

[Editor's note: The Occupational Safety and Health Administration promulgated the permanent standard for occupational exposure to lead on November 13, 1978 (43 FR 52952, November 14, 1978). The U.S. Supreme Court June 29, 1981 denied a writ of certiorari to the U.S. Court of Appeals for the District of Columbia Circuit thereby allowing that court's decision (8 OSHC 1810), which substantially upheld the lead standard, to go unreviewed. The D.C. circuit ordered further administrative proceedings as to the applicability of the lead standard to non-ferrous foundries: pigment manufacture; shipbuilding; auto manufacturing; solder manufacture; wire patenting; pottery; brick manufacture; agricultural pesticides manufacture; leather manufacture; pipe galvanizing; gasoline additives manufacture; linoleum-rubber-plastics manufacture; paint spraying; ammunition manufacture; smelting and refining of zinc, silver, gold, platinum, copper and aluminum; machining; lead burning; glass manufacture; textile manufacture; book binding; steel alloy manufacture; ferrous metal manufacturing; glass polishing and spinning; cutlery manufacture; diamond processing; plumbing; jewelry manufacture; pearl processing; casting; cable coating; electroplating; explosive manufacture; lamp manufacture; sheet metal manufacture; tin rolling; telecommunications; and independent collecting and processing of scrap lead (excluding collecting and processing that is part of a secondary smelting operation).]

§ 1910.1025 Lead.

(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.

[Section 1910.1025(a)(2) amended at 44 FR 50338, August 28, 1979, effective immediately]

(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 $\mu\text{g}/\text{m}^3$) 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 $\mu\text{g}/\text{m}^3$) 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 $\mu\text{g}/\text{m}^3$) = 400 hours worked in the day.

[Section 1910.1025(c)(2) corrected at 44 FR 5446, January 26, 1979, effective February 24, 1979]

(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.* (1) 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 (d)(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 the 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 (d)(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) Within 5 working days after the receipt of monitoring results, the employer shall notify each employee in writing of the

[Sec. 1910.1025(d)(8)(ii)]

results which represent that employee's exposure.

(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 $30 \mu\text{g}/\text{m}^3$.

(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 $200 \mu\text{g}/\text{m}^3$, 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 $50 \mu\text{g}/\text{m}^3$.

TABLE I—IMPLEMENTATION SCHEDULE

Industry ¹	Compliance dates ²		
	$200 \mu\text{g}/\text{m}^3$	$100 \mu\text{g}/\text{m}^3$	$50 \mu\text{g}/\text{m}^3$
Primary lead production	(3)	3	10
Secondary lead production	(3)	3	5
Lead acid battery manufacture	(3)	2	5
Automobile manufacture/solder grinding	(3)	N/A	7
Electronics, gray iron foundries, ink manufacture, paints and coatings manufacture, wall paper manufacture, can manufacture, and printing	(3)	N/A	1

TABLE I—IMPLEMENTATION SCHEDULE—Continued

Industry ¹	Compliance dates ²		
	$200 \mu\text{g}/\text{m}^3$	$100 \mu\text{g}/\text{m}^3$	$50 \mu\text{g}/\text{m}^3$
Lead pigment manufacture, nonferrous foundries, leaded steel manufacture, lead chemical manufacture, shipbuilding and ship repair, battery breaking in the collection and processing of scrap (excluding collection and processing of scrap which is part of a secondary smelting operation), secondary lead smelting of copper, and lead casting	(3)	N/A	N/A
All other industries	(3)	N/A	2 1/2

¹ Includes ancillary activities located on the same worksite.
² Expressed as the number of years from the effective date by which compliance with the given airborne exposure level, as an 8-hour TWA must be achieved.

³ On effective date. This continues an obligation from Table Z-2 of 29 CFR 1910.1000, which had been in effect since 1971 but which was deleted upon the effectiveness of this section.

[Section 1910.1025 (e)(1) table amended by 46 FR 6228, January 21, 1981]

[Editor's note: The effective date of Section 1910.1025 (e)(1) table was extended from February 20, 1981, to March 30, 1981, in the February 6, 1981 Federal Register, in accordance with President Reagan's Directive.]

[Section 1910.1025(e)(1) and Table I revised by 46 FR 60775, December 11, 1981]

(2) *Respiratory protection.* Where engineering and work practice controls do not reduce employee exposure to or below the $50 \mu\text{g}/\text{m}^3$ permissible exposure limit, the employer shall supplement these controls with respirators in accordance with paragraph (f).

[Editor's note: The Occupational Safety and Health Administration December 3, 1982 (47 FR 54433) stayed Sections 1910.1025(e)(3)(ii)(B) and (E) for primary and secondary smelters and battery manufacturers, pending completion of an overall review of the entire standard. Employers in the three affected industries still must meet the required compliance level of 50 micrograms of lead per cubic meter of air and are subject to requirements in other subparagraphs of 1910.1025 (e) (3) (ii)-for development of more general compliance plans.]

