DEPARTMENT OF LABOR
Occupational Safety and Health Administration

OCCUPATIONAL EXPOSURE TO LEAD
Final Standard
RULES AND REGULATIONS

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to Lead

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final Standard for Occupational Exposure to Lead.

SUMMARY: This final standard limits occupational exposure to lead to 50yg/m³ (micrograms per cubic meter) based on an 8 hour time-weighted average. The basis for this action is evidence that exposure to lead must be maintained below this level to prevent material impairment of health or functional capacity to exposed employees. Provisions for environmental monitoring, recordkeeping, employee education and training, medical surveillance, medical removal protection, hygiene facilities, and other requirements are also included in the standard.

DATES: Effective date: February 1, 1979. Startup dates for individual provisions which are different than the effective date are in paragraph (r) of the regulation.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

I. INTRODUCTION

The statement of reasons accompanying this regulation (the preamble) is divided into six parts, numbered I through VI. The following table sets forth the contents of the preamble:

<table>
<thead>
<tr>
<th>Section</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>Introduction.</td>
</tr>
<tr>
<td>II.</td>
<td>Pertinent legal authority.</td>
</tr>
<tr>
<td>III.</td>
<td>Executive summary.</td>
</tr>
<tr>
<td>A.</td>
<td>Health effects of lead exposure.</td>
</tr>
<tr>
<td>B.</td>
<td>Permissible exposure limit.</td>
</tr>
<tr>
<td>C.</td>
<td>Medical removal protection.</td>
</tr>
<tr>
<td>D.</td>
<td>Feasibility of compliance.</td>
</tr>
<tr>
<td>IV.</td>
<td>Explanation of the standard.</td>
</tr>
<tr>
<td>V.</td>
<td>Authority and signature.</td>
</tr>
<tr>
<td>VI.</td>
<td>Attachments.</td>
</tr>
<tr>
<td>A.</td>
<td>Health effects of lead exposure.</td>
</tr>
<tr>
<td>B.</td>
<td>Permissible exposure limit.</td>
</tr>
</tbody>
</table>

- C. Medical removal protection.
- D. Feasibility.

Part VI of the preamble is divided into four attachments (A-D) (to be published separately in the Federal Register on or about November 21, 1978) which provide a detailed, complex, and technical discussion of the evidence and OSHA's conclusions on most of the major issues raised in the rulemaking. Part III is a brief, non-technical summary of these attachments and is intended for the reader who wishes to understand the basis for OSHA's conclusions in this standard without having to examine the more technical attachments.

Part IV is a provision-by-provision discussion of the regulation in lettered paragraphs corresponding to the lettered paragraphs of the regulation. It provides a brief summary of each provision and the evidence and rational supporting it. This is followed by part V, which in turn is followed by the regulation and its appendices.

References to the rulemaking record in the text of the preamble are in parentheses, and the following abbreviations have been used:

1. Ex.: Exhibit number.
2. Tr.: Transcript page number.
3. Ref.: Reference number.
4. Att.: Attachment number or letter.
5. App.: Appendix number or letter.

This permanent occupational safety and health standard is issued pursuant to sections 6(b) and 6(c) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1593, 1599, 29 U.S.C. 655, 657), the Secretary of Labor's Order No. 8-76 (41 FR 25059) and 39 CFR Part 111. It amends Part 1910 of 29 CFR by adding a new §1910.1025, entitled "Lead," and by deleting the reference to "lead and its inorganic compounds" in Table Z-2 of 29 CFR 1910.1000. The standard applies to employment in all industries covered by the Act except construction and agriculture.

Pursuant to section 4(b)(2) of the Act, OSHA has determined that this standard is more effective than the corresponding standards now applicable to the maritime industries currently contained in Subpart B of Part 1910, and Parts 1915, 1916, 1917, and 1918 of Title 29, CFR. Therefore, those corresponding standards are superseded by the new lead standard in §1910.1025. A new paragraph (g) is added to §1910.19 to clarify the applicability of this new lead standard to the maritime industries.

A. BACKGROUND

Lead (Pb) occurs naturally in the Earth's crust and is also found in the atmosphere and hydrosphere. It has been used for thousands of years because of its availability and desirable properties. Even in early times, there was recognition of health hazards associated with its use, both as a metal or in a compound form. Thus it was found that lead could be absorbed by inhalation and ingestion and that lead absorption was responsible for loss of movement in printers' fingers exposed to heated lead type and for "dry gripes" in pottery and glass workers.

By the early 20th century, studies revealed that the absorption of excessive quantities of lead (lead intoxication or plumbism) caused diseases of the kidney and peripheral and central nervous systems. For example, an analysis of death rates in the United Kingdom in 1921 (Ex. 5(1)) and 1931 (Ex. 5(2)) showed a considerable excess of deaths due to nephritis and cerebrovascular disease in plumbers and painters.

In excess of 1 million tons of lead are annually consumed yearly by industries in the United States. Potential occupational exposure to lead and its compounds occurs 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 repairing, auto manufacturing, and printing.

B. HISTORY OF THE REGULATION

Although the prevalence of lead intoxication in ancient times has been the subject of some speculation, it seems likely that there was a lack of appreciation of the hazards of lead and preventive methods of limiting exposure until recent times. Modern tests for estimating lead exposures, such as measurements of urinary and blood lead levels, urinary coproporphyrins, and preventive methods of limiting exposure to lead, have been generally used to establish acceptable air lead levels and thereby to control occupational lead intoxication. At one time, an airborne exposure limit of 500 ug/m³ was generally accepted. Based on a recommendation of the U.S. Public Health Service in 1933, however, a value of 150 μg/m³ was a common goal in industry in the 1940's.

150 μg/m³ continued to be the most often accepted until 1957, when the American Conference of Governmental Industrial Hygienists (ACGIH) increased the value to 200 μg/m³. In 1971, however, ACGIH recommended lowering this exposure limit back to 150 μg/m³. (Ex. 5(3).)

The present occupational safety and health standard for "lead and its inorganic compounds" is found in Table Z-2 of 29 CFR 1910.1000 and was adopted in 1971 pursuant to section 6(a) of the act. The permissible exposure limit, which is 200 μg/m³ as determined on the basis of an 8-hour time-
lowering the existing permissible exposure limit on the Proposed Lead standard.

for the Environmental Impact Statement. On February 1977, parties were invited to submit comments that would be useful in preparing and other protective measures.

In publishing the proposal, OSHA noted its intention to prepare an Environmental Impact Statement to assess the effect of the proposed standard on the human environment. Interested parties were invited to submit comments that would be useful in preparing a draft of the Environmental Impact Statement. On February 25, 1977, the availability of OSHA's draft for the Environmental Impact Statement on the Proposed Lead standard was announced by the Council on Environmental Quality (42 FR 11036) (Ex. 30).

In a Federal Register notice on March 8, 1977, OSHA announced that in addition to the March 15, 1977 hearing in Washington, D.C., two regional hearings would be held (42 FR 13025).

The first regional hearing began on April 26, 1977, in St. Louis, Mo., and the second regional hearing began on May 3, 1977, in San Francisco, Calif. During the hearing in Washington, D.C., which lasted 7 weeks, OSHA presented 15 expert witnesses from around the world to discuss various aspects of the proposal. In addition to witnesses invited by OSHA, NIOSH, and approximately 90 public participants testified. In St. Louis, 9 public parties testified; in San Francisco, 13.

The hearing record was reopened by OSHA on September 16, 1977, for the purpose of taking additional evidence on the issue of medical removal protection. A Federal Register notice was published giving notice that a hearing would be held on November 1, 1977 (42 FR 46547) (Ex. 353). A hearing was held (November 11, and December 22, 1977) and additional exhibits were added to the record including an OSHA-sponsored study on labor costs for implementation of medical removal protection (Ex. 439).

Final certification of the hearing record was completed on August 8, 1978, by Administrative Law Judges Julius J. Johnson and Garvin Lee Oliver.

II. Pertinent Legal Authority

The primary purpose of the Act is to assure, so far as possible, safe and healthful working conditions for every working man and woman. One means prescribed by Congress to achieve this goal is the authority vested in the Secretary of Labor to set mandatory safety and health standards. The standards setting process under section 6 of the Act is an integral part of an occupational safety and health program in that the process permits the participation of interested parties in consideration of medical data, industrial processes and other factors relevant to the identification of hazards. Occupational safety and health standards mandate the requisite conduct or exposure level and provide a basis for insuring the existence of safe and healthful workplaces.

The Act provides that:

The Secretary in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure during his lifetime to such standard.

Development of standards under this subsection shall be based on research, demonstrations, experiments, and other such information as may be appropriate. In addition to the statement of the highest degree of health and safety protection for the employee, other considerations shall be the feasibility of the standards, and experience gained under this and other health and safety laws (Sec. 6(b)(5)).

