncertain whether adequate general laboratory ventilation will be maintained when it is "off" (200).

(o) Vigilance: Be alert to unsafe conditions and see that they are corrected when detected (22).

(p) Waste disposal: Assure that the plan for each laboratory operation includes plans and training for waste disposal (230).

Deposit chemical waste in appropriately labeled receptacles and follow all other waste disposal procedures of the Chemical Hygiene Plan (22, 24).

Do not discharge to the sewer concentrated acids or bases (231); highly toxic, malodorous, or lachrymatory substances (231); or any substances which might interfere with the biological activity of waste water treatment plants, create fire or explosion hazards, cause structural damage or obstruct flow (242).

(q) Working alone: Avoid working alone in a building; do not work alone in a laboratory if the procedures being conducted are hazardous (28).

2. Working with Allergens and Embryotoxins

(a) Allergens (examples: diazomethane, isocyanates, bichromates): Wear suitable gloves to prevent hand contact with allergens or substances of unknown allergenic activity (35).

(b) Embryotoxins (34-5) (examples: organomercurials, lead compounds, formamide): If you are a woman of childbearing age, handle these substances only in a hood whose satisfactory performance has been confirmed, using appropriate protective apparel (especially gloves) to prevent skin contact.

Review each use of these materials with the research supervisor and review continuing uses annually or whenever a procedural change is made.

Store these substances, properly labeled, in an adequately ventilated area in an unbreakable secondary container.

Notify supervisors of all incidents of exposure or spills; consult a qualified physician when appropriate.

3. Work with Chemicals of Moderate Chronic or High Acute Toxicity

Examples: diisopropylfluorophosphate (41), hydrofluoric acid (43), hydrogen cyanide (45).

Supplemental rules to be followed in addition to those mentioned above (Procedure B of "Prudent Practices", pp. 39-41):

(a) Aim: To minimize exposure to these toxic substances by any route using all reasonable precautions (39).

(b) Applicability: These precautions are appropriate for substances with moderate chronic or high acute toxicity used in significant quantities (39).

(c) Location: Use and store these substances only in areas of restricted access with special warning signs (40, 229).

Always use a hood (previously evaluated to confirm adequate performance with a face velocity of at least 60 linear feet per minute) (40) or other containment device for procedures which may result in the generation of aerosols or vapors containing the substance (39); trap released vapors to prevent their discharge with the hood exhaust (40).

(d) Personal protection: Always avoid skin contact by use of gloves and long sleeves (and other protective apparel as appropriate) (39). Always wash hands and arms immediately after working with these materials (40).

(e) Records: Maintain records of the amounts of these materials on hand, amounts used, and the names of the workers involved (40, 229).

(f) Prevention of spills and accidents: Be prepared for accidents and spills (41).

Assure that at least 2 people are present at all times if a compound in use is highly toxic or of unknown toxicity (39).

Store breakable containers of these substances in chemically resistant trays; also work and mount apparatus above such trays or cover work and storage surfaces with removable, absorbent, plastic backed paper (40).

If a major spill occurs outside the hood, evacuate the area; assure that cleanup personnel wear suitable protective apparel and equipment (41).

(g) Waste: Thoroughly decontaminate or incinerate contaminated clothing or shoes (41). If possible, chemically decontaminate by chemical conversion (40).

Store contaminated waste in closed, suitably labeled, impervious containers (for liquids, in glass or plastic bottles half-filled with vermiculite) (40).

4. Work with Chemicals of High Chronic Toxicity

(Examples: dimethylmercury and nickel carbonyl (48), benzo-a-pyrene (51), N-nitrosodiethylamine (54), other human carcinogens or substances with high carcinogenic potency in animals (38).)

Further supplemental rules to be followed, in addition to all these mentioned above, for work with substances of known high chronic toxicity (in quantities above a few milligrams to a few grams, depending on the substance) (47). (Procedure A of "Prudent Practices" pp. 47-50).

(a) Access: Conduct all transfers and work with these substances in a "controlled area": a restricted access hood, glove box, or portion of a lab, designated for use of highly toxic substances, for which all people with access are aware of the substances being used and necessary precautions (48).

(b) Approvals: Prepare a plan for use and disposal of these materials and obtain the approval of the laboratory supervisor (48).

(c) Non-contamination/Decontamination: Protect vacuum pumps against contamination by scrubbers or HEPA filters and vent them into the hood (49). Decontaminate vacuum pumps or other contaminated equipment, including glassware, in the hood before removing them from the controlled area (49, 50).

Decontaminate the controlled area before normal work is resumed there (50).

(d) Exiting: On leaving a controlled area, remove any protective apparel (placing it in an appropriate, labeled container) and thoroughly wash hands, forearms, face, and neck (49).

(e) Housekeeping: Use a wet mop or a vacuum cleaner equipped with a HEPA filter instead of dry sweeping if the toxic substance was a dry powder (50).

(f) Medical surveillance: If using toxicologically significant quantities of such a substance on a regular basis (e.g., 3 times per week), consult a qualified physician concerning desirability of regular medical surveillance (50).

(g) Records: Keep accurate records of the amounts of these substances stored (229) and used, the dates of use, and names of users (48).