(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 shall be revised and updated at least every 6 months to reflect the current status of the program.

(4) *Bypass of interim level.* Where an employer's compliance plan provides for a reduction of employee exposures to or below the PEL solely by means of engineering and work practice controls in accordance with the implementation schedule in table I, and the employer has determined that compliance with the $100 \mu\text{g}/\text{m}^3$ interim level would divert resources to the extent that it clearly precludes compliance, otherwise attainable, with the PEL by the required time, the employer may proceed with the plan to comply with the PEL in lieu of compliance with the interim level if:

(i) The compliance plan clearly documents the basis of the determination;

(ii) The employer takes all feasible steps to provide maximum protection for employees until the PEL is met; and

(iii) The employer notifies the OSHA Area Director nearest the affected workplace in writing within 10 working days of the completion or revision of the compliance plan reflecting the determination.

(5) *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

[Sec. 1910.1025 (e)(5)(ii)]

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.

(6) *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.* Where the use of respirators is required under this section, the employer shall provide, at no cost to the employee, and assure the use of respirators which comply with the requirements of this paragraph. Respirators shall be used in the following circumstances:

(i) During the time period necessary to install or implement engineering or work practice controls, except that after the dates for compliance with the interim levels in table I, no employer shall require an employee to wear a negative pressure respirator longer than 4.4 hours per day;

(ii) In work situations in which engineering and work practice controls are not sufficient to reduce exposures to or below the permissible exposure limit; and

(iii) Whenever an employee requests a respirator.

(2) *Respirator selection.*

(i) Where respirators are required under this section the employer shall select the appropriate respirator or combination of respirators from table II below.

TABLE II.—*Respiratory Protection for Lead Aerosols*

Airborne concentration of lead or condition of use	Required respirator ¹
Not in excess of 0.5 mg/m ³ (10X PEL).	Half-mask, air-purifying respirator equipped with high efficiency filters. ²
Not in excess of 2.5 mg/m ³ (50X PEL).	Full facepiece, air-purifying respirator with high efficiency filters. ²
Not in excess of 50 mg/m ³ (1000X PEL).	(1) Any powered, air-purifying respirator with high efficiency filters ² ; or (2) Half-mask supplied-air respirator

TABLE II.—*Respiratory Protection for Lead Aerosols*

Airborne concentration of lead or condition of use	Required respirator ¹
Not in excess of 100 mg/m ³ (200X PEL).	operated in positive-pressure mode. ¹ Supplied-air respirators with full facepiece, hood, helmet, or suit, operated in positive pressure mode.
Greater than 100 mg/m ³ , unknown concentration or fire fighting.	Full facepiece, self-contained breathing apparatus operated in positive-pressure mode.

¹Respirators specified for high concentrations can be used at lower concentrations of lead.

²Full facepiece is required if the lead aerosols cause eye or skin irritation at the use concentrations.

³A high efficiency particulate filter means 99.97 percent efficient against 0.3 micron size particles.

(ii) The employer shall provide a powered, air-purifying respirator in lieu of the respirator specified in Table II whenever:

(A) An employee chooses to use this type of respirator; and

(B) This respirator will provide adequate protection to the employee.

(iii) The employer shall select respirators from among those approved for protection against lead dust, fume, and mist by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11.

(3) *Respirator usage.*

(i) The employer shall assure that the respirator issued to the employee exhibits minimum facepiece leakage and that the respirator is fitted properly.

(ii) Employers shall perform either quantitative or qualitative face fit tests at the time of initial fitting and at least every six months thereafter for each employee wearing negative pressure respirators. The qualitative fit tests may be used only for testing the fit of half-mask respirators where they are permitted to be worn, and shall be conducted in accordance with Appendix D. The tests shall be used to select facepieces that provide the required protection as prescribed in table II.

[Section 1910.1025 (f)(3)(ii) revised by 47 FR 51117, November 12, 1982]

(iii) If an employee exhibits difficulty in breathing during the fitting test or during use, the employer shall make available to the employee an examination in accordance with paragraph (j)(3)(i)(C) of this section to determine whether the employee can wear a respirator while performing the required duty.

(4) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e) and (f).

(ii) The employer shall permit each employee who uses a filter respirator to change the filter elements whenever an increase in breathing resistance is detected and shall maintain an adequate supply of filter elements for this purpose.

(iii) Employees who wear respirators shall be permitted to leave work areas to wash their face and respirator facepiece whenever necessary to prevent skin irritation associated with respirator use.

(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 § 191.133 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 µg/m³ 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.

(vii) The employer shall assure that the containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) are labelled as follows: CAUTION: CLOTHING CONTAMINATED WITH LEAD. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD

[Sec. 1910.1025(g)(2)(vii)]

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.

(Section 1910.1025(g) became effective March 31, 1979, according to action by U.S. Court of Appeals for District of Columbia Circuit. (44 FR 14554, March 13, 1979))

(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.