Sections 20(b) (5) and (6), 20, 21, 22, and 24 of the Act show that Congress recognizes that conclusive medical or scientific evidence on the causative factors, epidemiological studies or dose-response data, may not exist for many toxic materials or harmful physical agents. Nevertheless, final standards cannot be postponed because definitive medical or scientific evidence is not currently available. Indeed, while standards are to be based on the best available evidence, the legislative history clearly shows that "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Committee on Education and Labor (Rept. No. 91-1291, 91st Cong., 2d sess., p. 18 (1970)). This Congressional judgment is supported by cases which have reviewed standards promulgated under the Act.

In sustaining the standard for occupational exposure to vinyl chloride (29 CFR 1910.1011), the U.S. Court of Appeals for the Second Circuit said that the court could not fill a gap in the law by the exercise of discretion. Society of the Plastics Industry Inc. v. Occupational Safety and Health Administration, 509 F. 2d 1301, 1308 (2d Cir. 1975), cert. den. sub nom., Firestone Plastics Co. v. United States Department of Labor, 95 S. Ct. 1998, 4 L. Ed. 2d 483 (1975). A similar rationale was applied by the U.S. Court of Appeals for the District of Columbia Circuit in reviewing the standards for occupational exposure to asbestos (29 CFR 1910.1001). The Court stated that:

Some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently, as to them insufficient data is presently available to make a fully informed factual determination. Decisionmaking must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual judgments. Industrial Union Department, AFL-CIO v. Hodgson, 499 F. 2d 467, 474 (D.C. Cir. 1974).

In setting standards, the Secretary is expressly required to consider the feasibility of the proposed standards. Senate Committee on Labor and Public Welfare (S. Rept. No. 91-1282, 91st Cong., 2d sess., p. 58 (1970). Nevertheless, considerations of technological feasibility are not limited to de-
NAUSEA, PALLOR, EXCESSIVE TIREDNESS, FROM STUDIES CARRIED OUT MANY YEARS SEVERE LEAD INTOXICATION ARE KNOWN IC DISEASE, AND DEATH.

BEHAVIORAL CHANGES, AND MILD CENTRAL PERHAPS REVERSIBLE STAGES SUCH AS INHIBITION, TENSION, AND CONVULSIONS. IT MAY ARISE PRECIPITOUSLY WITH THE ONSET OF INTRACTABLE SEIZURES, FOLLOWED BY COMA, CARDIORESPIRATORY ARREST AND DEATH. THERE IS A TENDENCY TOWARD THE OCCURRENCE OF WEAKNESS OF EXTENSOR MUSCLE GROUPS, THAT IS MOTOR IMPAIRMENT. THIS WEAKNESS MAY PROGRESS TO PALSY, OFTEN OBSERVED AS A CHARACTERISTIC “WRIST DROP” OR “FOOT DROP” AND IS A MANIFESTATION OF A DISEASE TO THE PERIPHERAL NERVous SYSTEM (LEAD NEUROPATHY). LEAD INTOXICATION ALSO RESULTS IN KIDNEY DAMAGE WITH FEW, IF ANY, SYMPTOMS APPEARING UNTIL EXTENSIVE AND MOST LIKELY PERMANENT KIDNEY DAMAGE HAS OCCURRED. NIOSH TESTIFIED THAT:

OF CONSIDERABLE CONCERN ARE THE EFFECTS RESULTING FROM LONG-TERM EXPOSURE. THERE IS EVIDENCE THAT PROLONGED EXPOSURE CAN INCREASE THE RISK OF NEPHRITIS, MENTAL DEFICIENCY, PREMATURITY, AGING, AND HIGH BLOOD PRESSURE (EX. 84, P. 6).

EXPOSURE TO LEAD RESULTS IN DECREASED LIBIDO, IMPOTENCE AND STERILITY IN MEN AND DECREASED FERTILITY, ABNORMAL MENSTRUAL AND OVARIAN CYCLES IN WOMEN. THE COURSE OF PREGNANCY IS ADVERSELY AFFECTED BY EXPOSURE TO LEAD. THIS IS CONCLUSIVE EVIDENCE OF MISCARRIAGE AND STILLBIRTH IN WOMEN WHO WERE EXPOSED TO LEAD OR WHOSE HUSBANDS WERE EXPOSED. CHILDREN BORN OF PARENTS EITHER OF WHOM WERE EXPOSED TO LEAD ARE MORE LIKELY TO HAVE DEFECTS, MENTAL RETARDATION, BEHAVIORAL DISORDERS OR DI during the first year of childhood.

DURING THE PAST 10 YEARS THERE HAVE BEEN MANY NEW OBSERVATIONS AND RESEARCH ON THE HEALTH EFFECTS OF LEAD AT LEVELS HERETOFOR THOUGHT TO BE INCONSEQUENTIAL. THIS RESEARCH HAS BEEN STIMULATED BY THE AVAILABILITY OF MANY NEW METHODS FOR DETECTING AND MEASURING THE DEGREE OF IMPAIRMENT CAUSED BY LEAD EXPOSURE. THESE TECHNIQUES MEASURE A VARIETY OF BIOCHEMICAL, PHYSIOLOGICAL AND PATHOPHYSIOLOGICAL CHANGES. THE METHODS ARE HIGHLY SENSITIVE AND REVEAL EARLIER CHANGES INDICATIVE OF ADVERSE EFFECTS IN WORKERS EXPOSED TO LEAD.

THE MAIN RESEARCH TOPICS WHICH HAVE BEEN ADDRESSED ARE EARLY BIOCHEMICAL CHANGES IN THE SYNTHESIS OF THE RESPIRATORY PIGMENT HEME; AND THE EFFECTS ON THE NERVOUS SYSTEM INCLUDING BEHAVIORAL AND PERIPHERAL NERVE EFFECTS. INCLUDED ARE STUDIES ON THE INVOLVEMENT OF LEAD IN KIDNEY DISEASE, ON EFFECTS ON REPRODUCTIVE CAPACITY OF MALE AND FEMALE WORKERS, AND ON THE RELATION BETWEEN EXPOSURE TO LEAD IN AIR AND RESULTING BLOOD LEAD CONCENTRATION.

ALTHOUGH THE TOXICITY OF LEAD HAS BEEN KNOWN FOR 2,000 YEARS THE COMPLEX RELATIONSHIP BETWEEN LEAD EXPOSURE AND HUMAN RESPONSE IS STILL IMPERFEETLY UNDERSTOOD. OSHA BELIEVES THAT WHILE INCAPACITATING ILLNESS AND DEATH REPRESENT ONE EXTREME OF A SPECTRUM OF RESPONSES, OTHER BIOLOGICAL EFFECTS SUCH AS METABOLIC OR PATHOPHYSIOLOGICAL CHANGES ARE PRECURSORS OR SENTINELS OF DISEASE WHICH SHOULD BE PREVENTED. THIS DISEASE PROCESS CAN BE SUBDIVIDED ACCORDING TO "DILBOROW, TR. 1976-02, INTO FIVE STAGES: NORMAL, PHYSIOLOGICAL CHANGE OF UNCERTAIN SIGNIFICANCE, PATHOPHYSIOLOGICAL CHANGE, OVERT SYMPTOMS (MORBIDITY), AND MORTALITY. WITHIN THIS PROCESS THERE IS NO SHARP DISTINCTION, BUT RATHER A SPECTRUM OF RESPONSES. BOUNDARIES BETWEEN CATEGORIES OVERLAP DUE TO THE VARIATION OF INDIVIDUAL SUSCEPTIBILITIES AND EXPOSURES IN THE WORKING POPULATION. OSHA BELIEVES THAT THE STANDARD ADOPTED MUST PREVENT PATHOPHYSIOLOGICAL CHANGES ARE EARLY STAGES IN THE DISEASE PROCESS WHICH WOULD GROW WORSE WITH CONTINUED EXPOSURE AND WHICH MAY INCLUDE EARLY EFFECTS WHICH EVEN AT EARLY STAGES ARE IRREVERSIBLE, AND THEREFORE REPRESENT MATERIAL IMPAIRMENT THEMSELVES. SECONDLY, PREVENTION OF PATHOPHYSIOLOGICAL CHANGES WILL PREVENT THE ONSET OF THE MORE SERIOUS, IRREVERSIBLE AND DEBILITATING MANIFESTATIONS OF DISEASE.

THE EVIDENCE IN THIS RECORD DEMONSTRATES THAT PREVENTION OF ADVERSE HEALTH EFFECTS FROM EXPOSURE TO LEAD THROUGHOUT A WORKING LIFETIME REQUIRE THAT BLOOD (PDB) LEAD LEVELS BE MAINTAINED AT OR BELOW 40 µG/100 G. OSHA CONCLUDES THAT WORKERS EXPOSED TO LEAD LEADING TO BLOOD LEAD LEVELS IN EXCESS OF 40 µG/100 G WILL DEVELOP PHYSIOLOGICAL AND PATHOPHYSIOLOGICAL CHANGES WHICH WILL GROW PROGRESSIVELY WORSE AND INCREASE THE RISK OF MORE SEVERE DISEASE. OSHA BELIEVES THE STANDARD MUST PREVENT THESE CHANGES FROM OCCURRING SINCE THIS WOULD PROVIDE GREATER ASSURANCES OF HEALTH PROTECTION. FEASIBILITY CONSTRAINTS PREVENT OSHA FROM ESTABLISHING A STANDARD WHICH WOULD ELIMINATE ALL PATHOPHYSIOLOGICAL CHANGES, REPRODUCTIVE EFFECTS OR...
mild signs and symptoms but the agency believes the vast majority of workers will be protected by this standard. These considerations formed the basis upon which OSHA evaluated the health effects evidence in the record. OSHA recognizes that the primary agent that will address the health effects evidence in each system: heme synthesis inhibition, and damage to the nervous, renal, and blood forming system. In addition, the air lead to blood lead relationship will be addressed.

