DEPARTMENT OF LABOR AND INDUSTRY

Proposed Appendix C to MN Rule 5205.XXXX
Medical Surveillance Requirements

This appendix outlines the medical surveillance provisions of the construction standard for lead and provides further information to the physician or other licensed health care professional (PLHCP) regarding the examination and evaluation of employees exposed to lead.

Introduction

The primary purpose of the Occupational Safety and Health Act of 1970 is to ensure, so far as possible, safe and healthful working conditions for every working person. The occupational health standard for lead in construction is designed to protect employees exposed to inorganic lead including metallic lead, all inorganic lead compounds and organic lead soaps.

Under this standard occupational exposure to inorganic lead is to be limited to 50 µg/m3 (micrograms per cubic meter) calculated as an 8-hour time-weighted average (TWA). This permissible exposure limit (PEL) must be achieved through a combination of engineering, work practice and administrative controls to the extent feasible. Where these controls are in place but are found not to reduce employee exposures to or below the PEL, they must be used nonetheless.

The standard establishes an action level of 10 µg/m3 calculated as an 8-hour TWA. The action level refers to employee exposure, without regard to the use of respirators. The action level triggers several ancillary provisions of the standard such as exposure monitoring, respiratory protection, protective clothing, hygiene facilities, medical surveillance, a training program, and signs.

The standard lists certain construction tasks which, when lead is present, may likely result in exposures to lead in excess of the action level and, in some cases, exposures in excess of 50 times the action level. These tasks are known as trigger tasks, and are described in subsection (d)(2) of the lead standard. Trigger tasks are categorized as level 1, level 2, or level 3 trigger tasks. Performing level 3 trigger tasks is presumed to result in the highest exposures to lead. Level 1 trigger tasks include manual demolition of structures (such as dry wall), manual scraping, and heat gun applications. Level 2 trigger tasks include manual sanding, power tool cleaning, grinding, or sanding with dust collection systems, and spray painting with lead paint. Level 3 trigger tasks include using lead-containing mortar or lead burning, and rivet busting, power tool cleaning, grinding or sanding without dust collection systems, cleanup activities where dry expendable abrasives are used, abrasive blasting enclosure movement and removal, abrasive blasting, welding, torch cutting, and torch burning. If an employee performs any of these trigger tasks when lead is present, or if the employer has any reason to believe that the employee may be exposed to lead over the action level, the employer must provide the employee with interim protection, until such time that an exposure assessment is conducted which demonstrates that the employee's exposure level to lead is below the action level. Interim protections include appropriate respiratory protection, protective

clothing and equipment, change areas, shower facilities (for level 3 trigger tasks), eating areas, regulated areas, and medical surveillance.

The standard also provides for a program of medical surveillance for employees, as outlined in section I of this Appendix. This program consists of initial blood lead testing and medical evaluation, along with periodic blood lead testing and medical evaluation, to be performed on a schedule which is defined by previous laboratory results, employee complaints or concerns, and the clinical assessment of the examining PLHCP.

Section I provides a detailed description of the medical surveillance procedures including the required frequency of blood lead testing and medical examination and consultation for exposed employees, provisions for medical removal protection (MRP), the right of the employee to a second medical opinion, and notification and recordkeeping requirements of the PLHCP and the employer. A discussion of the requirements for respirator use and respirator monitoring and OSHA's position on prophylactic chelation therapy are also included in this section.

Section II discusses the toxic effects and clinical manifestations of lead poisoning and effects of lead intoxication on the cardiovascular, neurologic, renal, gastrointestinal and hematologic systems. 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 employee 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 employees. Included also is a discussion of the relative value of each test and the limitations and precautions which are necessary in the interpretation of the laboratory results.

I. Medical Surveillance Requirements for Employees Exposed to Inorganic Lead

A. Blood Lead Testing

Under the standard for lead in the construction industry, initial blood lead testing shall be provided to employees prior to assignment to work where exposure to lead is or is likely to be at or above the action level. An exception exists if the employee had a blood lead test in the preceding two months, then initial blood lead testing is not required to be provided.

Initial blood lead testing shall also be provided to employees as interim protection, unless a negative initial determination has been made, prior to performing trigger tasks described in subsection (d)(2) of the lead standard.

After the initial blood lead testing, additional blood lead testing must be made available to employees. An exception is if they only perform level 1 trigger tasks, and perform these level 1 trigger tasks on less than 10 days in any 12 consecutive months, then additional blood lead testing is not required to be provided. Also, if the employee's initial blood lead level (BLL) is at or above 10 μg/dl, they must be provided with additional blood lead testing, as described in the next paragraph. There are no exceptions to this.

