Cal/OSHA GENERAL INDUSTRY SAFETY ORDERS, LEAD SECTION 5198, last amended November 6, 2013

Title 8 California Code of Regulations

Reprinted by the Occupational Lead Poisoning Prevention Program Occupational Health Branch California Department of Public Health

TABLE OF CONTENTS

Subsection

(a)	Scope and Application	2
(b)	Definitions	
(c)	Permissible Exposure Limit (PEL)	
(d)	Exposure Monitoring	
(e)	Compliance	
(f)	Respiratory Protection	
(g)	Protective Work Clothing and Equipment	
(h)	Housekeeping	
(i)	Hygiene Facilities and Practices	
(j)	Medical Surveillance	
(k)	Medical Removal Protection	10
(1)	Employee Information and Training	12
(m)	Communication of Hazards	
(n)	Recordkeeping	
(0)	Observation of Monitoring	
(p)	Appendices	
	Appendix A. Substance Data Sheet for Occupational Exposure to Lead	A-1
	Appendix B. Section 5198 Summary	
	Appendix C. Medical Surveillance Guidelines	
	Appendix D. Qualitative Fit Test (QLFT) Protocols	

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Sec. 5198. Lead.

(a) Scope and Application.

- 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.

(b) Definitions.

For purposes of this section, the definitions in section 5161 do not apply to the terms used throughout this section.

<u>Action Level</u>. Employee exposure, without regard to the use of respirators, to airborne lead at an 8-hour time-weighted average concentration of 30 micrograms per cubic meter of air ($30 \ \mu g/m^3$).

<u>Chief</u>. The Chief of the Division of Occupational Safety and Health, P.O. Box 420603, San Francisco, California 94142.

<u>Director</u>. The Director, National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

<u>Lead</u>. 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 an 8-hour time-weighted average concentration greater than 50 micrograms per cubic meter of air ($50 \ \mu g/m^3$).
- (2) If an employee is exposed to lead for more than 8 hours in any work day, the permissible exposure limit for that day, as a time-weighted average concentration (TWA), shall be reduced according to the following formula:

Maximum permissible limit (in $\mu g/m^3$) = 400 ÷ hours worked in the day.

(3) When respirators are used to supplement engineering and work practice controls to comply with the PEL, 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) <u>General</u>.
 - (A) For the purposes of subsection (d), employee exposure is that exposure which would occur if the employee were not using a respirator.
 - (B) With the exception of monitoring under subsection (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.
 - (C) Full shift personal samples shall be representative of the monitored employee's regular, daily exposure to lead.
- (2) <u>Initial Determination</u>. 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.
 - (A) The employer shall monitor employee exposures and shall base initial determinations on the employee exposure monitoring results and any of the following, relevant considerations:
 - Any information, observations, or calculations which would indicate employee exposure to lead;

- 2. Any previous measurements of airborne lead; and
- 3. Any employee complaints of symptoms which may be attributable to exposure to lead.
- (B) 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 concentrations of airborne lead in the workplace.
- (C) Measurements of airborne lead made in the preceding 12 months may be used to satisfy the requirement to monitor under subsection (d)(3)(A) if sampling and analytical methods used meet the accuracy and confidence levels of subsection (d)(9).
- (4) <u>Positive Initial Determination and Initial</u> <u>Monitoring</u>.
- (A) Where a determination conducted under subsections (d)(2) and (d)(3) 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.
- (B) Measurements of airborne lead made in the preceding 12 months may be used to satisfy this requirement if the sampling and analytical methods used meet the accuracy and confidence levels of subsection (d)(9).
- (5) <u>Negative Initial Determination</u>. Where a determination conducted under subsections (d)(2) and (d)(3) is made that no employee is exposed to concentrations of airborne 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 subsection (d)(3) 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.
- (A) If initial monitoring reveals an employee's exposure to be above the permissible exposure limit, the employer shall repeat monitoring quarterly until at least two consecutive measurements, taken at least 7 days apart, are at or below the permissible exposure limit.

Subsequent monitoring for that employee shall conform with the applicable provisions of subsections (d)(6)(B) or (C).

- (B) If initial monitoring or monitoring conducted in accordance with subsection (d)(6)(A) reveals an employee's exposure to be at or above the action level but no greater than the permissible exposure limit, the employer shall repeat monitoring 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 by subsection (d)(7).
- (C) Whenever initial monitoring or monitoring conducted in accordance with subsection
 (d)(6)(A) reveals an employee's exposure to be below the action level, further measurements are not required except as otherwise provided by subsection (d)(7).
- (7) <u>Additional Monitoring</u>. 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 subsection shall be conducted.
- (8) Employee Notification.
 - (A) Within 5 working days after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employee's exposure.
 - (B) 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) <u>Accuracy of Measurement</u>. The employer shall use a method of monitoring and analysis which has an accuracy (to a confidence level of 95%) within plus or minus 20 percent at concentrations of airborne lead equal to or greater than 30 μg/m³.
- (e) Compliance.

(1) <u>Methods</u>.

- (A) Where any employee is exposed to lead above the permissible exposure limit for more than 30 days per year, the employer shall implement engineering, work practice, and administrative controls to reduce and maintain employee exposure to lead except to the extent that the employer can demonstrate that such controls are not feasible. Where engineering, work practice, and administrative controls which can be instituted are not sufficient to reduce employee exposure to or below the permissible exposure limit, they shall nonetheless be used by the employer to reduce exposures to the lowest feasible level. Small non-ferrous foundries (fewer than 20 employees), however, are only required to achieve 75 μ g/m³ by such controls.
- (B) Where controls which can be instituted in accordance with subsection (e)(1)(A) are not sufficient to reduce and maintain employee exposure to or below the permissible exposure limit, the employer shall supplement these controls with respiratory protection, in conformance with subsection (f), to control employee exposure within the permissible exposure limit.
- (C) Where any employee is exposed to lead above the permissible exposure limit, but for 30 days or less per year, the employer shall implement feasible engineering controls to reduce exposure to $150 \mu g/m^3$, but thereafter may implement any combination of engineering, work practice, administrative and respiratory controls to reduce and maintain exposure to lead to or below the permissible exposure limit.
- (2) Compliance Program.
 - (A) Where applicable, each employer shall establish and implement a written compliance program to reduce exposures to or below the permissible exposure limit and interim levels solely by means of engineering and work practice controls in accordance with the implementation schedule in subsection (e)(1).
 - (B) Written plans for these compliance programs shall include at least the following:
 - 1. 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;

- 2. 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;
- 3. A report of the technology considered in meeting the permissible exposure limit;
- 4. Air monitoring data which documents the source of lead emissions;
- 5. A detailed schedule for implementation of the program, including documentation such as copies of purchase orders for equipment, construction contracts, etc.;
- 6. A work practice program which includes items required under subsections (g), (h), and (i);
- 7. An administrative control schedule required by subsection (e)(5), if applicable; and
- 8. Other relevant information.
- (C) Written programs shall be submitted upon request to the Chief and the Director, and shall be available at the worksite for examination and copying by the Chief, the Director, and any affected employee or authorized employee representatives.
- (D) Written programs shall be revised and updated at least every 6 months to reflect the current status of the program.
- (3) [Reserved.]
- (4) Mechanical Ventilation.
 - (A) When ventilation is used to control exposure, measurements which demonstrate the effectiveness of the system in controlling exposure, such as capture velocity, duct velocity, or static pressure shall be made at least every 3 months. Measurements of the system's effectiveness in controlling exposure shall be made within 5 days of any change in production, process, or control which might result in a change in employee exposure to lead.
 - (B) <u>Recirculation of Air</u>. If air from exhaust ventilation is recirculated into the workplace, the employer shall assure that:
 - 1. The exhaust has a high efficiency filter with a reliable back-up filter; and

- 2. Controls are installed, operating, and maintained which monitor the concentration of lead in the return air and which, in case of failure, automatically prevent the recirculation of exhaust air.
- (5) <u>Administrative Controls</u>. 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:
 - (A) Name or identification number of each affected employee;
 - (B) Duration and exposure levels at each job or work station where such affected employee is located; and
 - (C) Any other information which may be useful in assessing the reliability of administrative controls to reduce exposure to lead.