1. Heme Synthesis Inhibition. Heme is a complex molecule which has two functions in the body. First, heme is a constituent of hemoglobin, a protein present in red blood cells whose primary function is to transport oxygen to the tissues. Interference with the formation of heme, if sufficient, results in decreased hemoglobin and ultimately anemia. Anemia is characterized by weakness, pallor and fatigability as a result of decreased oxygen carrying capacity in the blood.

Heme is also a constituent of another group of extremely important proteins, the cytochromes, which are present in every cell of the body. The function of heme in the cytochromes is to allow the cell to utilize oxygen. Heme may therefore be described as the "respiratory pigment" for the entire body. Interference with heme formation leads to interference in the respiration of every cell in the body. This is the most important effect of heme synthesis impairment. Piomelli has suggested that heme impairment in the cells would lead to a condition in each cell similar to that which would occur in the lungs as a result of heme synthesis impairment in the brain. For example, Piomelli testified that "It is very well known that the human being cannot stop breathing for more than 2 or 3 minutes without developing irreversible brain damage." (Tr. 460) This effect would be expected to occur from impaired respiration resulting from impaired heme synthesis. In other words, heme synthesis impairment could potentially affect every cell through reduced respiration.

The effects of lead exposure on heme synthesis have been studied extensively by the scientific community. Nevertheless, there is considerable debate over certain issues concerning the health effects of lead on this system. The Agency found three major issues particularly important in evaluating the health effects of lead in reference to heme synthesis. (1) What is the meaning of the enzyme inhibition and physiological changes known to occur in this system at low PbB levels, and should these effects be considered as per se impairment of health in the establishment of a permissible level of worker exposure to lead. (2) At what blood lead (PbB) level does a lowering of hemoglobin begin? Is there a threshold for this effect? (3) To what extent are lead effects on heme synthesis in the blood forming system indicative of changes in heme synthesis in other tissues?

The earliest demonstrated effect of lead-involves its ability to inhibit the formation of heme. Scientific evidence has established that lead inhibits at least two enzymes of the heme synthesis pathway at very low PbB levels. Inhibition of delta-aminolevulinic acid dehydratase (ALAD), an enzyme responsible for the synthesis of a precursor to heme, is observed at PbB levels below 20 \( \mu g/100 \text{g} \). At a PbB level of 40 \( \mu g/100 \text{g} \) more than 20 percent of the population would have urinary elevations of ALA-D. In the human body when an enzyme system is inhibited two effects are often seen: First, the molecule upon which the enzyme would act accumulates because it cannot undergo chemical reaction to produce the desired product and second, the desired product therefore decreases. Significant urinary excretion of the products of ALAD inhibition, such as delta aminolevulinic acid (ALA-U) and porphobilinogen (PBG), would have 70 percent inhibition of ALA-D. 37 percent would have urinary ALA (ALA-U) values larger than 10 \( \mu g/10^5 \text{g} \) and 80 percent of men and 100 percent of women would have increased free erythrocyte protoporphyrin (FEP), which is the product of inhibition of ferrochelatase. (Ex. 294 E.) Industry representatives argued that these effects are the manifestation of the body attempting to maintain a stable internal environment to lead. OSHA believes that it is inappropriate and simplistic to describe these changes as biochemical adjustments. The depression of heme synthesis in response to toxic levels of the blood of potentially far reaching proportion and prevention of enzyme effects is the key to the prevention of more serious clinical effects of lead toxicity, which become more obvious as the exposure continues. These measurable effects are a direct result of lead exposure and are considered by the agency to indicate the occurrence of disruptions of a fundamental and vital subcellular process, heme synthesis. These processes are not only essential to the process of hemoglobin synthesis, they are also vital to the function of all cells since heme is ubiquitous in the human.

OSHA believes the evidence indicates a progression of health effects of lead exposure starting with inhibition of enzymes, continuing through effects indicating measurable disruption of specific cellular processes, such as the buildup of the products of impaired heme synthesis and eventually developing into the overt symptoms of lead poisoning as manifested by disorders in the nervous, renal, and blood forming system. Biological variability among individuals will alter the PbB level at which a particular person will move through each stage in this disease continuum. Therefore, at each stage individualize the a great environmental of the population will manifest each given effect. Given this understanding of the progressive stages of lead effects, OSHA has concluded that enzyme effects indicative of the disruption of heme synthesis are early stages of a disease process which eventually results in the clinical symptoms of lead poisoning. OSHA agrees with Piomelli who concluded, "It is the responsibility of preventive medicine to detect those alterations (in heme synthesis) which may precede frank symptomatology and to prevent the occurrence of these symptoms." (Tr. 456).

OSHA believes that good health is not limited to the narrow definition of "absence of clinical symptoms." The early steps of the progression to disease cannot be considered as an attempt by the body to merely adjust and stabilize the a great environmental to exposure to lead: They are early indications of significant physiological disruption. Whether or not the effects have proceeded to the later stages of clinical disease, disruption of these processes over a working lifetime must be considered as material impairment of health. As was previously discussed, at a PbB level of 40 \( \mu g/100 \text{g} \) and above, a significant proportion of the population would manifest extensive inhibition of ALA-D, elevations of ALA-U and of protoporphyrin levels. The agency believes that PbB levels should ideally be kept below 40 \( \mu g/100 \text{g} \) to minimize these effects.

Anemia is one of the established symptoms of lead poisoning. The symptoms of anemia are weakness, tiredness, pallor, waxy, sallow complexion, headache, irritability, and other symptoms characteristic of the increased load on the cardiac system. The clinical symptoms of anemia due to lead are often indistinguishable from those of chronic anemias with a
variety of other causes. Anemia due to lead is often seen in association with acute abdominal colic. The occurrence of anemia, as a result of lead exposure, is known to occur above PbB levels of 80 μg/100 g. The occurrence of this symptom at PbB levels below 80 was debated by experts and hazardous.

OSHA believes that the debate concerning the occurrence of this symptom can better be comprehended within the context of an understanding of the full disease process which eventually results in anemia. The evidence concerning the mechanisms of this disease process indicates that the effect of lead on the hematopoietic system is subtle and complex. In evaluating the disease mechanisms of anemia, it was found that lead is an insidious poison which attacks, not one, but many of the physiological processes within the cell.

Because anemia is the result of a complex of different lead effects, there is considerable room for individual variability in the PbB level at which anemia will occur. Hemoglobin level is a continuous variable which may cause individuals to have a problem to a greater or lesser degree at any particular blood lead level. Anemia should be viewed as a late step in a complicated progression of lead effects.

Since anemia is a consequence of lowered hemoglobin (the protein in red cells responsible for respiration) OSHA has carefully analyzed those studies which reported reduced hemoglobin. Studies have associated PbB levels as low as 50 μg/100 g with lowered hemoglobin (Hb) levels. (Ex. 6(37); 146-A; 5(9)). In particular, Tola's study, which showed a lowering of Hb over time during lead exposure of 50 μg/100 g, is considered by OSHA as an example of lead affecting Hb levels at this low PbB range. In addition studies by the Mt. Sinai group (Ex. 24(14)), and Wolfe (Ex. 146(A)) also demonstrated lowered anemia in lead exposed workers.

Based on evidence that indicates decreases in Hb levels with blood leads above 50 μg/100 g, OSHA has concluded that a lowering of Hb level to a measurable degree will occur at PbB levels as low as 50 μg/100 g. The degree to which Hb is lowered at this PbB range may be undetected since symptoms may be mild and are not likely to be so large as to require treatment for anemia. However, these changes must not be evaluated only as short-term effects alone but rather as changes that would occur over prolonged times. This implies that with reduced hemoglobin in an asymptomatic or mildly symptomatic individual there is a lifetime alteration in the oxygen carrying capacity of the blood, in the blood viscosity and in particular, in the cardiac work load. These alterations are distinct from the frank symptoms of anemia but are far more insidious and may be deleterious to the worker over the long term. Lastly, the data does support the view that lead induced anemia is clinically apparent at PbB's as low as 50 μg/100 ml.