(Section 1910.1025(h)(2)(ii) corrected at 44 FR 5446, January 26, 1979, effective February 24, 1979)

(Section 1910.1025(h) effective date was March 31, 1979, to extent that employers must acquire vacuums to comply, according to action by U.S. Court of Appeals for District of Columbia Circuit. (44 FR 14554, March 13, 1979))

(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)-(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.

(Sections 1910.1025(i)(1), (i)(2), (i)(3) (i) and (ii), and (i)(4)(i) and (iii) amended, and (i)(6) deleted, at 44 FR 5446, January 26, 1979, effective February 24, 1979)

(j) Medical surveillance. (1) General.

(i) The employer shall institute a medical surveillance program for all employees who are or may be exposed 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 µg/100 g of whole blood. This frequency shall con-

tinue until two consecutive blood samples and analyses indicate a blood lead level below 40 µg/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 exceeds the numerical criterion for medical removal under paragraph (k)(1)(i), 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 µg/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 exceeds 40 µg/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 µg/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 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 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 Mechanism.* 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.

[Sec. 1910.1025(j)(3)(vi)]

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(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.*

(i) *Temporary medical removal and return of an employee.*

(i) *Temporary removal due to elevated blood lead levels.*

(A) *First year of the standard.* During the first year following the effective date of the standard, the employer shall remove an employee from work having a daily eight hour TWA exposure to lead at or above 100 $\mu\text{g}/\text{m}^3$ 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 80 $\mu\text{g}/100$ g of whole blood;

(B) *Second year of the standard.* During the second year following the effective date of the standard, the employer shall remove an employee from work having a daily 8-hour TWA exposure to lead at or above 50 $\mu\text{g}/\text{m}^3$ 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 70 $\mu\text{g}/100$ g of whole blood;

(C) *Third year of the standard, and thereafter.* Beginning with the third year following the effective date of the standard, 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 $\mu\text{g}/100$ g of whole blood; and,

(D) *Fifth year of the standard, and thereafter.* Beginning with the fifth year following the effective date of the standard, 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 $\mu\text{g}/100$ g of whole blood; provided, however, that an employee need not be removed if the last blood sampling test indicates a blood lead level at or below 40 $\mu\text{g}/100$ 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 80 $\mu\text{g}/100$ g, when two consecutive blood sampling tests indicate that the employee's blood lead level is at or below 60 $\mu\text{g}/100$ g of whole blood;

(2) For an employee removed due to a blood lead level at or above 70 $\mu\text{g}/100$ g, when two consecutive blood sampling tests indicate that the employee's blood lead level is at or below 50 $\mu\text{g}/100$ g of whole blood;

(3) For an employee removed due to a blood lead level at or above 60 $\mu\text{g}/100$ g, or due to an average blood lead level at or above 50 $\mu\text{g}/100$ g, when two consecutive blood sampling tests indicate that the employee's blood lead level is at or below 40 $\mu\text{g}/100$ g of whole blood;

(4) 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 steps 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.

(1) *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 institute a training program for and assure the participation of all employees who are subject to exposure to lead at or above the action level or for whom the possibility of skin or eye irritation exists.

(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.

[Sec. 1910.1025 (l)(2)(iii)]

(iii) In addition to the information required by paragraph (i)(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.*

(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.

(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.

(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**

(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 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 1910.20(a)-(e) and (g)-(i). Medical removal records shall be provided in the same manner as environmental monitoring records.

[Section 1910.1025(n)(4)(ii) amended by 45 FR 35212, May 23, 1980, effective August 21, 1980; corrected by 45 FR 54333, August 15, 1980]

(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 1910.20(h).

[Section 1910.1025(n)(5)(iv) added at 45 FR 35212, May 23, 1980, effective August 21, 1980]

(c) *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 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) *Effective date.* This standard shall become effective March 1, 1979, except as noted throughout standard.

[Section 1910.1025(p) corrected at 44 FR 5446, January 26, 1979, effective February 24, 1979; Section 1910.1025(p) amended to revise effective date in accordance with action of U.S. Court of Appeals for the District of Columbia Circuit, (44 FR 14554, March 13, 1979)]

(q) *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.

(r) *Startup dates.* All obligations of this standard commence on the effective date except as follows:

(1) The initial determination under paragraph (d)(2) shall be made as soon as possible but no later than 30 days from the effective date.

(2) Initial monitoring under paragraph (d)(4) shall be completed as soon as possible but no later than 90 days from the effective date.

(3) Initial biological monitoring and medical examinations under paragraph (j) shall be completed as soon as possible but no later than 180 days from the effective date. Priority for biological monitoring and medical examinations shall be given to employees whom the employer believes to be at greatest risk from continued exposure.

(4) Initial training and education shall be completed as soon as possible but no later than 180 days from the effective date.

(5) Hygiene and lunchroom facilities under paragraph (i) shall be in operation as soon as possible but no later than 1 year from the effective year.