(f) Respiratory Protection.

- (1) <u>General</u>. For employees who are required to use respirators by this section, the employer must provide respirators that comply with the requirements of this subsection. Respirators must be used during:
 - (A) Work operations for which engineering and work practice controls are not sufficient to reduce exposures to or below the permissible exposure limit;
 - (B) Periods necessary to implement engineering or work practice controls.
 - (C) Periods when an employee requests a respirator.
- (2) <u>Respirator Program</u>.
- (A) The employer must implement a respiratory protection program in accordance with Section 5144 (c) (except (d)(1)(C)) through (m).
- (B) If an employee exhibits breathing difficulty during fit testing or respirator use, the employer must provide the employee with a medical examination in accordance with subsection (j)(3)(A)3. to determine whether or not the employee can use a respirator while performing the required duty.
- (3) <u>Respirator Selection</u>.

- (A) The employer shall select, and provide to employees, the appropriate respirators specified in Section 5144(d)(3)(A)1.
- (B) The employer shall provide a powered, airpurifying respirator in lieu of the respirator specified in subsection (f)(3)(A) whenever:
 - 1. An employee chooses to use this type of respirator; and
 - 2. This respirator will provide adequate protection to the employee.
- (C) The employer shall provide employees with full facepiece respirators instead of half mask respirators for protection against lead aerosols that cause eye or skin irritation at the use concentrations.
- (D) The employer shall provide HEPA filters for powered and non-powered air-purifying respirators.

(g) Protective Work Clothing and Equipment.

- Provisions 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:
 - (A) Coveralls or similar full-body work clothing;
 - (B) Gloves, hats, and shoes or disposable shoe coverlets; and
 - (C) Face shields, vented goggles, or other appropriate protective equipment which complies with Article 10.
- (2) Cleaning and Replacement.
 - (A) The employer shall provide the protective clothing required in subsection (g)(1), in a clean and dry condition at least weekly, and daily to employees whose exposure levels without regard to respirator use are over 150 μ g/m³ of lead on an 8-hour time-weighted average basis.
 - (B) The employer shall provide for the cleaning, laundering, or disposal of protective clothing and equipment required by subsection (g)(1).
 - (C) The employer shall repair or replace required protective clothing and equipment as needed to maintain their effectiveness.

- (D) The employer shall assure that all protective clothing is removed at the completion of a work shift and only in change rooms provided for that purpose as prescribed in subsection (i)(2).
- (E) 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.
- (F) 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.
- (G) Labeling of contaminated protective clothing and equipment.
- 1. The employer shall ensure that labels of bags or containers of contaminated protective clothing and equipment include the following information:

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

2. Prior to June 1, 2015, employers may include the following information on bags or containers of contaminated protective clothing and equipment in lieu of the labeling requirements in subsections (g)(2)(G)1. of this section:

> CAUTION: CLOTHING CONTAMINATED WITH LEAD. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD-CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE OR FEDERAL REGULATIONS.

(H) 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. **Note**: A downdraft booth, "air shower," or other appropriate means for the removal of lead dust may be used provided employee exposure to airborne lead dust is prevented during such use.

(h) Housekeeping.

- (1) <u>Surfaces</u>. All surfaces shall be maintained as free as practicable of accumulations of lead.
- (2) <u>Cleaning Floors</u>.
 - (A) Floors and other surfaces where lead accumulates may not be cleaned by the use of compressed air.
 - (B) 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) <u>Vacuuming</u>. Where vacuuming methods are selected, the vacuums shall be used and emptied in a manner which minimizes the re-entry of lead into the workplace. Those vacuum systems which exhaust air into the workplace shall be equipped with air filters at least as effective as high efficiency particulate air filters. High efficiency particulate air filter means 99.97% efficient against 0.3 micrometer size particles.

(i) Hygiene Facilities and Practices.

- 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 subsections (i)(2) - (i)(4).
- (2) Change Rooms.
 - (A) 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.
 - (B) 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.

Exception: Separate storage facilities are not required where clean protective clothing and equipment are provided on a daily basis.

- (3) Showers.
- (A) The employer shall assure that employees who work in areas where their exposure to airborne lead is above the PEL, without regard to the use of respirators, shower at the end of the work shift.
- (B) The employer shall provide shower facilities in accordance with Section 3366(f).
- (C) The employer shall assure that employees who are required to shower pursuant to subsection (i)(3)(A) do not leave the work place wearing any clothing or equipment worn during the work shift.
- (4) Lunchrooms.
- (A) The employer shall provide readily accessible lunchroom facilities, in accordance with Section 3368, for employees who work in areas where their exposure to airborne lead is above the PEL, without regard to the use of respirators.
- (B) Lunchroom facilities shall have a temperature controlled, positive pressure, filtered air supply except that such facilities need not be under positive pressure if workplace operations produce no contamination by airborne lead. (Title 24, Part 2-1724(c)(1)(D)(2).)
- (C) The employer shall assure that employees who work in areas where their exposure to airborne lead is above the PEL, without regard to respirator use, wash their hands and face prior to eating, drinking, smoking or applying cosmetics.
- (D) 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) <u>Lavatories</u>. The employer shall provide an adequate number of lavatory facilities which comply with Section 3366.

(j) Medical Surveillance.

- (1) General.
- (A) The employer shall institute a medical surveillance program for all employees who are or may be exposed at or above the action level for more than 30 days per year.

- (B) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician.
- (C) The employer shall provide the required medical surveillance including multiple physician review under subsection (j)(3)(C) without cost to employees and at a reasonable time and place.
- (2) Biological Monitoring.
 - (A) <u>Blood Lead and Zinc Protoporphyrin Sampling</u> <u>and Analysis</u>. The employer shall make available biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin (ZPP) levels to each employee covered under subsection (j)(1)(A) on the following schedule:
 - At least every 6 months to each employee covered under subsection (j)(1)(A);
 - 2. At least every two months for each employee whose last blood sampling and analysis indicated a blood lead level at or above $40 \mu g/100$ g of whole blood. This frequency shall continue until two consecutive blood samples and analysis indicate a blood lead level below $40 \mu g/100$ g of whole blood; and
 - 3. At least monthly during the removal period of each employee removed from exposure to lead due to an elevated blood lead level.
 - 4. ZPP determinations shall be made available as soon as possible but no later than the first biological monitoring scheduled for an employee.
 - (B) <u>Follow-Up Blood Sampling Tests</u>. Whenever the results of a blood lead level test indicate that an employee's blood lead level is at or above the numerical criterion for medical removal under subsection (k)(1), 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.
 - (C) <u>Accuracy of Blood Lead Level Sampling and</u> <u>Analysis</u>. 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/100 ml, whichever is greater, and shall be conducted by a laboratory licensed

by the Centers for Disease Control (CDC), U.S. Department of Health and Human Services, or which has received a satisfactory grade in blood lead proficiency testing from the CDC in the prior 12 months.