Unless an employee's exposure to lead or work with lead falls under one the exceptions described above, blood lead testing under the standard must be provided on the following schedule: at least every two months for the first six months after initial placement, and also for the six months after any change in task resulting in higher exposure; and every six months thereafter. If an employee's last BLL is at or above 10 µg/dl but is below 20 µg/dl, the testing frequency must be at least every two months. This frequency must continue until two consecutive BLLs, taken at least 30 days apart, are less than 10 µg/dl. Blood lead testing then must be provided as described in the schedule given at the start of this paragraph. For employees whose last blood lead test indicated a BLL at or above 20 µg/dl or who are removed from exposure to lead due to an elevated blood lead, a new BLL must be measured monthly. Monthly blood lead tests must also be provided as an interim protection for each employee who performs a level 3 trigger task as listed in subsection (d)(2)(D), including a blood test taken within 3 days after discontinuing all level 3 trigger task work. Finally, blood lead tests must be provided at least monthly to each employee whose airborne exposure to lead is above 500 µg/m3 as an 8-hour TWA, without regard to the use of respirators, including a blood test taken within 3 days after discontinuing all work associated with airborne exposure above 500 µg/m3 as an 8-hour TWA.

B. Medical Examination and Consultation

An initial medical examination and consultation performed under the guidelines discussed in section III is to be made available to an employee where exposure to lead will be at or above the action level, and as interim protection prior to performing trigger tasks. There is an exception to this requirement. The exception is if an employee only performs level 1 trigger tasks, and they perform these level 1 trigger tasks on less than 10 days in any 12 consecutive months, then a medical evaluation is not required to be provided.

Medical examinations must be made available prior to assignment to lead work. There is an exception to this requirement. A medical examination is not required prior to assignment if an employee had a lead-specific medical examination in the preceding two months. Medical examinations beyond the initial one must be made available on an annual basis if an employee's BLL is 20 µg/dl or greater at any time during the preceding year. This medical examination must be made available as soon as possible upon receiving a blood lead test result of 20 µg/dl or greater if the employee has not had a lead-specific medical examination in the last 12 months. In addition, a medical examination must be provided as soon as possible after notification by an employee that the employee has developed signs and 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 fit test or during respirator use. A medical examination beyond the initial one is also to be made available to each employee removed from exposure to lead due to an elevated blood lead level, as discussed in the next section, or otherwise limited or specially protected pursuant to medical recommendations.

The requirements for the medical surveillance of employees who are exposed to lead are summarized in Table 1.

Table 1. Minimum Requirements for Medical Surveillance.

A. Initial Blood lead level (BLL) tests required to be made available.	**Prior to assignment to work where exposure to lead is or reasonably expected to be ≥ the action level (10 µg/m3 as an 8-hour TWA); and**

	Prior to performing trigger tasks, and an exposure assessment has not been completed.
B. Additional BLL tests required to be made available.	**For employees:**
	whose last BLL was ≥ 10 µg/dl; or
	who are exposed ≥ action level; or
	who perform trigger tasks, and an exposure assessment has not been completed.
C. Schedule of BLL tests required to be made available for employees when their:	
1. Last BLL was < 10 µg/dl, and the employee is included in B above.	Every 2 months for the first 6 months after initial placement, and also for the first 6 months after a change in task resulting in higher exposure, and then every 6 months.
2. Last BLL was ≥ 10 µg/dl but < 20 µg/dl.	Every 2 months. Continue until 2 BLLs, taken at least 30 days apart, are < 10 µg/dl.
3. Last BLL was ≥ 20 µg/dl.	Every 1 month.
D. Schedule of BLL tests required to be made available for employees whose airborne exposure is above 500 µg/m3 as an 8-hour TWA.	Every 1 month. Include a blood test taken within 3 days after discontinuing all work associated with airborne exposure> 500 µg/m3 as an 8-hour TWA.
E. Schedule of BLL tests required to be made available for employees who perform a level 3 trigger task, and an exposure assessment has not been completed.	Every 1 month. Include a blood test taken within 3 days after discontinuing all level 3 trigger task work.
F. Initial medical examination and consultation required to be made available.	**Prior to assignment for employees who will be:**
	exposed ≥ action level.
	performing trigger tasks, and an exposure assessment has not been completed.
	Additionally, medical examinations are not required prior to assignment if an employee had a lead-specific medical examination in the preceding two months.
G. Additional medical examinations and consultations required to be made available.	**For employees who are:**

	exposed ≥ action level; or
	performing trigger tasks, and an exposure assessment has not been completed.
H. Schedule of additional medical examinations and consultations required to be made available, for employees included in G above.	As soon as possible when an employee's BLL is ≥ 20 µg/dl, if no lead-specific medical examination was done in the preceding 12 months; and
	annually until the employee's BLL is < 20 µg/dl.
	As soon as possible, upon notification by an employee either that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice concerning the effects of current or past exposure to lead on the employee's ability to procreate a healthy child, that the employee is pregnant, or that the employee has demonstrated difficulty in breathing during a respirator fit test or during use.