(6) Respiratory protection required by paragraph (f) shall be provided as soon as possible but no later than the following schedule:

(A) Employees whose 8-hour TWA exposure exceeds 200 $\mu\text{g}/\text{m}^3$ on the effective date.

(B) Employees whose 8-hour TWA exposure exceeds the PEL but is less than 200 $\mu\text{g}/\text{m}^3$ —150 days from the effective date.

(C) Powered, air-purifying respirators provided under (f)(2)(ii)—210 days from the effective date.

(D) Quantitative fit testing required under (f)(3)(ii) — one year from effective date. Qualitative fit testing is required in the interim.

(7) Written compliance plans required by paragraph (e)(3) shall be completed and available for inspection and copying as soon as possible but no later than the following schedule:

(A) Employers for whom compliance with the PEL or interim level is required within 1 year from the effective date—6 months from the effective date.

(B) Employers in secondary smelting and refining, lead storage battery manufacturing, lead pigment manufacturing and nonferrous foundry industries—1 year from the effective date.

(C) Employers in primary smelting and refining industry—1 year from the effective date for the interim level; 5 years from the effective date for PEL.

(D) Plans for construction of hygiene facilities, if required—6 months from the effective date.

(8) The permissible exposure limit in paragraph (c) shall become effective 150 days from the effective date.

Appendix A to Section 1910.1025—Substance Data Sheet for Occupational Exposure to Lead

I. Substance Identification

- A. Substance
- B. Compounds Covered by the Standard
- C. Uses
- D. Permissible Exposure
- E. Action Level

II. Basic Health Hazard Data

- A. Ways in which lead enters your body
- B. Effects of overexposure to lead
 - 1. Short-term (acute) overexposure
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 - 3. Health protection goal of the standard
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Appendix B to Section 1910.1025—Employee Standard Summary

- I. Permissible Exposure Limit—paragraph (c)
- II. Exposure Monitoring—paragraph (d)
- III. Methods of Compliance—paragraph (e)
- IV. Respiratory Protection—paragraph (f)
- V. Protective Work Clothing & Equipment—paragraph (g)
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- IX. Medical Removal Protection—paragraph (k)
- X. Employee Information & Training—paragraph (l)
- XI. Signs—paragraph (m)
- XII. Recordkeeping—paragraph (n)
- XIII. Observation of Monitoring—paragraph (o)
- XIV. Effective Date—paragraph (p)

XV. For additional information

Appendix C to Section 1910.1025—Medical Surveillance Guidelines

- I. Medical Surveillance and monitoring requirements for workers exposed to inorganic lead
- II. Adverse health effects of inorganic lead
- III. Medical evaluation
- IV. Laboratory evaluation

Appendix A to Section 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 $\mu\text{g}/\text{m}^3$), averaged over an 8-hour work-day.

E. *Action Level:* The standard establishes an action level of 30 micrograms per cubic meter of air (30 $\mu\text{g}/\text{m}^3$), 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

[Sec. 1910.1025, Appendix A]

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. (Section 1910.1025, Appendix A(II)(B) (1) corrected at 44 FR 68827, November 30, 1979)

(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 µg/100g). The blood lead levels of workers (both male and female workers) who intend to have children should be maintained below 30 µg/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 (µg) of lead (1 mg = 1000 µg) 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 µg%. 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 $\mu\text{g}/100\text{g}$, 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 $\mu\text{g}/100\text{g}$. Other studies have shown other forms of diseases in some workers with PbBs well below 80 $\mu\text{g}/100\text{g}$. 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 $\mu\text{g}/100\text{g}$. 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.

Appendix B to Section 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 ($50 \mu\text{g}/\text{m}^3$), 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 $40 \mu\text{g}/\text{m}^3$.

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 ($30 \mu\text{g}/\text{m}^3$) 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 three 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 ($200 \mu\text{g}/\text{m}^3$).

IV. Respiratory Protection—paragraph (f)

Your employer is required to provide and assure your use of respirators when your exposure to lead is not controlled below the PEL by other means. The employer must pay the cost of the respirator. Whenever you request one, your employer is also required to provide you a respirator even if your air exposure level does not exceed the PEL. You might desire a respirator when, for example, you have received medical advice that your lead absorption should be decreased. Or, you may intend to have children in the near future, and want to reduce the level of lead in your body to minimize adverse reproductive effects. While respirators are the best satisfactory means of controlling your exposure, they are capable of providing significant protection if properly chosen, fitted, worn, cleaned, maintained, and replaced when they stop providing adequate protection.

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 assure that your respirator facepiece fits properly. Proper fit of a respirator facepiece is critical. Obtaining a proper fit on each employee may require your employer to make available two or three different mask types. In order to assure that your respirator fits properly and that facepiece leakage is minimized, beginning on March 1, 1980 your employer must give you a "quantitative fit test" if you use a negative pressure respirator. Any respirator which has a filter, cartridge or canister which cleans the work room air before you breathe it and which requires the force of your inhalation to draw air thru the filtering element is a negative pressure respirator. A positive pressure respirator supplies air to you directly. A quantitative fit test uses a sophisticated machine to measure the amount, if any,

of test material that leaks into the facepiece of your respirator.