- (D) <u>Employee Notification</u>. Within five working days after the receipt of biological monitoring results, the employer shall notify in writing each employee whose blood lead level is at or above 40 μg/100 g:
 - 1. Of that employee's blood lead level; and
 - That the standard requires temporary medical removal with Medical Removal Protection benefits when an employee's blood lead level is at or above the numerical criterion for medical removal under subsection (k)(1).
- (3) Medical Examinations and Consultations.
- (A) <u>Frequency</u>. The employer shall make available medical examinations and consultations to each employee covered under Section 5198(j)(1)(A) on the following schedule:
 - 1. 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 $40 \mu g/100 g;$
 - Prior to assignment for each employee being assigned for the first time to an area in which 8-hour time-weighted concentrations of airborne lead are at or above the action level;
 - 3. 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
 - 4. As medically appropriate for each employee removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited pursuant to a final medical determination.

- (B) <u>Content</u>. Medical examinations made available pursuant to subsections (j)(3)(A)1-2 shall include the following elements:
 - 1. A detailed work history and a medical history, with particular attention to past lead exposure (occupational and nonoccupational), personal habits (smoking, hygiene), and past gastrointestinal, hematologic, renal, cardiovascular, reproductive and neurological problems;
 - 2. 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;
 - 3. A blood pressure measurement;
 - 4. A blood sample and analysis which determines:
 - a. Blood lead level;
 - b. Hemoglobin and hematocrit determinations, red cell indices, and examination of peripheral smear morphology;
 - c. Zinc protoporphyrin
 - d. Blood urea nitrogen; and
 - e. Serum creatinine.
 - 5. A routine urinalysis with microscopic examination; and
 - 6. Any laboratory or other test which the examining physician deems necessary by sound medical practice.

The content of medical examinations made available pursuant to subsections (j)(3)(A)3-4shall be determined by an examining physician and, if requested by an employee, shall include pregnancy testing or laboratory evaluation of male fertility.

- (C) Multiple Physician Review Mechanism.
 - 1. 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 to review any findings, determinations or recommendations of the initial physician and to conduct such

examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

- 2. 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 participation in, and payment for, the multiple physician review mechanism by requiring the employee (within 15 days from the date of the foregoing notice or receipt of the initial physician's written opinion, whichever is later) to inform the employer that the employee intends to seek a second medical opinion and to initiate steps to make an appointment with a second physician.
- 3. 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.
- 4. If the two physicians are unable to resolve their disagreement quickly, the employer and employee through their respective physicians shall designate a third physician to review any findings, determinations, or recommendations of the prior physicians and to conduct such examinations, consultations, laboratory tests, and discussions with the prior physicians which the third physician deems necessary to resolve the disagreement of the prior physicians.
- 5. 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.
- (D) <u>Alternate Physician Determination</u> <u>Mechanisms</u>. 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 section so long as the alternate mechanism otherwise satisfies the requirements contained in this section.

- (4) <u>Information Provided to Examining and</u> <u>Consulting Physicians</u>.
- (A) The employer shall provide the following information to an initial physician conducting a medical examination or consultation under the provisions of this section:
 - 1. A copy of this regulation and its 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.

(5) Written Medical Opinions.

- (A) The employer shall obtain and furnish the employee with a copy of a written medical report 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 the 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 the examining 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 the employee's occupational exposure to lead; and
 - 2. Advise the employee of any medical condition, occupational or non-occupational, which dictates further medical examination or treatment.
- (6) Chelation.
- (A) 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.
- (B) If therapeutic or diagnostic chelation is to be performed by any person in subsection (j)(6)(A), the employer shall assure that it be done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring and that the employee is notified in writing prior to its occurrence.

(k) Medical Removal Protection.

(1) <u>Temporary Removal Due to Elevated Blood Lead</u> <u>Levels</u>.

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 μ 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 below 40 μ g/100 g of whole blood.

- (2) <u>Temporary Removal Due to a Final Medical</u> <u>Determination</u>.
- (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.

Note: For the purposes of this section, the phrase "final medical determination" shall mean the outcome of the multiple physician review mechanism or alternate physician determination mechanism used pursuant to the medical surveillance provisions of this section.

- (B) 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.
- (3) <u>Return of the Employee to Former Job Status</u>.
 - (A) The employer shall return an employee to his or her former job status:
 - 1. For an employee removed due to a blood lead level at or above $50 \mu g/100 g$ when two consecutive blood sampling tests indicate that the employee's blood lead level is below $40 \mu g/100 g$ of whole blood; and
 - 2. For an employee removed due to a final medical determination, when a subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead.
 - (B) For the purposes of this section, the requirement that an employer return an employee to his or her former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.
- (4) <u>Removal of Other Employee Special Protective</u> <u>Measures or Limitations</u>.

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.

- (5) Employer Options Pending a Final Medical <u>Determination</u>. 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) <u>Removal</u>. 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) <u>Return</u>. 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.

Exceptions:

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

2. If the employee has been on removal status for the preceding eighteen months due to an elevated blood lead level, the employer shall await a final medical determination.

- (6) Medical Removal Protection Benefits.
- (A) <u>Provision of Medical Removal Protection</u> <u>Benefits</u>. 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.
- (B) <u>Definition of Medical Removal Protection</u> <u>Benefits</u>. 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.

- (C) <u>Follow-Up Medical Surveillance During the</u> <u>Period of Employee Removal or Limitation</u>. 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.
- (D) <u>Worker's Compensation Claims</u>. If a removed employee files a claim for worker's 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 worker's compensation payments received by the employee for treatment related expenses.
- (E) <u>Other Credits</u>. 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.
- (F) 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.
 - 1. The employer shall make available to the employee a medical examination pursuant to this section to obtain a final medical determination with respect to the employee.
 - 2. The employer shall assure that the final medical determination obtained indicates whether or not the employee may be returned to his or her former job status, and if not,

what steps should be taken to protect the employee's health.

- 3. Where the final medical determination has not yet been obtained, or once obtained indicates that the employee may not yet be returned to his or her former job status, the employer shall continue to provide medical removal protection benefits to the employee until either the employee is returned to former job status, or a final medical determination is made that the employee is incapable of ever safely returning to his or her former job status.
- 4. Where the employer acts pursuant to a final medical determination which permits the return of the employee to his or her former job status despite what would otherwise be an unacceptable 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.
- (G) <u>Voluntary Removal or Restriction of an</u> <u>Employee</u>. 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 subsection (k)(5)(A).

(I) Employee Information and Training.

- (1) <u>Training Program</u>.
 - (A) 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.
 - (B) 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 exists of skin or eye irritation from exposure to lead.
 - (C) The employer shall provide initial training prior to the time of initial job assignment for

those employees subsequently covered by this paragraph.

- (D) The training program shall be repeated at least annually for each employee covered by subsection (l)(1)(C).
- (E) The employer shall assure that each employee covered by subsection (l)(1)(C) is informed of the following:
 - 1. The content of this standard and its appendices;
 - 2. The specific nature of the operations which could result in exposure to lead above the action level;
 - 3. The purpose, proper selection, fitting, use, and limitations of respirators;
 - 4. 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 reproduction effects on both males and females);
 - 5. The engineering controls and work practices associated with the employee's job assignment;
 - 6. The contents of any compliance plan in effect; and
 - 7. 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.
 - (A) The employer shall make a copy of this standard and its appendices readily available to all affected employees including employees exposed below the action level.
 - (B) The employer shall provide, upon request, all materials relating to the employee information and training program to the Chief.

(m) Communication of Hazards.

(1) <u>Hazard Communication - General</u>.