Note: Exposure levels in Table 1 are without regard to an employee's use of a respirator.

C. Medical Removal Protection

Results of BLL testing or the recommendations of an examining PLHCP may necessitate removal of an employee from further lead exposure pursuant to the standard's medical removal protection (MRP) program. The object of the MRP program is to provide temporary medical removal to employees either with substantially elevated BLLs or otherwise at risk of sustaining material health impairment from continued substantial exposure to lead.

Under the standard's employee medical removal criteria, an employee is to be removed from any work having an exposure to lead at or above the action level, involving a trigger task as listed in subsection (d)(2) of the lead standard, or altering or disturbing any material containing lead at a concentration equal to or greater than 0.5% by weight, on each occasion that:

1. The last blood lead test indicates that the employee's BLL is at or above 30 µg/dl; or

2. Effective January 1, 2026, the last two blood lead test results are at or above 20 µg/dl; or

3. Effective January 1, 2026, the average of the results of all blood lead tests conducted in the last 6 months is at or above 20 µg/dl, unless the last blood test indicates a blood lead level below 15 µg/dl, in which case the employee need not be removed.

Medical removal is to continue until two consecutive BLLs, taken at least 30 days apart, are below 15 µg/dl.

In addition to the above BLL criteria, temporary medical removal for employees 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 PLHCP includes a medical finding, determination or opinion that the employee has a health-related condition which places the employee's health, including the ability to procreate a healthy child, at increased risk of material impairment from exposure to lead, then the

employee must be removed from work having an exposure to lead at or above the action level, involving a trigger task as listed in subsection (d)(2) of the lead standard, or altering or disturbing any material containing lead at a concentration equal to or greater than 0.5% by weight. Alternatively, if the examining PLHCP 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.

Monthly BLL tests must be made available during the medical removal period for an employee who is removed from exposure to lead due to an elevated BLL. In addition, unless an employee's exposure or work is covered by the exceptions described in subsection I.B. of this appendix, a medical examination is to be made available as soon as possible and then as medically appropriate to each employee removed from exposure to lead due to an elevated BLL or due to a risk of sustaining material impairment to health, or otherwise limited or specially protected pursuant to medical recommendations.

Recommendations may be more stringent than the specific provisions of the standard. The examining PLHCP, 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 employees and employees who are planning to raise children. Based on the history, physical examination, and laboratory studies, the PLHCP 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 PLHCP's judgment, continued exposure to lead at the current job would pose a significant risk. The return of the employee to their former job status, or the removal of special protections or limitations, depends upon the examining PLHCP 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 employee's earnings, seniority, and other employment rights and benefits (as though the employee had not been removed) for a period of up to 18 months or for as long as the job the employee was removed from lasts if less than 18 months. This economic protection will maximize meaningful employee participation in the medical surveillance program, and is appropriate as part of the employer's overall obligation to provide a safe and healthful workplace. The provisions of MRP benefits during the employee's removal period may, however, be conditioned upon participation in medical surveillance.

The requirements for the temporary removal of an exposed employee and their subsequent return to work with lead are summarized in Table 2.

Table 2. Minimum Requirements During the Medical Removal Protection (MRP) Period.

A.	**BLL requiring employee medical removal.**	**one BLL ≥ 30 µg/dl; or**
		effective January 1, 2026, the last two BLLs are ≥ 20 µg/dl; or

		effective January 1, 2026, the average of all BLLs over the last 6 months is ≥ 20 µg/dl, unless the last blood test indicates a blood lead level below 15 µg/dl, in which case the employee need not be removed.
B.	MRP due to a final medical determination.	A written medical opinion on the employee's health status by the examining PLHCP results in a medical finding, determination, or opinion that the employee has a detected health-related condition which places the employee's health, including the ability to procreate a healthy child, at increased risk of material impairment from exposure to lead.
C.	Frequency of BLL tests required to be made available for an employee removed from exposure to lead because of an elevated BLL.	Every 1 month.
D.	Medical examinations and consultations required to be made available.	As soon as possible, then as medically appropriate, for an employee:
		removed from exposure to lead due to elevated blood lead levels, or
		whose exposure to lead is otherwise limited pursuant to a final medical determination.
E.	Permissible working conditions for an employee on MRP.	Employee must be removed from any work:
		having an exposure to lead (without regard to respirator use) ≥ the action level; or
		involving a trigger task; or

		altering or disturbing any material containing lead at a concentration ≥ 0.5% by weight.
F.	When an employee has been placed on MRP due to elevated BLL, the BLL at which an employee shall be returned to their former work.	Two consecutive BLLs, taken at least 30 days apart, both indicate a BLL < 15 µg/dl.
G.	When an employee has been placed on MRP due to a final medical determination, the conditions under which an employee shall be returned to their former work.	A subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected health-related condition that places the employee's health, including the ability to procreate a healthy child, at increased risk of material impairment from exposure to lead.