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 $200 \mu\text{g}/\text{m}^3$. 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. 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.

[Section 1910.1025, Appendix B(V) corrected at 44 FR 68827, November 30, 1979]

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 effectively 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 µg/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 µg/100g. Each time your PbB is determined to be over 40 µg/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 µg/100g. Anytime your PbB exceeds 80 µg/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 µg/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.

[Sec. 1910.1025, Appendix B]

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Medical examinations beyond the initial one must be made available on an annual basis if your blood lead level exceeds 40 µg/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. This multiple physician review mechanism, however, has been temporarily delayed by the Court of Appeals. 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 (penicillamine 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.

[Section 1910.1025, Appendix B(VII) corrected at 44 FR 68827, November 30, 1979]

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 eighteen 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 µg/100g or above you must be removed from any exposure where your air lead level without a respirator would be 100 µg/m³ 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 µg/100g. These criteria for removal and return will change according to the following schedule:

	Removal blood lead (µg/100 g)	Air lead (µg/m ³)	Return blood lead (µg/100 g)
After Mar. 1, 1980	70 and above	50 and above	At or below 50.
After Mar. 1, 1981	80 and above	30 and above	At or below 40.
After Mar. 1, 1983	50 and above averaged over six months.	30 and above	At or below 40.

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**

This requirement, however, has been stayed by the Court of Appeals.

XI. 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.

[Section 1910.1025, Appendix B(XI) corrected at 44 FR 68827, November 30, 1979]

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. Effective Date—Paragraph (p)

The standard's effective date is March 1, 1979, and employer obligations under the standard begin to come into effect as of that date.

XV. For Additional Information

A. Copies of the Standard and explanatory materials can be obtained free of charge by calling or writing the OSHA Office of Publications, Room S-1212, United States Department of Labor, Washington, D.C. 20210; Telephone (202) 523-6138. 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.

[Appendix B, Section XV, Part A, item 7 revised by 47 FR 51117, November 12, 1982]

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 appendices (Appendices D and E), Federal Register, Vol. 47, pp. (pages for this notice), November 12, 1982.

[Appendix B, Section XV, Part A, item 8 and 9 added by 47 FR 51117, November 12, 1982]

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 Section 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 was promulgated to protect workers exposed to inorganic lead including metallic lead, all inorganic lead compounds and organic lead soaps.

Under this final standard in effect as of March 1, 1979, 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 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 $\mu\text{g}/\text{m}^3$ 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 $\mu\text{g}/\text{m}^3$ (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 1910.1025, Appendix C footnote added at 44 FR 68827, November 30, 1979]

*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.

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.

[Section 1910.1025, Appendix C corrected at 44 FR 68827, November 30, 1979]

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 strongly recommended on each occasion that a blood lead level measurement is made. ZPP monitoring is one of several requirements of the standard that has been temporarily stayed by pending litigation over the lead standard. Unless otherwise noted in this document, all provisions of the standard pertaining to medical surveillance and medical removal protection are currently in effect.

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

Table 1

Permissible airborne lead levels by industry ($\mu\text{g}/\text{m}^3$) ^a	Effective date					
	Mar. 1, 1979	Mar. 1, 1980	Mar. 1, 1981	Mar. 1, 1982	Mar. 1, 1984	Mar. 1, 1989 (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

^aAirborne 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.

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Table 2

	Effective date				
	Mar. 1, 1979	Mar. 1, 1980	Mar. 1, 1981	Mar. 1, 1982	Mar. 1, 1983 (final)
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.)	$\geq 80 \mu\text{g}/100 \text{ g}$	$\geq 70 \mu\text{g}/100 \text{ g}$	$\geq 60 \mu\text{g}/100 \text{ g}$	$\geq 60 \mu\text{g}/100 \text{ g}$	$\geq 60 \mu\text{g}/100 \text{ g}$ or average of last three blood samples or all blood samples over previous 6 months (whichever is over a longer time period) is $50 \mu\text{g}/100 \text{ g}$ or greater unless last blood sample is $40 \mu\text{g}/100 \text{ g}$ or less.
B. Frequency which employees exposed to action level of lead ($30 \mu\text{g}/\text{m}^3$ TWA) must have blood lead level checked (ZPP is also strongly recommended in each occasion that a blood lead is obtained):					
1. Last blood lead level less than $40 \mu\text{g}/100 \text{ g}$	Every 6 months.	Every 6 months.	Every 6 months.	Every 6 months.	Every 6 months.
2. Last blood lead level between $40 \mu\text{g}/100 \text{ g}$ and level requiring medical removal (see A above).	Every 2 months.	Every 2 months.	Every 2 months.	Every 2 months.	Every 2 months.
3. Employees removed from exposure to lead because of an elevated blood lead level.	Every 1 month.	Every 1 month.	Every 1 month.	Every 1 month.	Every 1 month.
C. Permissible airborne exposure limit for workers removed from work due to an elevated blood lead level (without regard to respirator protection).	$<100 \mu\text{g}/\text{m}^3$ 8 hr TWA.	$<50 \mu\text{g}/\text{m}^3$ 8 hr TWA.	$<30 \mu\text{g}/\text{m}^3$ 8 hr TWA.	$<30 \mu\text{g}/\text{m}^3$ 8 hr TWA.	$<30 \mu\text{g}/\text{m}^3$ 8 hr TWA.
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 1.	$\leq 60 \mu\text{g}/100 \text{ g}$	$\leq 50 \mu\text{g}/100 \text{ g}$	$\leq 40 \mu\text{g}/100 \text{ g}$	$\leq 40 \mu\text{g}/100 \text{ g}$	$\leq 40 \mu\text{g}/100 \text{ g}$