- (A) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (Section 5194) for lead.
- (B) In classifying the hazards of lead at least the following hazards are to be addressed: Reproductive/developmental toxicity; central nervous system effects; kidney effects; blood effects; and acute toxicity effects.
- (C) Employers shall include lead in the hazard communication program established to comply with the HCS (Section 5194). Employers shall ensure that each employee has access to labels on containers of lead and to safety data sheets, and is trained in accordance with the requirements of the HCS and subsection (l) of this section.
- (2) <u>Signs</u>.
 - (A) The employer shall post the following warning signs in each work area where the PEL is exceeded:

DANGER LEAD MAY DAMAGE FERTILITY OR THE UNBORN CHILD CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM DO NOT EAT, DRINK OR SMOKE IN THIS AREA

- (B) The employer shall ensure that no statement appears on or near any sign required by this subsection (m)(2) which contradicts or detracts from the meaning of the required sign.
- (C) The employer shall ensure that signs required by this subsection (m)(2) are illuminated and cleaned as necessary so that the legend is readily visible.
- (D) The employer may use signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs required by this subsection (m)(2).
- (E) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in subsection (m)(2)(B) of this section:

WARNING LEAD WORK AREA POISON NO SMOKING OR EATING

(n) Recordkeeping.

- (1) Exposure Monitoring.
 - (A) The employer shall establish and maintain an accurate record of all monitoring required in subsection (d).
 - (B) This record shall include:
 - 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;
 - 2. A description of the sampling and analytical methods used and evidence of their accuracy;
 - 3. The type of respiratory protective devices worn, if any;
 - 4. 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
 - 5. The environmental variables that could affect the measurement of employee exposure.
 - (C) 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.
 - (A) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by subsection (j).
 - (B) This record shall include:
 - 1. The name, social security number, and description of the duties of the employee;
 - 2. A copy of the physician's written opinions;
 - 3. Results of any monitoring of exposure to airborne lead done for that employee and the representative exposure level supplied to the physician; and
 - 4. Any employee medical complaints related to exposure to lead.
 - (C) The employer shall keep, or assure that the examining physician keeps, the following medical records:

- 1. A copy of the medical examination results including medical and work history required under subsection (j).
- 2. 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.
- 3. A copy of the results of biological monitoring.
- (D) 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.
- (A) The employer shall establish and maintain an accurate record for each employee removed from current exposure to lead pursuant to subsection (k).
- (B) Each record shall include:
 - 1. The name and social security number of the employee;
 - 2. 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;
 - 3. A brief explanation of how each removal was or is being accomplished; and
 - 4. A statement with respect to each removal indicating whether or not the reason for the removal was an elevated blood lead level.
- (C) The employer shall maintain each medical removal record for at least the duration of an employee's employment.
- (4) Availability.
 - (A) The employer shall make available upon request all records required to be maintained by this subsection to the Chief and the Director for examination and copying.

- (B) Environmental monitoring, medical removal, and medical records required by this section shall be provided upon request to employees, designated representatives, and authorized representatives of the Chief in accordance with Section 3204. Medical removal records shall be provided as prescribed by Section 3204 for monitoring records.
- (5) Transfer of Records.
 - (A) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by subsection (n).
 - (B) 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.
 - (C) 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.
 - (D) The employer shall also comply with any additional requirements involving the transfer of records set forth in Section 3204.

(o) Observation of Monitoring.

During any observation of monitoring under subsection (d) by an affected employee or employees or their representative (pursuant to Section 340.1) in an area where the use of respirators, protective clothing or equipment is required, the employer shall provide the observer with, and assure the use of, such respirators, clothing and equipment and shall require the observer to comply with all other applicable safety and health procedures. Without interfering with the monitoring, the observer shall be entitled to receive an explanation of the measurement procedures used.

(p) Appendices.

The information contained in the appendices to this section is not intended to create any additional obligations not otherwise imposed by this standard nor detract from any existing obligation.

Cal/OSHA GENERAL INDUSTRY SAFETY ORDERS, LEAD SECTION 5198

Title 8 California Code of Regulations

APPENDICES

TABLE OF CONTENTS

Append	<u>lix</u>	<u>Page</u>
А.	Substance Data Sheet for Occupational Exposure to Lead	A - 1
В.	Section 5198 Summary	A-4
C.	Medical Surveillance Guidelines	A-13
D.	Qualitative Fit Test (QLFT) Protocols	. A-24

APPENDIX A

Substance Data Sheet for Occupational Exposure to Lead

I. Substance Identification

- A. <u>Substance</u>. 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. <u>Compounds Covered by the Standard</u>. 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. <u>Uses</u>. 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. <u>Permissible Exposure</u>. The Permissible Exposure Limit (PEL) set by the standard is 50 micrograms of lead per cubic meter of air (50 μg/m³), averaged over an 8-hour workday.
- E. <u>Action Level</u>. The standard establishes an action level of 30 micrograms per cubic meter of air $(30 \ \mu g/m^3)$, time-weighted average, based on an 8-hour workday. The action level initiates several requirements of the standard, such as exposure monitoring, medical surveillance, and training and education.

II. Health Hazard Data

A. <u>Ways in which lead enters your body</u>. When absorbed into your body in certain doses, lead is a toxic substance. The object of the lead standard is to prevent absorption of harmful quantities of lead. The standard is intended to protect you not only from the immediate toxic effects of lead but also from the serious toxic effects that may not become apparent until years of exposure have passed.

Lead can be absorbed into your body by inhalation (breathing) and ingestion (eating). Lead (except for certain organic lead compounds not covered by the standard, such as tetraethyl lead) is not absorbed through your skin. When lead is scattered in the air as a dust, fume or mist it can be inhaled and absorbed through your lungs and upper respiratory tract. Inhalation of airborne lead is generally the most important source of occupational lead absorption. You can also absorb lead through your digestive system if lead gets into your mouth and is swallowed. If you handle food, cigarettes, chewing tobacco, or make-up which have lead on them or handle them with hands contaminated with lead, this will contribute to ingestion.

A significant portion of the lead that you inhale or ingest gets into your blood stream. Once in your blood system, lead is circulated throughout your body and stored in various organs and body tissues. Some of this lead is quickly filtered out of your body and excreted, but some remains in the blood and other tissues. As exposure to lead continues, the amount stored in your body will increase if you are absorbing more lead than your body is excreting. Even though you may not be aware of any immediate symptoms of disease, this lead stored in your tissues can be slowly causing irreversible damage, first to individual cells, then to your organs and whole body systems.

- B. Effects of overexposure to lead.
 - (1) Short-term (acute) overexposure. Lead is a potent, systemic poison that serves no known useful function once absorbed by your body. Taken in large enough doses, lead can kill you in a matter of days. A condition affecting the brain called acute encephalopathy may arise which develops quickly to seizures, coma, and death from cardiorespiratory arrest. A short-term dose of lead can lead to acute encephalopathy. Short-term occupational exposures of this magnitude are highly unusual, but not impossible. Similar forms of encephalopathy may, however, arise from extended, chronic exposure to lower doses of lead. There is no sharp dividing line between rapidly developing acute effects of lead and chronic effects which take longer to acquire. Lead adversely affects numerous body systems and causes forms of health impairment and disease which arise after periods of exposure as short as days or as long as several years.

(2) Long-term (chronic) overexposure. Chronic overexposure to lead may result in severe damage to your blood-forming, nervous, urinary and reproductive systems. Some common symptoms of chronic overexposure include loss of appetite, metallic taste in the mouth, anxiety, constipation, nausea, pallor, excessive tiredness, weakness, insomnia, headache, nervous irritability, muscle and joint pain or soreness, fine tremors, numbness, dizziness, hyperactivity and colic. In lead colic there may be severe abdominal pain.