Note: When a medical opinion indicates that an employee is at risk of material impairment from exposure to lead, the PLHCP 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 PLHCP so specifies. Return to work or removal of limitations and special protection is permitted when the PLHCP indicates that the employee is no longer at risk of material impairment.

The lead standard provides for a multiple PLHCP review in cases where the employee wishes a second opinion concerning potential lead poisoning or toxicity. If an employee wishes a second opinion, they can make an appointment with a PLHCP of their choice. This second PLHCP will review the findings, recommendations or determinations of the first PLHCP and conduct any examinations, consultations or tests deemed necessary in an attempt to make a final medical determination. If the first and second PLHCPs 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 PLHCP to resolve the dispute.

D. Requirements for Providing Information to Laboratories, Employees, Employers, and PLHCPs

For Blood Lead Tests:

The employer must instruct the PLHCP who orders blood lead tests to provide the analyzing laboratory with complete employee identification information. This information includes:

1. Employee name, date of birth, address, and phone number; and

2. Employer name, address, and phone number.

The employer must ensure that the ordering PLHCP explains the findings of any blood lead test and notifies the employee of the following:

1. The results of the blood lead test;

2. Any recommended follow-up blood lead testing in accordance with subsection (j)(2)(A) and the timing of that recommended blood lead testing; and

3. If the employee's blood lead level is 20 µg/dl or greater, the recommendation that the employee undergo a medical examination by a PLHCP if the employee has not had a lead-specific medical exam in the preceding 12 months.

In addition, the employer is required to provide a written notification to the employee within five working days after the receipt of the employee's blood lead test results. The employer must notify each employee:

1. Of that employee's BLL;

2. That the standard requires the employer to make medical examinations and consultations available to employees exposed at or above the action level, and as interim protection, to employees performing trigger tasks, unless an employee's exposure or work is covered by the exceptions in 1532.1(j)(1)(B). When they are required, the employer must make medical examinations and consultations available 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 breathing during a respirator fit test or during use; and

3. That the standard requires medical removal with MRP benefits when an employee's BLL exceeds any of the limits defined for medical removal.

For Medical Examination and Consultation:

The employer must provide examining and consulting PLHCPs with the following specific information:

1. A copy of the lead regulations and all appendices;

2. A description of the employee's duties as related to exposure;

3. The exposure level or anticipated level to lead and any other toxic substances (if applicable);

4. A description of personal protective equipment used;

5. Prior BLLs;

6. All prior written medical opinions regarding the employee in the employer's possession or control; and

7. A copy of the employer's written elevated blood lead level response plan (required when an employee's BLL is at or above 10 µg/dl).

The employer must ensure that the PLHCP explains to the employee the results of the medical examination and provides each employee with a written medical report within 30 days of each medical examination performed. The written report shall contain:

1. The PLHCP's opinion as to whether the employee has any detected health-related condition that would place the employee's health, including the ability to procreate a healthy child, at increased risk of material impairment from exposure to lead;

2. Any recommended special protective measures to be provided to the employee, or recommended limitations to be placed upon the employee's exposure to lead;

3. Any recommended limitations upon the employee's use of respirators, including a determination of whether the employee should wear a powered air-purifying respirator (PAPR) instead of a non-powered air-purifying respirator;

4. The employee's BLL;

5. Any recommended follow-up blood lead testing and medical examinations and the timing of each; and

6. The PLHCP's opinion as to whether the employee has any health-related condition, occupational or non-occupational, that dictates further medical examination or treatment.

The employer must also obtain a written medical opinion from the examining PLHCP within 30 days of the medical examination. The written opinion shall contain the following information:

1. The PLHCP's opinion as to whether the employee has any detected health-related condition that would place the employee's health, including the ability to procreate a healthy child, at increased risk of material impairment 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 PAPR if the PLHCP determines that the employee cannot wear a negative pressure respirator;

4. The employee's BLL; and

5. Any recommended follow-up blood lead testing and medical examinations and the timing of each.

Employers must instruct each PLHCP not to reveal to the employer in writing or in any other way their findings, laboratory results, or diagnoses which are felt to be unrelated to occupational lead exposure.

E. Additional Requirements

The standard provides for the use of respirators where engineering and other primary controls do not provide adequate protection. However, the use of respiratory protection shall not be used in lieu of temporary medical removal due to elevated BLLs 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 employees 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. If the employer selects filtering facepiece respirators for protection against lead, they shall be N100, R100, or P100. Also, a PAPR is much more protective than a typical negative pressure respirator, and may also be more comfortable to wear. The standard provides that an employer must provide a PAPR to an employee upon request.