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 protection is permitted when the physician indicates that the worker is no longer at risk of material impairment.

[Section 1910.1025, Appendix C, Table 2 corrected at 44 FR 68827, November 30, 1979]

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.

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 $30 \mu\text{g}/\text{m}^3$ or more whenever either of the following circumstances apply: (1) a blood lead level of $80 \mu\text{g}/100 \text{ g}$ 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 $50 \mu\text{g}/100 \text{ g}$, unless the last blood sample indicates a blood lead level at or below $40 \mu\text{g}/100 \text{ g}$ in which case the employee need not be removed. Medical removal is to continue until two consecutive blood lead levels are $40 \mu\text{g}/100 \text{ g}$ 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 $80 \mu\text{g}/100 \text{ g}$. 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 $100 \mu\text{g}/\text{m}^3$. Workers so removed are to be returned to work when their blood lead levels are at or below $60 \mu\text{g}/100 \text{ g}$ of whole blood. From March 1, 1980 to March 1, 1981, the blood lead level requiring medical removal is $70 \mu\text{g}/100 \text{ g}$. During this period workers need only be removed from jobs having a daily 8 hour TWA exposure to lead at or above $50 \mu\text{g}/\text{m}^3$ and are to be returned to work when a level of $50 \mu\text{g}/100 \text{ g}$ is achieved. Beginning March 1, 1981, return depends on a worker's blood lead level declining to $40 \mu\text{g}/100 \text{ g}$ of whole blood.

As part of the standard, the employer is required to notify in writing each

employee whose blood lead level exceeds $40 \mu\text{g}/100 \text{ g}$. 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.

[Section 1910.1025, Appendix C(I) corrected at 44 FR 68827, November 30, 1979]

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 $\mu\text{g}/100\text{ g}$ 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 $\mu\text{g}/100\text{ g}$ 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 $\mu\text{g}/100\text{ g}$. 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 80 $\mu\text{g}/100\text{ g}$ whole blood and therefore recommend a 40 $\mu\text{g}/100\text{ g}$ 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 µg/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 µg/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 µg/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 µg/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 µg/100 g and hypospermia and asthenospermia at 41 µg/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 µg/100 g in children can cause significant neurobehavioral impairments and there is evidence of hyperactivity at blood levels as low as 25 µg/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 µg/100 g with a population mean of 15 µg/100 g. Blood lead levels in the fetus and newborn likewise should not exceed 30 µg/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 µg/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

(Sec. 1910.1025, Appendix C)

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 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.

(Section 1910.1025, Appendix C(III), corrected at 44 FR 68827, November 30, 1979)

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 µg/100 g in some workers. Once the blood lead level has reached 40 µg/100 g there is more marked rise in the ZPP value from its normal range of less than 100 µg/100 ml. Increases in blood lead levels beyond 40 µg/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 µg/100 ml whole blood is obtained to rule out a significant underlying anemia. If the ZPP is in excess of 100 µg/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

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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 dehydratase (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 µg/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. [Section 1910.1025, Appendix C(IV) corrected at 44 FR 68827, November 30, 1979]

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 µg/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.

Appendix D to Section 1910.1025—Qualitative Fit Test Protocols

[Appendix D added by 47 FR 51117, November 12, 1982; corrected by 48 FR 9641, March 8, 1983]

This appendix specifies the only allowable qualitative fit test protocols permissible for compliance with paragraph (f)(3)(ii).

I. Isoamyl Acetate Protocol

A. Odor threshold screening.

1. Three 1-liter glass jars with metal lids (e.g. Mason or Bell jars) are required.
2. Odor-free water (e.g. distilled or spring water) at approximately 25°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. This solution shall be prepared new 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 may not be connected to the same recirculating ventilation system.

5. The odor test solution is prepared in a second jar by placing .4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. Shake for 30 seconds and allow to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution may be used for only one day.

6. A test blank is prepared in a third jar by adding 500 cc of odor free water.

7. The odor test and test blank jars shall be labelled 1 and 2 for jar identification. If the labels are put on the lids they can be periodically dried off and switched to avoid people thinking the same jar always has the IAA.