Damage to the central nervous system in general and the brain (encephalopathy) in particular is one of the most severe forms of lead poisoning. The most severe, often fatal, form of encephalopathy may be preceded by vomiting, a feeling of dullness progressing to drowsiness and stupor, poor memory, restlessness, irritability, tremor, and convulsions. It may arise suddenly with the onset of seizures, followed by coma, and death. There is a tendency for muscular weakness to develop at the same time. This weakness may progress to paralysis often observed as a characteristic "wrist drop" or "foot drop" and is a manifestation of a disease to the nervous system called peripheral neuropathy.

Chronic overexposure to lead also results in kidney disease with few, if any, symptoms appearing until extensive and most likely permanent kidney damage has occurred. Routine laboratory tests reveal the presence of this kidney disease only after about two-thirds of kidney function is lost. When overt symptoms of urinary dysfunction arise, it is often too late to correct or prevent worsening conditions, and progression to kidney dialysis or death is possible.

Chronic overexposure to lead impairs the reproductive systems of both men and women. Overexposure to lead may result in decreased sex drive, impotence and sterility in men. Lead can alter the structure of sperm cells raising the risk of birth defects. There is evidence of miscarriage and stillbirth in women whose husbands were exposed to lead or who were exposed to lead themselves. Lead exposure also may result in decreased fertility and abnormal menstrual cycles in women. The course of pregnancy may be adversely affected by exposure to lead since lead crosses the placental barrier and poses risks to developing fetuses. Children born of parents either one of whom were exposed to excess lead levels are more likely to have birth defects, mental retardation, or behavioral disorders or to 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 fatigue as a result of decreased oxygen-carrying capacity in the blood.

(3) <u>Health protection goals of the standard</u>. Prevention of adverse health effects for most workers from exposure to lead throughout a working lifetime requires that worker blood lead levels (PbB) be maintained at or below forty micrograms per one hundred grams of whole blood ($40 \mu g/100 g$). The blood lead levels of workers (both male and female workers) who intend to have children should be maintained below $30 \mu g/100 g$ to minimize adverse reproductive health effects to the parents and 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 (μ g) of lead (1 mg = 1,000 μ g) per 100 grams (100 g), 100 milliliters (100 ml) or deciliter (dl) of blood. These three units are essentially the same. Sometimes PbBs are expressed in the form of mg% or μ g%. This is a shorthand notation for 100 g, 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 leadrelated diseases, however, has focused heavily on associations between PbBs and various diseases. As a result, the relative level of your PbB is an important indicator of the probability of your acquiring a leadrelated health impairment or disease.

Once your blood lead level climbs above $40 \,\mu g/100 \,g$, 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 μ g/100 g. Other studies have shown other forms of disease in some workers with PbBs well below 80 μ g/100 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 leadrelated impairments and diseases (both short term and long term) is to maintain your PbB below 40 μ g/100 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) <u>Reporting signs and symptoms of health</u> <u>problems</u>. 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.

APPENDIX B

Section 5198 Summary

This appendix summarizes key provisions of the standard that you as a worker should become familiar with.

I. Permissible Exposure Limit (PEL)

The standard sets a permissible exposure limit (PEL) of fifty micrograms of lead per cubic meter of air (50 μ g/m³), averaged over an 8-hour workday. 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 workday 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 $40 \ \mu g/m^3$.

II. Exposure Monitoring

If lead is present in any quantity in the workplace where you work, 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 determination must have been completed within 30 days of the effective date of the standard. If this initial determination shows that a reasonable possibility exists that any employee may be exposed, without regard to the use of respirators, over the action level $(30 \,\mu g/m^3)$, 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 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 within 90 days of the effective date of the standard.

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 also 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 two 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. Compliance

Except for certain industries, the regulation requires employers to reduce and maintain employee exposure to lead at or below the permissible exposure limit by means of engineering, work practice, and administrative controls to the extent that such controls are feasible. Even though such controls may not be sufficient to effect compliance with the PEL, they must be instituted to achieve the lowest feasible exposure level and the employer must provide supplemental protection in the form of respirators.

The regulation's implementation schedule prescribes deadline dates at which employers in the various industries must have controls in operation to achieve compliance with the PEL without resorting to respirator use, to the extent that such controls are feasible. These dates are based on the projected difficulty in instituting engineering controls and vary from industry to industry. In electronics, gray iron foundries, ink manufacture, paints and coatings manufacture, wallpaper manufacture, can manufacture, and printing, the date is March 7, 1983; in secondary lead smelting and battery manufacturing, the deadline is March 7, 1983; in primary lead production, it is March 7, 1982; and for most other industries, it is September 7, 1984.

The regulation also requires that employers in the above-indicated industries establish a written plan within specified dates which will describe and project the means and implementation schedule whereby compliance with the PEL will be achieved by the applicable deadline.

For certain other industries, the feasibility of complying with the PEL by means of engineering controls has not been established, and as a consequence, employers within these industries are required to implement feasible controls to comply with an employee exposure limit of $150 \ \mu g/m^3$ and to supplement such controls with respiratory protection to achieve compliance with the PEL. These industries or operations include lead pigment manufacture, nonferrous foundries, leaded steel manufacture, lead chemical manufacture, shipbuilding and ship repair, battery breaking (excluding scrap collection and processing which is part of secondary lead production), the secondary lead smelting of copper, and lead casting.

Where employee exposure above the PEL occurs intermittently for no more than 30 days per year, feasible engineering controls must be implemented to achieve compliance with an exposure limit of $150 \ \mu g/m^3$ but compliance with the PEL may be accomplished by any combination of engineering, work practice, and administrative controls and respiratory protection.

IV. Respiratory Protection

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 the air exposure level does not exceed the PEL. You might desire a respirator when, for example, you 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 least satisfactory means of controlling your exposure, they are capable of providing significant protection when properly chosen, fitted, worn, cleaned, and maintained and are replaced when they stop providing adequate protection.

Your employer is required to select respirators from the types listed in the respiratory protection subsection of the standard. Any respirator chosen must be approved by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 42 CFR part 84. The respirator selection table will enable your employer to choose a type of respirator which will give you proper 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 that to which you are exposed.

An air purifying respirator is any respirator which has a filter, cartridge or canister which cleans the work room air as you breathe it. The typical air purifying respirator is a negative pressure respirator because it requires the force of your inhalation to draw air through the filtering element. It is less protective than a powered air purifying respirator (PAPR) which also has a filter, cartridge or canister to clean the air, but 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 negative pressure air purifying respirator for long periods of time. The standard provides that you can obtain a PAPR upon request.

Supplied-air respirators are also available which, as the name implies, are respirators to which breathing quality air is supplied from a source such as an air compressor, blower or compressed air cylinder. Three types of supplied-air respirators are available: demand, pressure demand, and continuous flow. The demand-type requires the force of inhalation to open a diaphragm valve thus admitting air from the supply source. As any leakage around the facepiece will permit the concurrent admission of contaminated air, the demand-type only provides protection generally equivalent to that of the typical negative pressure air purifying respirator of the same facepiece type. Greater protection is provided by either the pressure-demand or continuous-flow types as positive air pressure exists within the respirator at all times.

Your employer must also start a Respiratory Protection Program in accordance with General Industry Safety Order 5144. 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 and no single facepiece fits all facial configurations equally well. Obtaining a proper fit thus may require your employer to make available two or three different mask types in order that facepiece leakage is minimized for each employee. In order to assure that your respirator fits properly and that facepiece leakage is minimized, your employer must give you either a "quantitative or qualitative fit test" as specified in Appendix A of Section 5144, Respiratory Protection.

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.