Prophylactic chelation is prohibited by the lead standard. Diagnostic and therapeutic chelation are permitted only when done by a PLHCP with appropriate medical monitoring in an acceptable clinical setting. The decision to initiate chelation therapy must be made on an individual basis and take into account the severity of symptoms felt to be a result of lead toxicity along with BLLs, zinc protoporphyrin (ZPP) levels, and other laboratory tests as appropriate. Calcium disodium EDTA (Ca Na2 EDTA) and succimer, 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 employee. Unless frank and severe symptoms are present, therapeutic chelation is not recommended, given the opportunity to remove an employee from exposure and allow the body to naturally excrete accumulated lead. As a diagnostic aid, the chelation mobilization test has limited applicability. It offers very limited utility as a biomarker of long-term lead exposure, and does not predict the clinical efficacy of chelation.

Employers are required to ensure that accurate records are maintained on exposure assessment, including environmental monitoring, medical surveillance, and medical removal for each employee. Exposure assessment records must be kept for at least 30 years. Medical surveillance records must be kept for the duration of employment plus 30 years except in cases where the employment was less than one year. If duration of employment is less than one year, the employer need not retain this record beyond the term of employment if the record is provided to the employee upon termination of employment. Medical removal records also must be maintained for the duration of employment. All records required under the standard must be made available upon request to the Commissioner, and the National Institute for Occupational Safety and Health (NIOSH). Employers must also make environmental and biological monitoring and medical removal records available to affected employees and to former employees or their authorized employee representatives. Employees or their specifically designated representatives have access to their entire medical surveillance records.

In addition, the standard requires that the employer inform all employees who are exposed to lead at or above the action level on any one day; who are exposed to lead that may cause skin or eye irritation (e.g., lead arsenate, lead azide); or who perform trigger tasks 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. Scientific evidence shows multiple health effects at BLLs once thought to be without recognized harm. Prolonged exposure to lead levels below the previous OSHA BLL threshold of 50 µg/dl can result in adverse cumulative effects. Some of these health effects may be reversible and some may be permanent.

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 employee BLLs be maintained as low as possible, and second, the BLLs of employees who are trying to conceive should be maintained below 3.5 µg/dl to minimize adverse reproductive health effects. The lead standard is designed to detect BLL increases early and take action to control exposures. The adverse effects of lead on reproduction are being actively researched and the PLHCP's are encouraged to remain abreast of recent developments in the area to best advise pregnant employees or employees planning to conceive children.

The spectrum of health effects caused by lead exposure can be subdivided into four developmental stages: physiological changes of uncertain significance, pathophysiological changes, overt symptoms (morbidity), and mortality. Within this process there are no sharp distinctions, but rather a continuum of effects. Boundaries between categories overlap due to the wide variation of individual responses and exposures in the working population. Development of the lead standard focused on pathophysiological changes as well as later stages of disease.

In terms of mechanisms of disease, lead interferes with cellular metabolism in tissues throughout the body. As a divalent cation, lead interferes with calcium metabolism which affects, for example, neurotransmission and vascular tone. Lead has a high affinity for negatively charged sulfhydryl groups, ultimately affecting the synthesis of heme required for production of hemoglobin, cytochromes involved in cellular respiration, and microsomal oxidases involved in biotransformation pathways. In addition, lead increases reactive oxygen species, which effects vascular tone. Lead also affects cell membranes and nucleic acids with multi-system effects. In the nervous system, lead alters the permeability of the blood brain barrier and accumulates in astroglia. Other modes of action include cell death, genotoxicity, inflammation, and endocrine disruption.

1. Cardiovascular Effects. Current evidence indicates a causal relationship between lead exposure and hypertension, and between lead exposure and coronary heart disease. Prospective cohort studies have demonstrated an approximate 50% increase in cardiovascular mortality associated with chronic BLLs of 10 µg/dl or greater. Increased cardiovascular mortality has also been associated with BLLs below 10 µg/dl. Various mechanisms of action may mediate the hypertensive effect, including oxidative stress, inflammation, hormonal and blood pressure regulatory-system dysfunction, and vasomodulator imbalance. These mechanisms, and possibly subclinical atherosclerosis which has been demonstrated in some studies, likewise contribute to coronary heart disease. Since hypertension is a significant risk factor for heart disease, stroke, and renal insufficiency, lead exposure may exert an important influence on cardiovascular, cerebrovascular, and renovascular mortality. Nonetheless, lead exposure is associated with increased cardiovascular and stroke mortality even after accounting for the effects of hypertension.

2. Heme Synthesis Inhibition. The earliest hematologic effect involves lead's ability to inhibit at least two enzymes of the heme synthesis pathway at very low BLLs. Inhibition of delta-aminolevulinic acid dehydratase (ALA-D) which catalyzes the conversion of delta-aminolevulinic acid (ALA) to protoporphyrin is observed at a BLL as low as 10 µg/dl. At a BLL of 40 µg/dl, more than 20% of the population would have 70% inhibition of ALA-D. There is an exponential increase in ALA excretion at BLLs greater than 40 µg/dl.