In evaluating the effects of lead on heme synthesis, Piomelli suggested that hematopoietic effects such as anemia are not the most significant clinical effect of heme synthesis disruption. The most important fact is that the alteration of the mechanism of heme synthesis reflects the general toxicity of lead in the entire body. (Tr. 458)

Evidence indicates that there is disruption of heme synthesis in other tissues of the body besides blood, and that this disruption results in alteration of the oxygen transport into the cell of the body. Enzyme (ALA-D) inhibition due to lead has been found in the liver at PbB levels below 40 μg/100 g (Ex. 5(22)). Electron microscopy studies have revealed mitochondrial changes associated with lead exposure such as large granules in rat liver mitochondria (Tr. 459, ref. Walton in Nature 243, 1973) and broken distorted mitochondria in the renal cells of a lead-exposed worker. The mitochondria is that portion of the cell responsible for extracting nutrients and oxygen and in turn providing the energy needed elsewhere in the cell for performing cellular functions. (Cramer et al. Brit. J. Ind. Med. 1974.) Some of these studies related changes in heme synthesis in the blood forming tissues to changes in other tissues. Secchi (Ex. 5(22)) found a direct correlation of levels of ALA-D inhibition in the blood and in the brain PbB levels above 30. (Ex. 23(68)), ref. Millar. This evidence supports Piomelli's suggestions that observed changes in the blood forming (hematopoietic) system reflect changes that occur in other tissues. The work of Fishbain et al. related levels of products of enzyme inhibition, a measure of heme synthesis disruption in the hematopoietic system, to various signs and symptoms of lead exposure including central nervous system symptoms, muscle and joint pain, weight loss, and lead colic at blood lead levels below 80 μg/100 ml (mean PbB was approximately 60 μg/100 ml). (Ex. 106D). Fishbain also noted anemia in 37 percent of these same workers, 17 percent of whom had blood lead levels below 80 μg/100 ml.

While the evidence relating lead effects of heme synthesis to symptoms throughout the body is not complete, the evidence is extensive enough and the issue is important enough to warrant very serious consideration with reference to the establishment of the standard. OSHA believes this evidence demonstrates that one early stage of lead disease in various tissues is the disruption of heme synthesis and that these effects in other lead-sensitive tissues parallel the mechanisms of heme synthesis disruption in the hematopoietic system and occur at comparably low PbB levels (below 40 μg/100 g). The heme effect is clearly not the only mechanism by which lead exerts its toxicological effect but it is one mechanism which we have substantial understanding of, can measure, and therefore must utilize in an effort to prevent the more severe symptoms in the individual.

In reference to the hematopoietic system, OSHA believes that the effects of lead are a complex progression from various biochemical changes and alterations which may precede frank anemia effects. This is because at increasingly higher PbB levels an increasing proportion of the population will suffer more extreme effects. At a PbB level of 40 μg/100 g or above a sizable proportion of the population would show measurable effects of the disruption of heme synthesis. A comparable degree of disruption of heme synthesis would most likely occur in other cells in the body. Piomelli gave an excellent summary of the importance of lead's effects on heme synthesis stating:

It is my understanding that regulations have the purpose of preventing "mortal impairment of health." Alterations in heme synthesis do not produce subjective evidence of impairment of health, unless they reach the extreme depression in severe lead intoxication, when marked anemia occurs and the individual feels weak. However, it is not any longer possible to restrict the concept of health to the individuals subjective lack of feeling a good effect. This is because we know that individuals may get adjusted to suboptimal health, if changes occur slowly enough and also because we now have the ability to detect functional impairments by appropriate tests, much before the individual can perceive any adverse effect. In fact, it is the responsibility of preventive medicine to detect those alterations which may precede frank symptomatology, and to prevent its occurrence. The alterations in heme synthesis caused by lead fulfill, in my opinion, the criteria for material adverse effects on health and can be used to forecast further damage. The depression of heme synthesis in all cells of the body is an effect of far reaching proportion and it is the key to the multiple clinical effects of lead toxicity, which become obvious as the exposure continues. (Ex. 57, p. 21).

This does not in any way suggest that the lead effect on heme is the only mechanism of lead disease, but it does suggest that this effect is at least one of the important mechanisms in lead disease. An understanding of this spectrum of effects from subcellular to clinical symptoms is relevant not only to the occurrence of anemia but will
also be the expected pattern in lead induced neurological and renal disease. OSHA believes that there is evidence demonstrating the impairment of heme synthesis and mitochondrial disruption in tissues throughout the body, and that these effects are the early stages of disease in these various tissues. The disruption of heme synthesis measured at low PbB levels is not only a measure of an early hematopoietic effect, it is also a measure which indicates early disease in other tissues. The Agency believes that such a pervasive physiological disruption must be considered as a material impairment of health and must be prevented. PbB levels greater than 40 µg/100 g should, therefore, be prevented to the extent feasible.

2. Neurological effects. There is extensive evidence accumulated in both adults and children which indicates that toxic effects of lead have both central and peripheral nervous system manifestations. The effects of lead on the nervous system range from acute intoxication, coma, cardiorespiratory arrest and fatal brain damage to mild symptoms, subtle behavioral and electrophysiologic changes associated with lower level exposures. Although the severe effects of lead have been known for some time, only in the last several years has evidence accumulated which demonstrates neurologic damage at low blood lead levels. All of this data reinforces a disturbing clinical impression that nervous system damage from increased lead absorption occurs early in a worker's tenure, at low blood lead levels and is only partially reversible if at all. It is now understood that the location and degree of neurological damage depends on dose and duration of exposure.

The record in this rulemaking demonstrated that damage occurs in both the central and peripheral nervous systems at blood lead levels lower than previously recognized. In particular, Lills et al. (Ex. 24, (10)) have demonstrated central nervous system symptoms (tiredness, fatigue, nervousness, sleeplessness or somnolency, or anxiety) in 66 percent of workers with blood lead levels below 80 µg/100 ml. The mean blood level was approximately 60 µg/100 ml. This same study reported symptoms of muscle and joint pain and/or soreness in 39 percent of the workers. It is extremely important to note that many of these subjects had been exposed less than a year. They also were able to demonstrate biochemical changes which were correlated with enzyme inhibition products from heme synthesis. Given this data, the authors cautioned that blood lead levels should not be allowed to exceed 60 µg/100 ml and should be maintained at level 40 µg/100 ml. Lills testified that about 60 µg/100 ml, "one may expect florid lead poisoning, full blown lead poisoning" (Tr. 2700). She proceeded to state:

"Since ZPP starts to go up at around 40 or 45, that means that at those levels you already find something going wrong in the body" (Tr. 2702). Repko has carried out behaviorally sensitive psychological tests in workers. He has demonstrated decrease effects in visual reaction time, as well as deficits in hearing among workers having a mean blood lead level of 46 µg/100 ml. Valckus et al. and Haenninen et al. have also demonstrated impaired psychological performance among workers with low exposure to lead. Haenninen's work is particularly significant insofar as no single blood lead concentration had ever exceeded 70 µg/100 ml.

Based on the rulemaking record, OSHA has concluded that the earliest stages of lead-induced central nervous system disease first manifest themselves in the form of behavioral disorders and CNS symptoms. CNS disorders have been documented in numerous sound scientific studies and these behavioral disorders have been confirmed in workers whose blood lead levels are below 80 µg/100 g. Given the severity and potential reversibility of central nervous system disease, OSHA must pursue a conservative course of action. OSHA concludes that a blood lead level of 40 µg/100 g must be considered as a threshold level for behavioral changes and CNS symptoms in adults, and to protect against long-term neurological effects, blood levels should never exceed 60 µg/100 g.

Some of the most extensive evidence in the rulemaking record is the data presented which confirms the existence of the early stages of lead induced damage to the peripheral nervous system in workers exposed to PbB levels of 25 µg/100 g. Damage to the peripheral nervous system is named peripheral neuropathy and the distinguishing feature of it is the predominance of motor involvement as opposed to sensory damage. Three forms are noted. In the first, patients with acute abdominal colic may also complain of very severe pain and tenderness in the trunk muscles, as well as pain in the muscles of the extremities. As the pain and tenderness subside, weakness may emerge, with very slow recovery over the ensuing several months. In the second, more common form of peripheral neuropathy due to lead poisoning, the neuropathy is described as painless, peripheral weakness occurring either after termination of excessive exposure or after long, moderately increased exposure. This suggests that neuropathy of sufficient severity may cause irreversible impairment of peripheral nerve function.

The third form is seen in subjects with no obvious clinical signs of lead poisoning and is manifested by slowing of motor nerve conduction velocity. The latter effect represents the earliest sign of neurological disease of the peripheral nerves. OSHA believes prevention of this stage is necessary to prevent further development of the disease and its associated forms which are likely to be irreversible.