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

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 exposure to airborne lead is greater than 150 μ g/m³. Appropriate protective work clothing and equipment can include coveralls or similar full-body work clothing, gloves, hats, shoes or disposable

shoe coverlets, and face shields or vented goggles. Your employer is required to provide all such equipment at no cost to you. He is responsible for providing repairs and replacement as necessary, and also is responsible for the cleaning, laundering or disposal of protective clothing and equipment. Contaminated work clothing or equipment must be removed in change rooms and not worn home or you will extend your exposure and expose your family since lead from your clothing can accumulate in your house, car, etc. Contaminated clothing which is to be cleaned, laundered or disposed of must be placed in closed containers in the change room. At no time may lead be removed from protective clothing or equipment by any means which disperses lead into the workroom air.

VI. Housekeeping

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

The standard requires that change rooms, showers, and lunchrooms be made available to workers exposed to lead above the PEL. When the PEL is exceeded, 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 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

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 provisions 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 the 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 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 (without regard to the use of respirators) 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 within 150 days of the effective date of the lead standard. 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. If a worker's PbB exceeds 40 μ g/100 g, 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 μ g/100 g. Each time your PbB is determined to be over 40 μ g/100 g, 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). During the first year of the standard, this removal criterion is $80 \,\mu g/100$ g. Anytime your PbB exceeds 80 μ g/100 g your employer must make available to you a prompt follow-up PbB test to ascertain your PbB. If the two tests both exceed $80 \mu g/100 g$ and you are temporarily removed, then your employer must make successive PbB tests available to you on a monthly basis during the period of your removal.

Medical examinations beyond the initial one must be made available on an annual basis if your blood lead level exceeds 40 μ g/100 g at any time during the preceding year. The initial examination will provide information to establish a baseline with 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 concentration of airborne 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 preassignment 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, (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 provides you with the right to a second medical opinion from a physician of your choice if you are dissatisfied with an examination by a physician chosen by your employer. The standard requires the two physicians to attempt a resolution of any difference in their opinions. If any dispute remains unresolved, the standard provides that a third physician, selected by you and your employer, shall make a final, binding medical determination unless you and your employer reach an agreement which is otherwise consistent with the recommendations of one of the physicians. Generally, your employer will choose the physician who conducts medical surveillance under the lead standard unless you and your employer otherwise 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 these 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 may have. 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, workers may have legal rights to compensation from public agencies, their employers, firms that supply hazardous products to their employers, or other persons. The results of the medical surveillance program can significantly affect the legal remedies of a worker who has acquired a job-related disease or impairment.

The medical surveillance subsection 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, CaNa₂ 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 levels to pre-designated 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, such practice is generally 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 involves 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 medical opinion if you choose to do so.

IX. Medical Removal Protection

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 and administrative 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 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 μ g/100 g or above, you must be removed from any exposure where your air lead level without a respirator would be 100 μ g/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 μ g/100 g. These criteria for removal and return will change according to the following schedule during subsequent years.

	Removal blood lead (µg/100 g)	Air lead (µg/m³) lead	Return blood (µg/100 g)
Second Year	.70 and above	50 and above	At or below 50
Third and Fourth Years	. 60 and above	30 and above	At or below 40
Fifth and Succeeding Years	.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 medical determination indicates that you temporarily need reduced lead exposure for medical reasons. If the physician who is implementing your employer's medical program makes a 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 procedures or agreements for job assignments which may exist in your place of employment. 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 situations, MRP benefits must be provided during the period of removal that is, you continue to receive the same earnings, seniority, and other rights and benefits you would have had if you had not been removed. Earnings include more than just your base wage; they include 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 if you had not been removed. If you would still be in your old job if no removal had occurred, you are to be returned to this job. If you would not be in your old job, the job assignment to which you return must be consistent with the decision which your employer would have been obliged to make had no removal 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. Similarly, if you obtain other employment during the time you are laid off, the benefits you receive under MRP are reduced by the amount you earn in such other employment.

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 also 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

Your employer is required to provide an information and training program for all employees exposed to lead at or 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 these appendices.

Your employer is required to complete this training program for all employees within 180 days of the effective date of the lead standard. Subsequently, all new employees (who may be exposed to lead at or above the action level or for whom the possibility exists of eye or skin irritation from lead exposure) must be trained prior to initial assignment.

This training program must also be provided at least annually thereafter.

XI. Signs

The following warning sign must be posted in work areas where the exposure to lead exceeds the PEL: DANGER LEAD MAY DAMAGE FERTILITY OR THE UNBORN CHILD

CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM DO NOT EAT, DRINK OR SMOKE IN THIS AREA

However, prior to June 1, 2016, employers may use the following legend in lieu of that specified above:

> WARNING LEAD WORK AREA POISON NO SMOKING OR EATING

XII. Recordkeeping

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 result 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 employee, 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 the duration of an employee's employment.

The standard requires that if you request to see or copy environmental monitoring, blood lead level (PbB) 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. Upon your request, your complete medical records must also be provided 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 such access.

XIII. Observation of Monitoring

When air monitoring for lead is performed at your workplace as required by the standard, your employer must allow you or someone you designate to observe the monitoring. The observer is 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, the observer is 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

The standard's effective date is September 8, 1979, and the employer obligations under the standard begin to come into effect as of that date.

XV. For Additional Information

- A. Copies of the Federal lead 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:
 - The Federal lead 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, Volume 43, pp. 54354– 54509, November 21, 1978.
 - 3. Partial Administrative Stay and Corrections to the Federal lead standard, Federal Register, Volume 44, pp. 5446–5448, January 26, 1979.
 - 4. Notice of the Partial Judicial Stay, Federal Register, Volume 44, pp. 14554–14555, March 13, 1979.
 - 5. Corrections to the preamble, Federal Register, Volume 44, pp. 20680–20681, April 6, 1979.
 - 6. Additional correction to the preamble concerning the construction industry, Federal Register, Volume 44, p. 50338, August 28, 1979.
 - 7. Appendices A, B and C to the Federal lead standard, Federal Register, Volume 44, pp. 60980–60994, October 23, 1979. Corrections to the appendices, Federal Register, Volume 44, p. 68828, November 30, 1979.
 - 8. Notice of Limited Reopening of Rulemaking Record (and summary of U.S. Court of Appeals decision), Federal Register, Volume 45, pp. 63881–3, September 26, 1980.

- 9. Supplemental feasibility statement (in response to U.S. Court of Appeal's remand order), Federal Register, Volume 46, pp. 6134–6228, January 21, 1981.
- Revised supplemental feasibility statement, Federal Register, Volume 46, pp. 60758– 60776, December 11, 1981.
- 11. Revisions of the Federal standard and appendices and new Appendix D. Federal Register, Volume 47, pp. 51110–51119, November 12, 1982.
- B. Additional information about the California lead standard, its enforcement, and your employer's compliance can be obtained from the nearest CAL/OSHA Consulting Service Office in Downey, Fresno, Panorama City, Sacramento, San Diego, and San Francisco. The CAL/OSHA Consulting Service is listed in telephone directories under California State Government/Industrial Relations Department.

APPENDIX C Medical Surveillance Guidelines

Introduction

The occupational health standard for lead was promulgated to protect workers exposed to lead which, as defined by the standard, includes metallic lead, all inorganic lead compounds and organic lead soaps but excludes all other organic lead compounds. The term "inorganic lead" used throughout this appendix is meant to be synonymous with the definition of lead set forth in the standard.

Under this final standard in effect as of September 8, 1979, occupational exposure to inorganic lead is to be limited to $50 \,\mu g/m^3$ (micrograms per cubic meter) based on an 8-hour time-weighted average (TWA). This level of exposure must be achieved through a combination of engineering, work practice, and administrative controls (in periods of time ranging from 1 to 10 years) in primary lead smelting, secondary lead smelting, electronics, gray iron foundries, ink manufacture, paints and coatings manufacture, can manufacture, and printing. In these industries, respirators may be used to meet the 50 μ g/m³ exposure limit pending the implementation of the prescribed controls. For all other industries, there is no prescribed period during which compliance with the PEL must be achieved by controls other than respiratory protection.