Another enzyme, ferrochelatase, is also inhibited at low BLLs. Inhibition of ferrochelatase leads to increased free erythrocyte protoporphyrin (FEP) in the blood which can then bind to zinc to yield zinc protoporphyrin (ZPP). At a BLL of 50 µg/dl or greater, nearly 100% of the population will have an increase in FEP. There is also an exponential relationship between BLLs greater than 40 µg/dl and the associated ZPP level, which has led to the development of the ZPP screening test for lead exposure.

While the significance of these effects is subject to debate, these enzyme disturbances are 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 enzyme processes over a working lifetime is 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 is associated with a wide array of symptoms including dizziness, fatigue, and tachycardia when more severe. Hematopoietic effects tend to occur at a BLL threshold of 10-20 µg/dL; however, bone lead stores from chronic exposure may continue to exert subclinical effects on hematopoiesis, regardless of current BLL. Once BLLs reach 50 µg/dl, a definite decrease in hemoglobin is evident, although most cases of lead-induced anemia, as well as shortened red-cell survival times, occur at BLLs exceeding 80 µg/dl. Inhibited hemoglobin synthesis is more common in chronic cases, whereas shortened erythrocyte life span is more common in acute cases.

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

3. Neurological Effects. Inorganic lead has been found to have toxic effects on both the central and peripheral nervous systems. The earliest stages of lead-induced central nervous system effects 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, cardiopulmonary arrest, and death within 48 hours.

Lead exposure is associated with decrements in neurological function in adults. Effects at BLLs ≤10 µg/dl include decreased cognitive function, altered behavior and mood, and altered neuromotor and neurosensory function. At higher BLLs, a variety of decrements in cognitive function and behavior and nerve function can occur. These effects may be irreversible.

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 employees with BLLs over 30 µg/dl is manifested by slowing of motor nerve conduction velocity often without clinical symptoms. With progression of the neuropathy there is development of painless extensor muscle weakness usually involving the extensor muscles of the fingers and hand in the most active upper extremity, followed in severe cases by wrist drop or, much less commonly, foot drop.

In addition to slowing of nerve conduction, electromyographical studies in patients with BLLs greater than 50 µg/dl have demonstrated a decrease in the number of acting motor unit potentials, an increase in the duration of motor unit potentials, and spontaneous pathological activity including fibrillations and fasciculations. Essential tremor in some studies has been shown to occur at BLLs less than 10 µg/dl.

While the peripheral neuropathies can occasionally be reversed with therapy, again such recovery is not ensured 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.

4. Gastrointestinal. Lead may also affect the gastrointestinal system producing abdominal colic or diffuse abdominal pain, constipation, obstipation, diarrhea, anorexia, nausea, and vomiting. Lead colic may develop at 80 µg/dl, whereas milder, nonspecific gastrointestinal discomfort and constipation occur with levels higher than 60 µg/dl.

5. Renal. Renal toxicity represents one of the most serious health effects of lead poisoning. Kidney dysfunction is thought to occur at chronic BLLs of 5-10 µg/dl or greater but also may arise after acute high-dose lead exposures. In the early stages of disease nuclear inclusion bodies can frequently be identified in proximal renal tubular cells. Renal function remains normal and the changes in this stage are probably reversible. With more advanced disease there is progressive interstitial fibrosis and impaired renal function. Eventually extensive interstitial fibrosis ensues with sclerotic glomeruli and dilated and atrophied proximal tubules; all represent end stage kidney disease. Azotemia can be progressive, eventually resulting in frank uremia necessitating dialysis. There is occasionally associated hypertension and hyperuricemia with or without gout.

Early kidney disease is difficult to detect. The urinalysis is normal in early lead nephropathy and the blood urea nitrogen and serum creatinine increase only when two-thirds of kidney function is lost. Measurement of creatinine clearance can often detect earlier disease as can other methods of measurement of glomerular filtration rate. An abnormal chelation mobilization test has been used to differentiate between lead-induced and other nephropathies, but this procedure is not widely accepted.

6. Reproductive Effects. Exposure to lead can have serious effects on reproductive function in both males and females. In male employees 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. These adverse effects may occur at BLLs of 20 µg/dl or greater. Furthermore, there appears to be a dose-response relationship for teratospermia in lead-exposed employees.

Females exposed to lead may experience menstrual disturbances including dysmenorrhea, menorrhagia, and amenorrhea. Following exposure to lead, females have a higher frequency of sterility, premature births, miscarriages, and stillbirths.

Germ cells can be affected by lead and lead can cause genetic damage in the egg or sperm cells before conception and contribute to failure to implant, miscarriage, stillbirth, or birth defects.

Maternal lead exposure during pregnancy is associated with gestational hypertension, spontaneous abortion, low birth weight, and impaired neurodevelopment.