The work of Catton, Oh, Landigran, Feldman, Behse Mostafa et al., Gerald et al., Guadrigile et al., Araki, W. R., Lee, Repko, Lills, Fischbein et al., and Seppalainen et al. all demonstrate statistically significant loss of motor nerve conduction velocity in lead-exposed workers. Seppalainen was able to determine a dose-response relationship for the slowing of NCV compared with blood lead levels. It is apparent that slowing occurs in workers whose PbB levels are 50 µg/100 g and above but, whether there are effects as low as 40 µg/100 g is, as yet, undetermined. The 38 lead experts who participated in the International Workshop on Permissible Exposure Levels for Occupational Exposure to Inorganic Lead also reached this conclusion in their final report:

It is not known whether the maximum blood lead concentration or the integrated average concentration is the determining factor in the development of changes in nerve conduction velocity. However, the Group concluded from the data presented by Haenninen et al. that changes in the literature that changes in nerve conduction velocity occur in some lead workers at blood levels exceeding 50 µg/100 ml. It was thought that no conclusion could be drawn from the one case in the blood lead range 40-49 µg/100 ml.

It is not possible to decide what any given measured small deficit means in terms of specific nervous damage. However, it is generally recognized that a clear deficit in the nerve conduction velocity of a peripheral nerve is an early stage in the development of clinically manifest neuropathy. There is no evidence that these changes progress. Reversibility should be kept in mind. Slight changes may be measured in persons experiencing no symptoms, it was the consensus of the group that such changes should be regarded as a critical effect. (Ex. 282, p. 64.) (Critical effect is a defined point in the relationship between dose and effect in the individual, namely the point at which any adverse effect occurs in cellular function of the critical organ.)

These conclusions by recognized experts in the field were based largely on the work of Seppalainen and her co-workers. This work has been described by an industry spokesman, Dr. Malcolm, as being "immaculate." (Tr. 2073) Based on the extensive evidence in the record from Seppalainen and others, OSHA has concluded that exposure to lead at low levels causes peripheral neuropathy at PbB levels previously thought to be of relatively
little consequence. Seppäläinen has stated:

Of course, in terms of health, the importance of any neuropathy should be questioned, too. The reference to “the safety at the level of 50 μg/100 ml” (TR. 153), OSHA agrees that the current evidence demonstrates that nerve conduction velocity decreases after PbB levels of 50 μg/100 g and above. Therefore, a necessary goal of a standard for occupational lead exposure must be to assure that lead blood levels are maintained below 50 μg/100 g in order to provide an adequate margin of safety.

3. Renal system. One of the most important contributions to the understanding of adverse health effects associated with exposure to inorganic lead was the elucidation of evidence on kidney disease during the hearings. It is apparent that kidney disease from exposure to lead is far more prevalent than previously believed. In the past, the number of lead workers with kidney disease in the United States was thought to be negligible, but the record indicates that a substantial number of lead workers may be afflicted with kidney disease. Wedeen, a nephrologist (kidney specialist), who testified at the hearings for OSHA stated that a minimal estimate of the incidence of this disease (nephropathy) would be 10 percent of lead workers. “According to this estimate, there may be 100,000 cases of preventable renal disease in this country.”

If only 10 percent of these hundred thousand workers with occupational nephropathy came to chronic hemodialysis (kidney machines) the cost to Medicare alone would be about 200 million dollars per year.” (TR. 1741-42.)

The hazard here is compounded by the fact that, unlike the hematopoietic system, routine screening is ineffective in early diagnosis. Renal disease may be detected through routine screening only after about two-thirds of kidney function is lost or when manifestations of symptoms of renal failure are present. By the time lead nephropathy can be detected by usual clinical procedures, irreparable damage has most likely been sustained. When symptoms of renal failure are present, it is simply too late to correct or prevent the disease and progression to death or dialysis is likely.” (TR. 1757.)

The research of Wedeen and his co-workers, the health hazard evaluation by NIOSH at Eagle Picher Industries, Inc., and the research in secondary smelters by Lills, Fishbein, et al. demonstrated that lead exposure is a key etiologic agent in the development of kidney disease among occupationally exposed workers. Clearly, too little attention has been given to lead-induced renal disease in recent years and while OSHA recognizes that further research is required to understand fully the disease mechanisms, it is also necessary to protect the thousands of workers who are potentially in danger of developing renal disease. The record indicates that lead blood is an inadequate indicator or renal disease development. Dr. Bridbord questioned Dr. Wedeen on the issue of chronicity of exposure and blood lead levels:

Dr. Bridbord: Well, looking at a group of workers currently employed, having a blood lead level on that worker and having some information, that to the best of our knowledge there were no major changes in that particular plant during the past number of years. Would that not be a somewhat better index of what the blood level might have been in the past? Considering too, that these workers are currently employed.

Dr. Wedeen: Sure I think that the blood level measured close to the time of exposure is probably a more reflective. I worry very much, that this may occur after a few months of exposure and the blood lead level may remain the same for them. The problem, despite the fact that the individual is continually accumulating lead in the body.

Dr. Bridbord: Would you think that the chronicity of lead exposure, apart from directly whether the blood lead was above or below 80 or above or below 60 for example, might be an important factor in determining eventual development of renal disease in lead workers? Dr. Wedeen: Yes; that is just what I meant, that the accumulative effects and the magnitude of injury may be very different from the blood lead level at any one time in men. In other words, one could certainly imagine that a blood lead level of 80, for two years, may be very similar to a blood lead level of 40, for four years. I don’t have that data, but something like that may well exist in terms of the danger of the different levels of exposure.

Dr. Bridbord: Alright.

Particularly, in view of that, and given the requirements of the Occupational Safety and Health Act, that sets standards which protect workers during the hearings with Wedeen, you have some reservations about a blood lead maximum standard, even at 60? Dr. Wedeen: I think I just expressed the basis for it. You will note that in my recording of these patients, very few of them had blood lead levels over 60. I just feel that while the blood lead level may be better than nothing, it may be very practical. It probably doesn’t do the job we are trying to do and certainly not from the physician’s point of view, who has seen the individual patient, who may or may not be a current exposure at the level that got his disease (TR. 1760-1766).

The lead standard must therefore be directed towards limiting exposure so that occupational lead nephropathy is prevented. The Agency agrees with the views of Wedeen:

I have reported today 19 lead workers who have lost 30 to 50 percent of their kidney function. Since they showed no symptoms and had no routine laboratory evidence of kidney disease, it may be asked why this kidney function loss should be viewed as material damage. Lead nephropathy is lim
portant because the worker has lost the functional reserve, the safety, provided by two normal kidneys. If one kidney becomes damaged, the other can be relied upon. The lead worker with 50 percent loss of kidney function has no such security. Future loss of kidney function will normally occur with and may be accelerated by hypertension or infection. The usual life processes will bring the lead worker to the point of uremia, while in the normal individual there is considerable renal functional reserve. Loss of a kidney is therefore more serious than loss of an arm, for example. Loss of an arm leads to obvious limitations in activity. Loss or a kidney or an equivalent loss of kidney function means the lead worker's ability to survive the biologic events of life is severely reduced. By the time lead nephropathy can be detected by usual clinical procedures, enormous and irreparable damage has been sustained. The lead standard must be directed towards limiting exposure so that occupational lead nephropathy does not occur (Tr. 1747-1760).

And OSHA agrees with Dr. Richard Wedeen, that "40 µg/100 ml is the upper acceptable limit." (Tr. 1771). That is, while PbB levels are an inadequate measure of occupational exposure (though most agree the best available single measurement) they nonetheless provide a basis for determining when exposure is hazardous. When measured over an extended period of time, OSHA believes that maintenance of PbB levels at or below 40 µg/100 ml will reduce the overall dose to the worker, decrease the body burden of lead and prevent sufficient buildup of lead in the kidney to effect renal damage.

4. Reproductive effects. Exposure to lead has profoundly adverse effects on the course of reproduction in both males and females. In male workers exposed to lead there is evidence of decreased sexual drive, impotence, decreased ability to produce healthy sperm, and sterility. During the hearings there was considerable discussion of the evidence submitted by Lancranjan et al. which demonstrated that the reproductive ability of men occupationally exposed to lead is interfered with by altered sperm formation. Lancranjan et al. reported a significant increase in malformed sperm (teratosperma) among lead-poisoned workmen (blood lead mean 74.5 µg/100 ml) and workmen with moderately increased absorption (blood lead mean 52.8 µg/100 ml). Decreased number of sperm (hyposperma) and decreased sperm motility (athenosperma) were observed not only in the preceding groups but also in those with only slightly increased absorption (blood lead mean 41 µg/100 ml). The authors concluded that these alterations were produced by a direct toxic effect on the male gonads, and that a dose response relationship exists with respect to teratosperma. The other parameters measured, hyposperma and athenosperma, do not show as strong a relationship but are significantly altered over controls. This work is consistent with other earlier literature quoted by Lancranjan.

"Epidemiologic studies have pointed out previously both the reduction of number of offsprings in families of workers occupationally exposed to lead and increase of the miscarriages, while thousands of couples were exposed to lead. Experimental investigations have also shown both a reduction in the number of offspring of laboratory animals, and the reduced birthweight and survival of progenies of animals fed with diets containing lead." (Ex. 23 (Lancranjan et al.), p. 400.)