8. The following instructions 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 QLFT may not be used.

11. If the test subject correctly identifies the jar containing the odor test solution he may proceed to respirator selection and fit testing.

B. Respirator selection.

1. The test subject shall be allowed to select the most comfortable respirator from a large array of various sizes and manufacturers that includes at least three sizes of elastomeric half facepieces and units of at least two manufacturers.

2. The selection process shall be conducted in a room separate from the fit-test chamber to prevent odor fatigue. 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 assess an "comfortable" respirator. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This may not

constitute his formal training on respirator use, only a review.

3. The test subject should understand that he is being asked to select the respirator which provides the most comfortable fit for him. Each respirator represents a different size and shape and, if fit properly, will provide adequate protection.

4. The test subject holds each facepiece up to his face and eliminates those which are obviously not giving a comfortable fit. Normally, selection will begin with a half-mask and if a fit cannot be found here, the subject will be asked to go to the full facepiece respirators. (A small percentage of users will not be able to wear any half-mask.)

5. The more comfortable facepieces are recorded; 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 #6 below. If the test subject is not familiar with using a particular respirator, he shall be directed to don the mask several times and to adjust the straps each time, so that he becomes adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject:

- Chin properly placed.
- Positioning of mask on nose.
- Strap tension.
- Fit across nose bridge.
- Room for safety glasses.
- Distance from nose to chin.
- Room to talk.
- Tendency to slip.
- Cheeks filled out.
- Self-observation in mirror.
- Adequate time for assessment.

7. The test subject shall conduct the conventional negative and positive-pressure fit checks (e.g. see ANSI Z88.2-1980). Before conducting the negative- or positive-pressure checks, the subject shall be told to "seat" his mask by rapidly moving the head side-to-side and up and down, taking a few deep breaths.

8. The test subject is now ready for fit testing.

9. After passing the fit test, the test subject shall be questioned again regarding the comfort of the respirator. If it has become uncomfortable, another model of respirator shall be tried.

10. The employee shall be given the opportunity to select a different facepiece and be retested if during the first two weeks of on-the-job wear the chosen facepiece becomes unacceptably uncomfortable.

C. Fit test.

1. The fit test chamber shall be substantially similar to a clear 55 gallon drum liner suspended inverted over a 2 foot diameter frame, so that the top of 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 himself, 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 hook, to prevent general room contamination.

4. A copy of the following test exercises and rainbow (or equally effective) passage shall be taped to the inside of the test chamber:

Test Exercises

- i. Normal breathing.
- ii. Deep breathing. Be certain breaths are deep and regular.
- iii. Turning head from side-to-side. Be certain movement is complete. Alert the test subject not to bump the respirator on the shoulders. Have the test subject inhale when his head is at either side.
- iv. Nodding head up-and-down. Be certain motions are complete and made about every second. Alert the test subject not bump the respirator on the chest. Have the test subject inhale when his head is in the fully up position.
- v. Talking. Talk aloud and slowly for several minutes. The following paragraph is called the Rainbow Passage. Reading it will result in a wide range of facial movements, and thus be useful to satisfy this requirement. Alternative passages which serve the same purpose may also be used.

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.

vi. Normal breathing.

5. Each test subject shall wear his respirator for at least 10 minutes before starting the fit test.

6. 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 three-quarters of one cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

7. Allow two minutes for the IAA test concentration to be reached 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 cooperation, the purpose for the head exercises, or to demonstrate some of the exercises.

8. Each exercise described in No. 4 above shall be performed for at least one minute.

9. If at any time during the test, the subject detects the banana-like odor of IAA, he shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

10. Upon returning to the selection room, the subject shall remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber, etc. 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.

11. If a person cannot be fitted with the selection of half-mask respirators, include full facepiece models in the selection process. When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having him break the face seal and take a breath before exiting the chamber.

12. When the test subject leaves the chamber he shall remove the saturated towel, returning it to the test conductor. To keep the area from becoming contaminated, the used towels shall be kept in a self-sealing bag. There is no significant IAA concentration buildup in the test chamber from subsequent tests.

13. Persons who have successfully passed this fit test may be assigned the use of the tested respirator in atmospheres with up to 10 times the PEL of airborne lead. In other words this IAA protocol may be used to assign a protection factor no higher than 10.

II. Saccharin Solution Aerosol Protocol

A. Taste threshold screening.

1. Threshold screening as well as fit testing employees shall use 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 movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly of part # FT 14 and FT 15 combined is adequate.

2. The test enclosure shall have a three-quarter inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

3. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

4. The test subject shall don the test enclosure. For the threshold screening test, he shall breath through his open mouth with tongue extended.

5. Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, 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.

[Appendix D, II, step. A.5., corrected by 48 FR 9641, March 8, 1983]

6. The threshold check solution consists of 0.83 grams of sodium saccharin, USP in water. It can be prepared by putting 1 cc of the test solution (see C6 below) in 100 cc of water.