Lead can pass through the placental barrier and lead levels in the birthing parent's blood are comparable to concentrations of lead in the umbilical cord at birth. Transplacental passage becomes detectable at 12-14 weeks of gestation and increases until birth.

There is little direct data on damage to the fetus from exposure to lead but it is generally assumed that the fetus and newborn would be at least as susceptible to neurological damage as young children. Current evidence indicates that there is no known lower limit of toxicity at any age. Lead exposure in children can cause significant neurobehavioral impairments including cognitive dysfunction and hyperactivity. Therefore, people planning to conceive should maintain BLLs less than 3.5 µg/dl.

7. Other Toxic Effects. Debate and research continue on the effects of lead on the human body. Lead may impair the immune and endocrine systems, including thyroid function and the pituitary-adrenal axis, but these effects and the corresponding level of exposure have not been well defined. Also, although the epidemiologic data is limited and inconsistent, based on toxicologic data and animal studies, lead is considered a probable human carcinogen by several authoritative sources.

III. Medical Evaluation

The most important principle in evaluating an employee for any occupational disease including lead poisoning is a high index of suspicion on the part of the examining PLHCP. 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 an employee's employment can result in exposure to lead. The employee will frequently be able to define exposures to lead and lead containing materials but often will not volunteer this information unless specifically asked. In other situations the employee may not know of any exposures to lead but the suspicion might be raised on the part of the PLHCP because of the industry or occupation of the employee. Potential occupational exposure to lead and its compounds occur in many occupations in the construction industry, including demolition and salvaging operations, painting, removal or encapsulation of materials containing lead, construction, alteration, repair or renovation of structures containing lead, transportation, disposal, storage or containment of lead or lead-containing materials on construction sites, and maintenance operations associated with construction activities.

Once the possibility for lead exposure is raised, the focus can then be directed toward eliciting information from the medical history, physical exam, and finally from laboratory data to evaluate the employee for potential lead toxicity.

A complete and detailed work history is important in the initial evaluation. A listing of all previous employment with information on job description, exposure to fumes or dust, known exposures to lead or other toxic substances, a description of any personal protective equipment used, and previous medical surveillance should all be included in the employee's record. Where exposure to lead is suspected, information concerning on-the-job personal hygiene, smoking, eating and drinking 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 an employee 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 health-related conditions, current medications including proprietary drug intake and folk remedies, 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 cardiovascular, 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 employee might not appreciate as being significant. The review of symptoms should include the following:

1. General -- weight loss, fatigue, decreased appetite.

2. Head, Eyes, Ears, Nose, Throat (HEENT) -- headaches, visual disturbances or decreased visual acuity, hearing deficits or tinnitus, pigmentation of the oral mucosa, or metallic taste in mouth.

3. Cardiopulmonary -- shortness of breath, cough, chest pains, palpitations, or orthopnea.

4. Gastrointestinal -- nausea, vomiting, heartburn, abdominal pain, constipation, or diarrhea.

5. Neurologic -- irritability, insomnia, weakness (fatigue), dizziness, loss of memory, confusion, hallucinations, incoordination, ataxia, decreased strength in hands or feet, disturbances in gait, difficulty in climbing stairs, or seizures.

6. Hematologic -- pallor, easy fatigability, abnormal blood loss, or melena.

7. Reproductive (male and female, and spouse where relevant) -- history of infertility, impotence, loss of libido, abnormal menstrual periods, history of miscarriages, stillbirths, or children with birth defects.

8. Musculoskeletal -- muscle and joint pains.

The physical examination should emphasize the neurological, gastrointestinal, and cardiovascular systems. The employee's weight and blood pressure should be recorded. Historically, the oral mucosa was checked for pigmentation characteristic of a possible Burtonian or lead line on the gingiva. However, 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 ischemic heart disease and congestive heart failure. Pulmonary status should be addressed particularly if respiratory 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 (ZPP) level for each employee whose last BLL was at or above 20 µg/dl.

In addition to the above, the PLHCP is authorized to order any further laboratory or other tests which they deem necessary in accordance with sound medical practice. The evaluation must also include pregnancy testing or laboratory evaluation of male fertility if requested by the employee. Additional tests which are probably not warranted on a routine basis but may be appropriate when blood lead and ZPP levels are equivocal include delta-aminolevulinic acid and coproporphyrin concentrations in the urine, and dark-field illumination for detection of basophilic stippling in red blood cells.

If an anemia is detected further studies including a careful examination of the peripheral smear, reticulocyte count, stool for occult blood, serum iron, total iron binding capacity, bilirubin, and, if appropriate, vitamin B12 and folate may be of value in attempting to identify the cause of the anemia.

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

If renal disease is questioned, a 24-hour urine collection for creatinine clearance, protein, and electrolytes may be indicated. Elevated uric acid levels may result from lead-induced renal disease and a serum uric acid level might be performed.

An electrocardiogram and chest x-ray may be obtained as deemed appropriate.