In their paper entitled "Review paper: Susceptibility of adult females to lead; effects on reproductive function in females and males" Ziehuls and Wibowo criticized the study by Lancranjan et al., and there was considerable critical discussion of it during the hearings. It was concluded that methodological problems in the study do not negate the overall validity of the study especially when viewed in the context of other research in the literature. The Lancranjan study is strongly indicative of adverse effects on male reproductive ability at low lead levels, and there is evidence indicating a dose-response relationship with respect to teratosperma in these lead exposed workers. In OSHA's view altered spermatogenesis represents impaired reproductive capacity of the male given that sterility is the likely outcome. OSHA believes that this evidence and other studies support the conclusion that lead exerts markedly adverse effects on the reproductive ability of males.

Germ cells can be affected by lead which may cause genetic damage in the egg or sperm cells before conception and which can be passed on to the developing fetus. The record indicates that genetic damage from lead occurs prior to conception in either father or mother. The result of genetic damage could be failure to implant, miscarriage, stillbirth, or birth defects.

The record indicates that exposure of women to lead is associated with abnormal ovarian cycles, premature birth, menstrual disorders, sterility, spontaneous miscarriage, and stillbirths. Infants of mothers with lead poisoning have suffered from lowered birth weights, slower growth, and nervous system disorders, and death was more likely in the first year of life.

There is conclusive evidence in the record that lead passes through the placental barrier. Multiple studies have established that the fetus is exposed to lead because of the passage of lead through the placental membrane. This evidence was uncontested during the hearings. The lead levels in the mother's blood are comparable to concentrations of lead in the umbilical cord blood at birth. Transplacental passage becomes detectable at 12-14 weeks of gestation and increases from that point until birth.

Numerous parties at the hearings raised the issue of whether the fetus is the most sensitive organism requiring protection from exposure to lead. Bridbord, for example, argued that the immaturity of the blood brain barrier in the newborn raises additional concern about the presence of lead in fetal tissues.

There is little direct data on the fetus from exposure to lead but there are extensive studies which demonstrate neurological damage as would older children therefore data on children is relevant to the fetus, although acknowledging the duration of exposure may be more limited in the fetus. OSHA believes that damage to the fetus represents impairment of the reproductive capacity of the parent and must be considered material impairment of functional capacity under the OSH Act.

The proposed lead standard raised the possibility that "the risk of the fetus from intrauterine exposure to high levels of lead in the mother's blood is maximal in the first trimester of pregnancy when the condition of pregnancy may not be known with certainty" (Ex. 2, p. 46936; Ex. 95). OSHA agrees with Dr. Robert S. who testified that "the first trimester has not been shown to be the period of highest vulnerability for the fetus." (Ex. 59). OSHA has concluded that the fetus is at risk from exposure to lead throughout the gestation period, and therefore protection must be afforded throughout pregnancy.

Exposure to lead would be expected to adversely affect heme biosynthesis and the nervous system earliest and most profoundly in the fetus. Early enzyme inhibition in the heme forming system has been well documented, and the central nervous system has its most significant growth during gestation and the first 2 years following birth.

Lead is capable of damaging both the central and peripheral nervous systems of children. At high exposures to lead (80 µg/100 ml and above) the central nervous system may be severely damaged resulting in coma, cardio-respiratory arrest and death. Symptoms of acute encephalopathy similar to those in adults have been reported in young children with a markedly higher incidence of severe symptoms and deaths occurring in them than in adults. In children once acute encephalopathy occurs there is a high probability of permanent, irreversible
damage to the CNS. There is data that demonstrates permanent damage to CNS has occurred in children exposed at low lead levels and in whom no overt symptoms are evident. Children whose blood lead levels were 50 μg/100 ml and above have demonstrated mild CNS symptoms including behavioral difficulties. Behavioral disturbances in children such as hyperactivity have been associated with blood lead levels between 25 and 55 μg/100 ml. Animal studies have confirmed these findings. Beattie demonstrated an increased probability of mental retardation in children exposed to lead via maternal ingestion of lead in water. Elevated blood levels were found in the retarded children compared to the control group. There appeared to be a significant relationship between blood lead concentration and mental retardation. Mean blood lead for the retarded children was 25.5 μg/100 ml. Water lead concentrations in the maternal home during pregnancy also correlated with the blood levels from the mentally retarded children. Motor nerve conduction velocity (NCV) decrements indicating early peripheral neuropathy have been reported in children. Early studies showed NCV decrements in children whose blood lead levels were 40 μg/100 g and above.

While a critical review of the literature leads to the conclusion that blood lead levels of 50 to 60 μg/100 ml are likely sufficient to cause significant neurobehavioral impairments, there is evidence of effects such as hyperactivity as low as 25 μg/100 g. Given the available data OSHA concludes that in order to protect the fetus and newborn from the effects of lead on the nervous system, blood lead levels must be kept below 30 μg/100 g. In general, 30 μg/100 g appears to be a reasonably protective level, which will minimize enzyme inhibition (ALAD and FEP) in the heme biosynthetic pathway and should minimize neurological damage. OSHA agrees with the Center for Disease Control (Ex. 2(01)), the National Academy of Sciences (Ex. 8(6)), and the EPA (FlEIS 92) that the blood lead level in children should be maintained below 30 μg/100 g with a population mean of 15 μg/100 g. Levels above 30 μg/100 g should be considered elevated.

In general OSHA believes that the evidence overwhelmingly indicates the blood lead level of workers who wish to plan pregnancies should be maintained below 30 μg/100 g in order to avoid adverse effects from lead on the worker's reproductive abilities. To minimize the risk of genetic damage, menstrual disorders, interference with sexual function, lowered fertility, difficulties in conception, damage to the fetus during pregnancy, spontaneous miscarriage, stillbirth, toxic effects on the newborn, and problems with the healthy development of the newborn that occur at blood lead levels above 30 μg/100 g should be kept below 30 μg/100 g in both males and females exposed to lead who wish to plan pregnancies.

During the hearings there was considerable testimony on reproductive effects in relation to PEL, and equal employment opportunity considerations. No topic was covered in greater depth or from more vantage points than the subject of women in the lead industry. Modern women in general, are given the opportunity to plan pregnancies and to make a decision based on the risks that are involved and the benefits that will result. Whether OSHA should promulgate a standard that would be based on the reproductive effects of the general worker or the male and female workers in the lead industry is a matter of considerable controversy. The susceptible population is made up of certain groups of adult workers who are particularly at risk from the effects of lead. The susceptible population is made up of females in childbearing age themselves, who are more susceptible to the adverse effects of lead. The susceptible population is made up of females who are over the age of 15 years and who have been to "protect women workers from the effects of lead and hence can also be deemed susceptible." (Ex. 30, p. 925).

Based on the entire record, OSHA has reached the following conclusions regarding the reproductive effects of lead exposure.

A. Lead has profoundly adverse effects on the reproductive ability of male and female workers in the lead industry.

B. Lead exerts its effects prior to conception through genetic damage (germ cell alteration), effects on menstrual, and ovarian cycles and decreased fertility in women and increased libido and decreased fertility in men through altered spermatogenesis.

C. During pregnancy, the result of lead exposure may include spontaneous abortion, stillbirth, and damage to the fetus.

D. Following birth the child of lead exposed parents may exhibit birth defects, neurological damage and the chances of death within the first year may be increased.

E. To protect against the adverse effects of lead exposure to persons planning pregnancies (or pregnant) the blood lead level should be maintained below 30 μg/100 g. Although there is no evidence for a "no effect" level, OSHA believes that a level below 30 μg/100 g should be promulgated which would be based on the evidence presented in the record.

F. In conclusion, the record in this rulemaking demonstrates conclusively that workers exposed to lead suffer material impairment of health at blood lead levels far below those previously considered hazardous. Inhibition of the heme biosynthetic pathway, early stages of peripheral and central nervous system disease, reduced renal function and adverse reproductive effects are all evidence of adverse health effects from exposure to lead in workers at blood lead levels of 40 μg/100 g and above. Based on the record OSHA has concluded that blood lead levels should be maintained at or below 40 μg/100 g and even lower for workers who wish to plan pregnancies.

5. Air to blood relationship. The proposed lead standard reduced the permissible exposure limit from 200 μg/m² to an 8-hour time-weighted average concentration, based on a 40-hour workweek of 100 micrograms of lead per cubic meter of air (100 μg/m³).
The Lead Industries Association (LIA) recommended that OSHA adopt a biological enforcement limit instead of using a specific air lead number for all industries and operations. One of the key questions raised by LIA in justifying a biological standard was the purported lack of a relationship between air lead levels and blood lead measurements. The purpose of this section is to address the air lead to blood lead level relationship.

Based upon the evidence in the record OSHA has concluded that a relationship between air lead levels and population-average blood lead levels unquestioned. LIA and OSHA is confident that a permissible exposure limit based upon measurement of air lead levels will accomplish the intended goal of protecting worker health.