7. To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely then released and allowed to fully expand.

8. Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

9. If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

10. If the second response is negative ten more squeezes are repeated rapidly and the

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test subject is again asked whether the saccharin is tasted.

11. The test conductor will take note of the number of squeezes required to elicit a taste response.

12. If the saccharin is not tasted after 30 squeezes (Step 9), the test subject may not perform the saccharin fit test.

13. If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

14. Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

15. 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. Respirator selection.

Respirators shall be selected as described in section IB above, except that each respirator shall be equipped with a particulate filter cartridge.

C. Fit test.

1. The fit test uses the same enclosure described in B1 and B2 above.

2. Each test subject shall wear his respirator for at least 10 minutes before starting the fit test.

3. The test subject shall don the enclosure while wearing the respirator selected in section A above. This respirator shall be properly adjusted and equipped with a particulate filter cartridge.

4. The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

5. A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, 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.

[Appendix D, II, step C.5., corrected by 48 FR 9641 March 8, 1983]

6. The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

7. As before, the test subject shall breathe through the open mouth with tongue extended.

8. The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure and the fit test solution is sprayed into the enclosure using the same technique as for the taste threshold screening and the same number of squeezes required to elicit a taste response in the screening. (See B 10 above).

9. After generation of the aerosol the test subject shall be instructed to perform the following exercises for one minute each.

- i. Normal breathing.
- ii. Deep breathing. Be certain breaths are deep and regular.
- iii. Turning head from side-to-side. Be certain movement is complete. Alert the test subject not to bump the respirator on the

shoulders. Have the test subject inhale when his head is at either side.

iv. Nodding head up-and-down. Be certain motions are complete. Alert the test subject not to bump the respirator on the chest. Have the test subject inhale when his head is in the fully up position.

v. Talking. Talk aloud and slowly for several minutes. The following paragraph is called the Rainbow Passage. Reading it will result in a wide range of facial movements, and thus be useful to satisfy this requirement. Alternative passages which serve the same purpose may also be used.

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 his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

10. Every 30 seconds, the aerosol concentration shall be replenished using one-half the number of squeezes as initially (C8).

11. The test subject shall so indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

12. If the saccharin is detected the fit is deemed unsatisfactory and a different respirator shall be tried.

13. 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 assign protection factors no higher than ten.

III. Irritant Fume Protocol

A. Respirator selection.

Respirators shall be selected as described in section IB above, except that each respirator shall be equipped with high efficiency cartridges.

[Appendix D, III/A corrected by 48 FR 9641, March 8, 1983]

B. Fit test.

1. The test subject shall be allowed to smell a weak concentration of the irritant smoke to familiarize him with its characteristic odor. [Appendix D, III, step B.1., corrected by 48 FR 9641, March 8, 1983]

2. The test subject shall properly don the respirator selected as above, and wear it for at least 10 minutes before starting the fit test.

3. The test conductor shall review this protocol with the test subject before testing.

4. The test subject shall perform the conventional positive pressure and negative pressure fit checks. Failure of either check shall be cause to select an alternate respirator.

5. [Deleted]

6. [Deleted]

[Appendix D, III, steps B.5. and 6. deleted by 48 FR 9641, March 8, 1983]

5. Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach a short length of tubing to one end of the smoke tube. Attach the other end of the smoke tube to a low pressure air pump set to deliver 200 milliliters per minute.

6. Advise the test subject that the smoke can be irritating to the eyes and instruct him to keep his eyes closed while the test is performed.

7. The test conductor shall direct the stream of irritant smoke from the tube towards the faceseal area of the test subject. He shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

8. The following exercises shall be performed while the respirator seal is being challenged by the smoke. Each shall be performed for one minute.

- i. Normal breathing.
- ii. Deep breathing. Be certain breaths are deep and regular.
- iii. Turning head from side-to-side. Be certain movement is complete. Alert the test subject not to bump the respirator on the shoulders. Have test subject inhale when his head is at either side.

iv. Nodding head up-and-down. Be certain motions are complete. Alert the test subject not to bump the respirator on the chest. Have the test subject inhale when his head is in the fully up position.

v. Talking—slowly and distinctly, count backwards from 100.

vi. Normal breathing.

9. If the irritant smoke produces an involuntary reaction (cough) by the test subject, the test conductor shall stop the test. In this case the tested respirator is rejected and another respirator shall be selected.

10. 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 to determine whether he reacts to the smoke. Failure to evoke a response shall void the fit test.

11. Steps B4, B7, B8 of this protocol shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test irritant smoke.

[Appendix D, III, step B.11., corrected by 48 FR 9641, March 8, 1983]

12. Respirators successfully tested by the protocol may be used in contaminated atmospheres up to ten times the PEL. In other words this protocol may be used to assign protection factors not exceeding ten.

[Appendix D, III/B, steps 7 — 14 renumbered as 5 — 12 by 48 FR 9641, March 8, 1983]