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

IV. Laboratory Evaluation

The BLL 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 currently remains an ancillary test due to its lack of sensitivity.

This section will discuss the BLL 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.

BLL, a measure of the amount of lead currently found in the blood, reflects both recent exogenous exposure as well as endogenous redistribution of lead stored in bone. BLL does not reflect the total body burden. 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 BLLs 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.

When interpreting a person's BLL, three key questions to keep in mind are whether the exposure history has been acute or chronic; recent or remote; high or low. For instance, a high BLL may only represent recent heavy exposure to lead without a significant total body excess and likewise a low BLL does not exclude an elevated total body burden of lead.

Also due to its correlation with recent exposures, the BLL 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 that are CLIA-approved (under the federal Clinical Laboratory Improvement Amendments (CLIA) regulations).

he 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, employees with renal insufficiency, whether due to lead or some other cause, may have decreased lead clearance and consequently urine lead levels may underestimate the true lead burden. Therefore, urine lead levels should not be used as a routine test.

The ZPP test, unlike the blood lead determination, is an indirect and relatively insensitive biomarker of 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. The level of circulating ZPP may not rise until a BLL of 20 µg/dl in some adults and is not greater than 90% sensitive until the BLL exceeds 50 µg/dl. Increases in BLLs beyond 40 µg/dl are associated with exponential increases in ZPP. The upper limit of normal for ZPP varies some between labs but is usually between 35 and 40 µg/dl.

Whereas BLLs fluctuate over short time spans, ZPP levels remain relatively stable. ZPP is measured directly in red blood cells and is present for the cell's entire 120 day life-span. Therefore, the ZPP level in blood reflects the average ZPP production over the previous 3-4 months and consequently the average lead exposure during that time interval. 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, lagging the BLL by about 2-6 weeks. Therefore, the ZPP may be useful to assess chronicity of exposure. For example, an elevated BLL and normal ZPP suggest recent exposure, while an elevated BLL and elevated ZPP suggest chronic/ongoing exposure.

It is recommended that a hematocrit be determined whenever a confirmed ZPP of 50 µg/dl is obtained to rule out a significant underlying iron deficiency anemia. If the ZPP is in excess of 100 µg/dl and not associated with abnormal elevations in BLLs, the laboratory should be checked to be sure that blood leads were determined using a laboratory that is CLIA-approved. Repeat periodic blood lead studies should be obtained in all individuals with elevated ZPP levels to be certain that an associated elevated BLL has not been missed due to transient fluctuations in blood leads.

ZPP has a characteristic fluorescence spectrum with a peak at 594 nanometers which is detectable with a hematofluorometer. The hematofluorometer is accurate and portable and can provide on-site, instantaneous results for employees 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.

Levels of delta-aminolevulinic acid (ALA) in the urine are also used as a measure of lead exposure. Increasing concentrations of ALA are believed to result from the inhibition of the enzyme delta-aminolevulinic acid dehydratase (ALA-D). Although the test is relatively easy to perform, inexpensive, and rapid, the disadvantages include variability in results, the necessity to collect a complete 24 hour urine sample which has a specific gravity greater than 1.010, and also the fact that ALA decomposes in the presence of light.

The pattern of porphyrin excretion in the urine can also be helpful in identifying lead intoxication. With lead poisoning, the urine concentrations of coproporphyrins I and II, porphobilinogen and uroporphyrin I rise. The most important increase, however, is that of coproporphyrin III, but its correlations with BLLs and ZPP are not as good as those of ALA. Increases in urinary porphyrins are not diagnostic of lead toxicity and may be seen in porphyria, some liver diseases, and in patients with high reticulocyte counts.

V. Summary. The standard for inorganic lead in the construction industry places significant emphasis on the medical surveillance of all employees exposed to levels of inorganic lead at or above the action level of 10 µg/m3 TWA, and as interim protection for employees performing trigger tasks. The PLHCP has a fundamental role in this surveillance program, and in the operation of the medical removal protection program.

Even with adequate employee education on the adverse health effects of lead and appropriate training in work practices, personal hygiene and other control measures, the PLHCP has a primary responsibility for evaluating potential lead toxicity in the employee. It is only through a careful and detailed medical and work history, a complete physical examination, and appropriate laboratory testing that an accurate assessment can be made.

Many of the adverse health effects of lead toxicity are either irreversible or only partially reversible and therefore early detection of disease is very important.

This document outlines the medical monitoring program as defined by the occupational safety and health standard for inorganic lead. It reviews the adverse health effects of lead poisoning and describes the important elements of the history and physical examinations as they relate to these adverse effects. Finally, the appropriate laboratory testing for evaluating lead exposure and toxicity is presented.

It is hoped that this review and discussion will give PLHCPs a better understanding of the lead standard, with the ultimate goal of protecting the health and well-being of employees exposed to lead who are under their care.