In order to accurately predict the effects on the blood level as a multiple produced by changes in air lead levels, it was necessary to construct a model that takes into account the important factors which affect blood lead levels. The adaptation of the physiological model of the body by Bernard by the Center for Policy Alternatives (CPA) combines experimentally observed properties of mammalian lead transport and metabolism, including consideration of the transfer of blood lead to long term exposure, with observed physical properties of airborne particulates encountered in the workplace, in order to produce a complete and accurate picture of the response of blood lead levels to particulate lead exposure. The Bernard model is an example of one of the most common types of models used to describe the transport and metabolism of drugs or foreign substances in the body. Transfer is assumed to occur only between the blood and the organ compartments, not between organ compartments. The rate of transfer into and out of the blood stream from the various compartments depends upon a number of factors, such as whether or not that particular organ specifically takes up or metabolizes the substance in question. In general, especially in the case of substances which are not metabolized, the rate of transfer between compartments is linearly related to the concentration of the substances in the compartments. This is consistent with the basic physical principles of chemical kinetics that would govern the transfer of a substance across an inert membrane in the absence of any other driving force.

The relatively few exceptions to the linear transfer principle tend to occur only in cases where an organ specifically sequesters or metabolizes the substance in question.

In designing a model and calculating the rate of transfer between compartments, the experimenter has many guidelines as to how to proceed. First, one can simply follow total body excretion to ascertain the number of compartments that individually take up and excrete lead after an initial dose. The more exponential terms required to fit the data, the more compartments. Second, the intercept at which the rate of uptake and release of the substance from the various tissues by autopsy or biopsy, and measure the rate of release. This latter approach is impossible, of course, in the study of human subject. Therefore it is necessary to predict the response of large populations of workers to changes in air lead exposure. OSHA has determined that the Center for Policy Alternatives (CPA) application of the Bernard Model accurately predicts the effects on blood levels over time produced by changes in air lead levels.

OSHA considers that both the basic construction of the Bernard Model of physiological lead transport and the application of the Bernard Model for prediction of blood lead levels represents a unique accomplishment here-tofore unseen in attempts to establish air lead level to blood lead level relationships. Insofar as this model takes into account particle size and job tenure it has avoided the serious weaknesses of earlier studies. The findings of those previous studies were incorporated into the development of the model. The final model represents a synthesis of the best available evidence in the record with CPA application of the Bernard Model of physiological lead transport.

Participants in the hearings argued that total reliance be placed upon air sampling or biological monitoring to the exclusion of the other. OSHA will require use of both measures to maximize protection of the lead worker population in general and the individual worker in particular. However, in the enforcement context OSHA will place primary reliance on air lead level measurements to determine compliance with the permissible exposure limit. Further discussion of the permissible exposure limits is found in that section.

In order to establish the correlation between air lead levels and the corresponding blood lead levels OSHA relied in its proposal on the work of Williams et al. (Ex. 5(32)) which was the most comprehensive reported study of its kind at that time. OSHA, in this final standard, has evaluated the findings of a series of subsequent studies which became available during the rulemaking process.

Almost all of the studies, whether based on observation of general or occupational populations, attempt to relate measurements of blood lead values to observed air lead levels by means of linear regression techniques. Regression analysis is a technique used to study the change of the mean value of one variable (average blood lead) as the other variable (air lead) changes. There are a number of practical and theoretical difficulties in the design and execution of experiments of this type which should be considered before attempting to discuss and compare the results of the various studies in question. The limitations of the studies in the record include:

The contribution of lead from unmeasured long term air lead exposures to current blood lead level is not properly considered. When the simple regression equation:

\[ \text{Current Blood-Lead} = a \times \text{Current Air Lead} + b \times \text{Individual error} \]

is used to model the data, the blood lead contributed by the exchange of lead in bone and tissue to blood is not taken into consideration. This has the consequence that the intercept at zero current air lead exposure ("b" in the regression equation above) is biased high and the blood-lead-air lead slope ("a" in the regression equation) is biased low relative to the slope which would be found if the relationship were redefined in terms of long term average air lead exposure. This has the practical effect of incorrectly predicting that the mean PbB level at 200 \( \mu g/m^2 \) will be close to that at 100 \( \mu g/m^2 \), which was a criticism made by LIA during the hearings. To the degree that the contribution of prior exposure to current lead levels differs for different workers in the sample, the "individual error" term will also be increased.
The regression equation does not explicitly incorporate terms relating to particle size. If, as suggested by some data in the record, workers at high air lead exposure levels are exposed to a larger proportion of poorly-absorbed large particulates than workers at low air lead exposure levels, then this will cause an upward bias to the "b" zero occupational exposure intercept and a downward bias to the "a" blood lead-air lead slope coefficient. This creates an impression that the rate at which blood lead changes relative to the air lead would be less than it actually would be.

Measurement errors of different kinds affect the results in different ways. Any errors in measuring blood lead level will add to the "individual error" term. However, errors in measuring air lead levels (arising either from inevitable imprecision in sampling or analysis or from unrepresentativeness of the short sample period relative to true average exposure) will usually systematically bias the "a" blood lead-air lead slope downward. This is a particularly serious source of bias in one of the major studies, the Buncher analysis (Ex. 285) of the Delco-Remy data, where single air lead measurements were paired with blood lead determinations made within a month of the air sampling. All other major studies of air lead-blood lead relationships used averages of several independent air lead measurements (generally ten or more measurements) for assessments of individual worker air lead exposures.

None of the studies made measurements of work-load or total worker respiration on the job. To the degree that workers differ from each other in gross ventilation, the individual error term is larger than it might have been. To the degree that populations of workers in different plants or in different industries differ in average respiration rate, potentially controllable or avoidable discrepancies in the results of different studies may have been produced.

Viewed in this context, the fact that there are differences in the blood lead-air lead regressions derived from short term observations on different populations is hardly surprising. It is understandable that many of the studies find unreasonably high values of the intercept at zero exposure ("b"). From studies of general populations with no occupational lead exposure, it is clear that the true "b" intercept is certainly under 25 μg/100g, and is very probably under 20 μg/100g for most areas.

The following table summarizes the results of several regression analyses developed from the studies in the hearing record. This table also compares the studies to the model and demonstrates that even given the limitations of the studies the results are similar.

Table 1.—Suggested air lead/blood lead relationships

<table>
<thead>
<tr>
<th>Source of Relationship</th>
<th>b</th>
<th>a</th>
<th>Non-Linear</th>
</tr>
</thead>
<tbody>
<tr>
<td>King Smelting (3)</td>
<td>52</td>
<td>60.63</td>
<td></td>
</tr>
<tr>
<td>Battery (1)</td>
<td>46</td>
<td>8.32</td>
<td></td>
</tr>
<tr>
<td>Pigmments (2a)</td>
<td>20</td>
<td>5.87</td>
<td></td>
</tr>
<tr>
<td>Pigmments (Quadratic fl)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Globe-Union (5)</td>
<td>32</td>
<td>.1229</td>
<td></td>
</tr>
<tr>
<td>ASARCO (El Paso)</td>
<td>32</td>
<td>.183</td>
<td></td>
</tr>
<tr>
<td>Williams</td>
<td>39.1</td>
<td>.201</td>
<td></td>
</tr>
<tr>
<td>Delco-Remy (Buncher)</td>
<td>37.45</td>
<td>.0658</td>
<td></td>
</tr>
<tr>
<td>CPA Bernard model and.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Job tenure (years)</td>
<td>0.85</td>
<td>23.15</td>
<td></td>
</tr>
<tr>
<td>Job tenure (months)</td>
<td>3.4</td>
<td>23.30</td>
<td></td>
</tr>
<tr>
<td>Job tenure (weeks)</td>
<td>9.0</td>
<td>29.20</td>
<td></td>
</tr>
<tr>
<td>Job tenure (days)</td>
<td>16.0</td>
<td>30.68</td>
<td></td>
</tr>
<tr>
<td>CPA</td>
<td>28.5</td>
<td>31.46</td>
<td></td>
</tr>
<tr>
<td>CPA</td>
<td></td>
<td>27.78</td>
<td></td>
</tr>
</tbody>
</table>

The available studies also have some individual limitations which should be borne in mind when considering the results:

The King studies (Ex. 234(22)) included many workers exposed at very high (300-900 μg/m³) air lead exposure levels. There is reason for concern that (1) because of particle size and absorption effects, the blood lead-air slope at very high air lead levels may not accurately reflect the slope in the air lead exposure region of interest for standard-setting (25-300 μg/m³), and that (2) there is risk that selection effects may have biased the observed air lead slope low, some workers who show high blood lead levels in response to a given air level may be absent from the high air lead exposure groups because of medical transfer to lower or no exposure jobs.

The Globe Union study (Ex. 150A) is based on a relatively small sample, although many of the points are of better quality than the points of other studies because they are based on averages of many air lead and blood lead determinations over a relatively long time (6 months or more).

The ASARCO El Paso (Ex. 142 D) and Williams (Ex. 232) studies each measured air lead and blood lead levels over a quite brief period (2 weeks). Additionally, the use of a control group of plastics workers at low air lead exposure levels in the Williams study has been criticized on the ground that the particulate air lead in the plastics workers' exposures may have been qualitatively different from those at the exposures of the battery workers at higher air lead exposure levels.