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 μ g/m³ (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 I provides a detailed description of the monitoring procedure including the required frequency of blood testing for exposed workers, provisions for medical removal protection (MRP), and notification and recordkeeping requirements of the employer. Discussions of respirator use, respirator monitoring, and chelation therapy are also included.

Section II 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 III 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 II.

Section IV provides detailed information concerning the laboratory tests available for the monitoring of exposed workers. Also discussed are the relative value of each test and the limitations and precautions which are necessary in the interpretation of laboratory results.

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 $30 \ \mu g/m^3$ 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 μ g/m³ 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 μ g/100 g whole blood and the level requiring employee medical removal to be discussed below. For employees who are removed from exposure to lead due to an elevated blood lead, a new blood lead level must be measured monthly. A zinc protoporphyrin (ZPP) measurement is required on each occasion that a blood lead level measurement is made.

An annual medical examination and consultation performed under the guidelines discussed in Section III 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 μ g/100 g. Also, an examination is to be given to all employees prior to their assignment to an area in which airborne lead concentrations reach or exceed the action level. In addition, a medical examination must be provided as soon as possible after notification by an employee that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice regarding lead exposure and the ability to procreate a healthy child, or that the employee has

demonstrated difficulty in breathing during a respirator fitting test or during respirator use. An examination is also to be made available to each employee removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited or specially protected pursuant to medical recommendations.

Results of biological monitoring or the recommendations of an examining physician may necessitate removal of an employee from further lead exposure pursuant to the standard's medical removal protection (MRP) program. The objective 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 guidelines which are summarized in the following table 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.

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.

Effective Date

					- /- /
	9/8/79	9/8/80	9/8/81	9/8/82	9/8/82
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.)	≥ 80 µg/100 g	≥ 70 µg/100 g	≥ 60 µg/100 g	≥ 60 µg/100 g	≥ 60 µg/100 g or average of last three blood samples over previous 6 months (whichever is over a longer time period) is 50 µg/100 g or greater unless last blood sample is 40 µg/100 g or less.
B. Frequency which employees exposed to action level of lead (30 μg/100 g TWA) must have blood lead level checked (ZPP is also strongly recommended in each occasion that a blood lead level is obtained):					
 Last blood lead level less than 40 μg/100 g 	Every 6 months	Every 6 months	Every 6 months	Every 6 months	Every 6 months
 Last blood lead level between 40 μg/100 g and level requiring medical removal (see A above) 	Every 2 months	Every 2 months	Every 2 months	Every 2 months	Every 2 months
 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 µg/m ³ 8-hr. TWA	< 50 µg/m ³ 8-hr. TWA	< 30 µg/m ³ 8-hr. TWA	< 30 µg/m ³ 8-hr. TWA	< 30 µg/m ³ 8-hr. TWA
D. Blood lead level confirmed with a second blood analysis at which employee may return to work.	≤ 60 µg/100 g	≤ 50 µg/100 g	≤ 40 µg/100 g	≤ 40 µg/100 g	$\leq 40 \ \mu g/100 \ g$

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 $30 \ \mu g/m^3$ or more (without regard to the use of respirators) whenever either of the following

circumstances apply: (1) a blood lead level of $60 \mu g/100$ g or greater is obtained and confirmed by a second follow-up blood lead level performed within two weeks after the employer receives the results of the first blood sampling test, or (2) the

average of the previous three blood lead determinations or the average of all blood lead determinations conducted during the previous six months, whichever encompasses the longest time period, equals or exceeds 50 μ g/100 g, unless the last blood sample indicates a blood lead level at or below 40 μ g/100 g in which case the employee need not be removed. Medical removal is to continue until two consecutive blood lead levels are 40 μ g/100 g or less.

During the first two years that the ultimate removal criteria are being phased in, the return criteria have been set to assure that a worker's blood lead level has substantially declined during the period of removal. From September 8, 1979 to September 8, 1980, the blood lead level requiring employee medical removal is $80 \,\mu g / 100 \,g$. Workers found to have a confirmed blood lead level at or above this value need only be removed from work having a daily 8-hour TWA exposure to lead at or above $100 \,\mu\text{g/m}^3$. (Respirators are not to be used as a means of achieving this level of exposure.) Workers so removed are to be returned to work when their blood lead levels are at or below 60 μ g/100 g of whole blood. From September 8, 1980 to September 8, 1981, the blood lead level requiring medical removal is 70 μ g/100 g. During this period workers need only be removed from jobs having a daily 8-hour TWA exposure to lead at or above $50 \,\mu g/m^3$ (without respirator use) and are to be returned to work when a blood lead level no greater than 50 μ g/100 g is achieved. Beginning September 8, 1981, return depends on a worker's blood lead level declining to $40 \,\mu g/100$ g of whole blood.

As part of the standard, the employer is required to notify in writing each employee whose blood lead level exceeds $40 \ \mu g/100$ g. In addition each such employee is to be informed that the standard requires medical removal with MRP benefits, discussed below, when an employee's blood lead level exceeds the above defined limits.

In addition to the above blood lead level criteria, temporary worker removal may also take place as a result of medical determinations and recommendations. A written medical opinion 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 judgement, 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.

The employer must provide examining and consulting physicians with the following specific information: a copy of the lead standard 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 physician'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 nonoccupationally 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.

Prophylactic chelation is prohibited by the lead standard. 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 must 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 available upon request to the Chief of the Division of Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health. Employees must also make environmental and biological monitoring and medical removal records available to affected employees and to former employees or their authorized employee representatives. Employees or their specifically designated representatives have access to their entire medical surveillance records.

In addition, the standard requires that the employer inform all workers exposed to lead at or above the action level of the provisions of the standard and all its appendices, the purpose and description of medical surveillance and provisions for medical removal protection if temporary removal is required. An understanding of the potential health effects of lead exposure by all exposed employees along with full understanding of their rights under the lead standard is essential for an effective monitoring program.

II. Adverse health effects of inorganic lead

Although the toxicity of lead has been known for 2,000 years, the knowledge of the complex relationship between lead exposure and human response is still being refined. Significant research into the toxic properties of lead continues throughout the world, and it should be anticipated that our understanding of thresholds of effects and margin 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 $40 \,\mu g/100$ g; and second, the blood lead levels of workers, male or female, who intend to parent in the near future should be maintained below $30 \,\mu g/100 \,g$ to minimize adverse reproductive health effects to the parents and developing fetus. The adverse effects of lead on reproduction are being actively researched and the physician is encouraged 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, 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. The development of the lead standard focused on pathophysiological changes as well as later stages of disease.

1. <u>Heme Synthesis Inhibition</u>. The earliest demonstrated effect of lead involves its ability to inhibit at least two enzymes of the heme synthesis pathway at very low blood lead 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 μ g/100 g of whole blood. At a blood lead level of 40 μ g/100 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 μ g/100 g.

Another enzyme, ferrochelatase, is also inhibited at low blood lead levels. Inhibition of ferrochelatase leads to increase free erythrocyte protoporphyrin (FEP) in the blood which can then bind to zinc to yield zinc protoporphyrin (ZPP). At a blood lead level of $50 \ \mu g/100$ 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 $\ \mu g/100$ g and the associated ZPP level, which has led to the development of the ZPP screening test for lead exposure.