(h) Signs and labels: Assure that the controlled area is conspicuously marked with warning and restricted access signs (49) and that all containers of these substances are appropriately labeled with identity and warning labels (48).

(i) Spills: Assure that contingency plans, equipment, and materials to minimize exposures of people and property in case of accident are available (233-4).

(j) Storage: Store containers of these chemicals only in a ventilated, limited access (48, 227, 229) area in appropriately labeled, unbreakable, chemically resistant, secondary containers (48, 229).

(k) Glove boxes: For a negative pressure glove box, ventilation rate must be at least 2 volume changes/hour and pressure at least 0.5 inches of water (48). For a positive pressure glove box, thoroughly check for leaks before each use (49). In either case, trap the exit gases or filter them through a HEPA filter and then release them into the hood (49).

(l) Waste: Use chemical decontamination whenever possible; ensure that containers of contaminated waste (including washings from contaminated flasks) are transferred from the controlled area in a secondary container under the supervision of authorized personnel (49, 50, 233).

5. Animal Work with Chemicals of High Chronic Toxicity

(a) Access: For large scale studies, special facilities with restricted access are preferable (56).

(b) Administration of the toxic substance: When possible, administer the substance by injection or gavage instead of in the diet. If administration is in the diet, use a caging system under negative pressure or under laminar air flow directed toward HEPA filters (56).

(c) Aerosol suppression: Devise procedures which minimize formation and dispersal of contaminated aerosols, including those from food, urine, and feces (e.g., use HEPA filtered vacuum equipment for cleaning, moisten contaminated bedding before removal from the cage, mix diets in closed containers in a hood) (55, 56).

(d) Personal protection: When working in the animal room, wear plastic or rubber gloves, fully buttoned laboratory coat or jumpsuit and, if needed because of incomplete suppression of

aerosols, other apparel and equipment (shoe and head coverings, respirator) (56).

(e) Waste disposal: Dispose of contaminated animal tissues and excreta by incineration if the available incinerator can convert the contaminant to non-toxic products (238); otherwise, package the waste appropriately for burial in an EPA-approved site (239).

F. Safety Recommendations

The above recommendations from "Prudent Practices" do not include those which are directed primarily toward prevention of physical injury rather than toxic exposure. However, failure of precautions against injury will often have the secondary effect of causing toxic exposures. Therefore, we list below page references for recommendations concerning some of the major categories of safety hazards which also have implications for chemical hygiene:

1. Corrosive agents: (35-6)
2. Electrically powered laboratory apparatus: (179-92)
3. Fires, explosions: (26, 57-74, 162-64, 174-5, 219-20, 226-7)
4. Low temperature procedures: (26, 88)
5. Pressurized and vacuum operations (including use of compressed gas cylinders): (27, 75-101)

G. Material Safety Data Sheets

Material safety data sheets are presented in "Prudent Practices" for the chemicals listed below. (Asterisks denote that comprehensive material safety data sheets are provided).

- *Acetyl peroxide (105)
- *Acrolein (106)
- *Acrylonitrile
- Ammonia (anhydrous)(91)
- *Aniline (109)
- *Benzene (110)
- *Benzo[a]pyrene (112)
- *Bis(chloromethyl) ether (113)
- Boron trichloride (91)
- Boron trifluoride (92)
- Bromine (114)
- *Tert-butyl hydroperoxide (148)
- *Carbon disulfide (116)
- Carbon monoxide (92)
- *Carbon tetrachloride (118)
- *Chlorine (119)
- Chlorine trifluoride (94)

*Chloroform (121)
Chloromethane (93)
*Diethyl ether (122)
Diisopropyl fluorophosphate (41)
*Dimethylformamide (123)
*Dimethyl sulfate (125)
*Dioxane (126)
*Ethylene dibromide (128)
*Fluorine (95)
*Formaldehyde (130)
*Hydrazine and salts (132)
Hydrofluoric acid (43)
Hydrogen bromide (98)
Hydrogen chloride (98)
*Hydrogen cyanide (133)
*Hydrogen sulfide (135)
Mercury and compounds (52)
*Methanol (137)
*Morpholine (138)
*Nickel carbonyl (99)
*Nitrobenzene (139)
Nitrogen dioxide (100)
N-nitrosodiethylamine (54)
*Peracetic acid (141)
*Phenol (142)
*Phosgene (143)
*Pyridine (144)
*Sodium azide (145)
*Sodium cyanide (147)
Sulfur dioxide (101)
*Trichloroethylene (149)
*Vinyl chloride (150)

1910.1450 App B References (Non-Mandatory)
Appendix B to 1910.1450 - References (Non-Mandatory)

The following references are provided to assist the employer in the development of a Chemical Hygiene Plan. The materials listed below are offered as non-mandatory guidance. References listed here do not imply specific endorsement of a book, opinion, technique, policy or a specific

solution for a safety or health problem. Other references not listed here may better meet the needs of a specific laboratory. (a) Materials for the development of the Chemical Hygiene Plan:

1. American Chemical Society, Safety in Academic Chemistry Laboratories, 4th edition, 1985.
2. Fawcett, H.H. and W.S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd edition, Wiley-Interscience, New York, 1982.
3. Flury, Patricia A., Environmental Health and Safety in the Hospital Laboratory, Charles C. Thomas Publisher, Springfield IL, 1978.
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