While the significance of these effects is subject to debate, these enzymatic disturbances may be early stages of a disease process which eventually results in the clinical symptoms of lead poisoning. Whether or not the effects do progress to the later stages of clinical disease, disruption of these enzymatic 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 μ g/100 g can be associated with a definite decreased hemoglobin, although most cases of leadinduced anemia, as well as shortened red-cell survival times, occur at lead levels exceeding 80 μ g/100 g. Inhibited hemoglobin synthesis is more common in chronic cases whereas shortened erythrocyte life span is more common in acute cases.

In lead-induced anemias, there is usually a reticulocytosis along with the presence of basophilic stippling, and ringed sideroblasts, although none of the above are pathognomonic for lead-induced anemia.

2. <u>Neurological Effects</u>. 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 are manifested by behavioral disturbances and central nervous system symptoms including irritability, restlessness, insomnia and other sleep disturbances, fatigue, vertigo, headache, poor memory, tremor, depression, and apathy. With more severe exposure, symptoms can progress to drowsiness, stupor, hallucinations, delirium, convulsions and coma.

The most severe and acute form of lead poisoning which usually follows ingestion or inhalation of large amounts of lead is acute encephalopathy which may arise precipitously with the onset of intractable seizures, coma, cardiorespiratory arrest, and death within 48 hours.

While there is disagreement about what exposure levels are needed to produce the earliest symptoms, most experts agree that symptoms definitely can occur at blood lead levels of $60 \mu g/100 g$ whole blood and therefore recommend a $40 \mu g/100 g$ maximum. The central nervous system effects frequently are not reversible following discontinued exposure or chelation therapy and when improvement does occur, it is almost always only partial.

The peripheral neuropathy resulting from lead exposure characteristically involves only motor function with minimal sensory damage and has a marked predilection for the extensor muscles of the most active extremity. The peripheral neuropathy can occur with varying degrees of severity. The earliest and mildest form which can be detected in workers with blood lead levels as low as $50 \mu g/100 g$ 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 μ g/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 μ g/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.

- <u>Gastrointestinal</u>. 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 twothirds 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. <u>Reproductive effects</u>. 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 μ g/100 g and hypospermia and asthenospermia at 41 μ g/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 to 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 to $60 \ \mu g/100 \ g$ in children can cause significant neurobehavioral impairments and there is evidence of hyperactivity at blood lead levels as low as 25 $\ \mu g/100 \ g$. Given the overall body of literature concerning the adverse health effects of lead in children, it is recommended that the blood lead level in children should be maintained below $30 \ \mu g/100 \ g$ with a population mean of $15 \ \mu g/100 \ g$. Blood lead levels in the fetus and newborn likewise should not exceed $30 \ \mu g/100 \ g$.

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, a $30 \ \mu g/100 \ g$ maximum permissible blood lead level is recommended for both males and females who wish to bear children.

6. <u>Other toxic effects</u>. 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 II, lead can affect numerous organ systems and produce a wide array of signs and symptoms, most of which are non-specific and subtle in nature at least in the early stages of disease. Unless serious concern for lead toxicity is present, many of the early clues to diagnosis may easily be overlooked.

The crucial initial step in the medical evaluation is recognizing that a worker's employment can result in exposure to lead. The worker will frequently be able to define exposures to lead and leadcontaining 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 known, the focus can then be directed toward eliciting information from the medical history, physical examination, 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.

Cardiopulmonary 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, easily fatigued, 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.

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 B_{12} and folate may be of value in attempting to identify the cause of the anemia.

If a peripheral neuropathy is suspected, nerve conduction studies are warranted both for diagnosis and as a basis to monitor any therapy.

If renal disease is questioned, a 24-hour urine collection for creatinine clearance, protein, and electrolytes may be indicated. Elevated uric acid levels may result from lead-induced renal disease and a serum uric acid level might be performed. An electrocardiogram and chest X-ray may be obtained as deemed appropriate.

Sophisticated and highly specialized testing should not be done routinely and where indicated should be under the direction of a specialist.

IV. Laboratory Evaluation

The blood lead level at present remains the single most important test to monitor lead exposure and is the test used in the medical surveillance program under the lead standard to guide employee medical removal. The ZPP has several advantages over the blood lead level, but 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 of 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 clearances 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 reach significantly elevated levels; the return to normal after discontinuing lead exposure is also slower. Furthermore, the ZPP test is simpler, faster, and less expensive to perform and no contamination is possible. Many investigators believe it is the most reliable means of monitoring chronic lead absorption.

Zinc protoporphyrin results from the inhibition of the enzyme ferrochelatase which catalyzes the insertion of an iron molecule into the protoporphyrin molecule, which then becomes heme. If iron is not inserted into the molecule then zinc, having a greater affinity for protoporphyrin, takes the place of the iron, forming ZPP.

An elevation in the level of circulating ZPP may occur at blood lead levels as low as $20-30 \ \mu g/100 \ g$ in some workers. Once the blood lead level has reached $40 \ \mu g/100 \ g$ there is more marked rise in the ZPP value from its normal range of less than $100 \ \mu g/100 \ ml$. Increases in blood lead levels beyond $40 \ \mu g/100 \ g$ 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 to 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 μ g/100 ml whole blood is obtained to rule out a significant underlying anemia. If the ZPP is in excess of $100 \,\mu g/100 \,ml$ and not associated with abnormal elevations in blood lead levels, the laboratory should be checked to be sure that blood leads were determined using atomic absorption spectrophotometry, anodic stripping voltammetry or other method meeting the accuracy requirements set forth by the standard and by a CDC-approved laboratory which is experienced in lead level determinations. Repeat periodic blood lead studies should be obtained in all individuals with elevated ZPP levels to be certain that an associated elevated blood lead level has not been missed due to transient fluctuations in blood leads.

ZPP has a characteristic fluorescence spectrum with a peak at 594 nm which is detectable with a hematofluorimeter. The hematofluorimeter is accurate and portable and can provide on-site, instantaneous results for workers who can be frequently tested via a finger prick.

However, careful attention must be given to calibration and quality control procedures. Limited data on blood-lead ZPP correlations and the ZPP levels which are associated with the adverse health effects discussed in Section II 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 are 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 deltaaminolevulinic acid dehydrase (ALA-D). Although the test is relatively easy to perform, inexpensive, and rapid, the disadvantages include variability in results, the necessity to collect a complete 24-hour urine sample which has a specific gravity greater than 1.010, and also the fact that ALA decomposes in the presence of light.

The pattern of porphyrin excretion in the urine can also be helpful in identifying lead intoxication. With lead poisoning, the urine concentrations of coproporphyrins I and II, porphobilinogen and uroporphyrin I rise. The most important increase, however, is that of coproporphyrin III; levels may exceed 5,000 μ g/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 prophyrins are not diagnostic of lead toxicity and may be seen in porphyria, some liver diseases, and in patients with high reticulocyte counts.

<u>Summary</u>. The 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 $30 \ \mu g/m^3$ TWA. The physician has a fundamental role in this surveillance program, and in the operation of the medical removal protection program.

Even with adequate worker education on the adverse health effects of lead and appropriate training in work practices, personal hygiene and other control measures, the physician has a primary responsibility for evaluating potential lead toxicity in the worker. It is only through a careful and detailed medical and work history, a complete physical examination and appropriate laboratory testing that an accurate assessment can be made. Many of the adverse health effects of lead toxicity are either irreversible or only partially reversible and therefore early detection of disease is very important.

This document outlines the medical monitoring program as defined by the occupational safety and health standard for inorganic lead. It reviews the adverse health effects of lead poisoning and describes the important elements of the history and physical examinations as they relate to these adverse effects.

APPENDIX D Qualitative Fit Test (QLFT) Protocols

[See Section 5144, Appendix A]