The Azar/Hammond relationship (Ex. 54) is an extrapolation of data from non-occupational exposures far below the exposure range of occupational situations. Use of a logarithmic model for such extrapolation is without theoretical justification.

As summarizations of available data on different populations, the existing studies are reasonably valid. It is one thing to say, however, that a linear relationship was observed between the blood lead levels and air lead exposure at a given level of statistical significance, for a given sample or workers, and another thing entirely to use the observed relationship to predict the effect of lowering air lead exposure on even that same sample of workers, let alone to generalize to other samples. Generally, data obtained at a given point in time, should be used conservatively when attempting to predict effects over time. Rarely will all other factors be held constant.

Recognizing these limitations by no means should be taken to imply that the data are useless or that no reliable relationship exists between long term air lead exposures and blood lead levels. To the extent that the likely systematic errors in the short term studies are understood (e.g., overestimation of the blood-air lead slope coefficient and overprediction of the intercept at zero occupational exposure), the observed regressions can be used to bound estimates of the true long-term relationships of blood lead to occupational air lead exposure. To the extent that the sources of uncontrolled variation within and between studies are understood, estimates of the likely effects of such factors can be explicitly incorporated into a more comprehensive description of the general system.

Because of the deficiencies in observational studies of air lead-blood lead relationship, it is useful to supplement the empirical air lead-blood lead correlations with relationships derived from physiological models of lead transport in the body. As previously stated the weight of the evidence demonstrates that the model developed by the Center of Policy Alternatives (CPA) is an accurate tool for assessing the blood lead level response to alternative air lead exposures.

In order to predict the numbers of workers who will be above a given blood level at any one time, it is necessary to have an estimate of the spread of individual workers' blood lead levels about a population mean. Observed variability in a worker population will have the basic form of:

(1) Individual differences in the long term (years) average blood lead response to a given air lead level;
In establishing 40 \( \mu g/100 \) g as the maximum blood lead level which the protection of employees and prudence permits, OSHA is mindful of the requirement of the Act that "no employee will suffer material impairment of health or functional capacity ... for the period of his working life." OSHA has concluded that maintenance of blood lead levels below 40 \( \mu g/100 \) g by engineering and work practice controls of airborne lead will provide protection of workers throughout their working lifetimes. There is a substantial amount of evidence which indicates that the blood level of workers, both men and women, who wish to plan pregnancies should be maintained at less than 30 \( \mu g/100 \) g during this period, and this knowledge forms the basis for the action level of 30 \( \mu g/100 \) g established in this final standard which the agency believes will maintain the majority of blood lead levels below 30 \( \mu g/100 \) g.

OSHA recognizes that a PEL of 50 \( \mu g/100 \) g per m3 will not achieve the goal of maintaining the blood lead levels in all, occupationally exposed workers below 40 \( \mu g/100 \) g. Based on the calculations using the CPA model, OSHA predicts 0.5 percent of worker blood levels will exceed 60 \( \mu g/100 \) g; 5.5 percent of the workers will have a PbB between 50–60 \( \mu g/100 \) g; 23.3 percent will be between 40–50 \( \mu g/100 \) g; and over 80 percent of exposed workers will have PbB above 40 \( \mu g/100 \) g at any one time when uniform compliance with 50 \( \mu g/100 \) g PEL is achieved. However, this represents a substantial improvement over current industry conditions. The current blood lead level distribution assuming compliance with 200 \( \mu g/100 \) g is approximately (1) greater than 60 \( \mu g/100 \) g, 22.4 percent; (2) 50–60 \( \mu g/100 \) g, 32.6 percent; (3) 40–50 \( \mu g/100 \) g, 28.7 percent; and (4) below 40 \( \mu g/100 \) g, 38.5 percent.

In establishing 40 \( \mu g/100 \) g as a maximum desirable blood lead level, the Agency is conscious of the fact that the OSHA Act mandates that a standard be set which will go "as far as practicable to prevent any further impairment of health or functional capacity resulting from exposure to lead." OSHA has determined that 50 \( \mu g/100 \) g represents the lowest level for which there is evidence of feasibility for primary and secondary smelters, SLI battery manufacturing, pigment manufacturing, and brass/bronze foundries. The 50 \( \mu g/100 \) g exposure limit is the level which properly balances the questions of feasibility and health effects of lead exposure and most adequately assures, to the extent feasible, the protection or workers exposed to lead. Compliance with this level will provide a dramatic reduction in the number of workers whose blood lead levels are currently greater than 40 \( \mu g/100 \) g, and will virtually eliminate all blood lead levels above 60 \( \mu g/100 \) g.

This level of 50 \( \mu g/m^3 \) is achievable almost entirely through engineering and work practice controls, the preferable control strategy. The exposure limit is based upon what can be achieved by the affected industries taken as a whole, using presently available technology or, in some instances, technology which may be on the horizon. The industries which will face the greatest difficulties in the implementation of engineering controls will be primary and secondary smelters, pigment manufacturing, brass/bronze foundries and SLI battery manufacturers. For this reason, the requirement for engineering and work practice controls will be phased-in with extended periods of time allotted for compliance in these industries. OSHA has determined that the standard is feasible, and that the PEL of 50 \( \mu g/m^3 \) represents the best intersection between maximization of health benefits and feasibility.

2. Health effects. In the proposal, OSHA questioned whether both clinical and subclinical effects should be considered in establishing a standard for lead. OSHA believes the original terms, clinical and subclinical, represent vast over-simplifications of a disease process and, therefore, have avoided their use in this final standard. The subclinical effects described in the health effects section are, in reality, the early to middle stages in a continuum of disease development process. It is axiomatic that the chronic, irreversible stage is preceded initially by an early, relatively mild, and apparently reversible stage of disease. This earliest stage is characterized by varying subjective and/or objective symptoms which may not at first alarm the victim, or present a physician with a clear-cut diagnosis. Nevertheless, this early developmental stage of disease is a pathological state, and OSHA finds persuasive the arguments for adopting a lead regulation which protects workers from this early consequence of lead exposure. OSHA believes these early stages of the disease process characterized by central-nervous system symptoms; behavioral changes, psychological impairment, peripheral nerve damage, anemia, reduced kidney function and adverse reproductive effects represent material impairment of the worker and should be prevented in order to eliminate further development of disabling disease and death.

OSHA must promulgate a standard which prevents occupational disease resulting from both acute and prolonged or chronic exposure to lead; it must likewise guard against the onset, progression or severity of chronic degenerative diseases of aging workers.
The degree of protection to be provided must extend over the full span of a working life and must cover the more susceptible, as well as the more robust members of the exposed group. Since the objective is to limit the latent effects of exposure, as well as to imitate illness, the mere absence of illness, or lack of severe clinical signs will not constitute adequate health protection. The PEL must be chosen such that is protects the worker not only from the most overt symptoms of illness, but also from the earliest indications of the onset of disease. The usual medical signs for disturbance, therefore, are wholly inadequate to provide employee protection. These considerations formed the basis of OSHA's interpretation of the health effects data in the record for purposes of establishing a PEL.

a. Inhibition of heme synthesis. In establishing the PEL, OSHA evaluated the health effects of lead on heme synthesis. Scientific evidence has established that very low levels of lead inhibit at least two enzymes (ALA-D and ferrochelatase) in the heme synthesis pathway. ALA-D inhibition is observed at PbB levels below 20 µg/100 g. At 40 µg/100 g significant excretion of the substance of one enzyme, ALA-D, occurs at this PbB level. The build-up of protoporphyrin levels indicates that inhibition of the enzyme, ferrochelatase, also occurs at low PbB levels. Some have argued that these effects are the manifestation of the human body's adjustment to lead. OSHA believes that it is inappropriate and simplistic to describe these changes as internal adjustments. These measurable effects are considered by the agency to indicate the occurrence of disruptions of a fundamental and vital subcellular process, heme synthesis. Such processes are not only essential to the production of hemoglobin, they are also vital to the mitochondrial function of all cells.

OSHA believes the evidence indicates a progression of lead's effects starting with the inhibition of specific enzymes, continuing to the measurable disruption of subcellular processes, such as the measurable build-up of heme synthesis products, and eventually developing into the overt symptoms of lead poisoning. Biological variability between individuals will necessarily cause differences in the PbB level at which a particular person will experience each of these effects. However, at each higher PbB level a greater proportion of the population will manifest each given effect. Given this understanding of the progressive stages of lead's effect, OSHA has concluded that enzyme inhibition indicative of the disruption of heme synthesis is an early stage of a disease process.

Anemia is one of the established symptoms of lead poisoning. That lead-induced anemia occurs above PbB levels of 80 µg/100 g is well established; however, the occurrence of this symptom at PbB levels below 80 µg/100 g has been debated. In evaluating the disease mechanisms of anemia, it was found that lead is an insidious poison which attacks not one, but many, of the subcellular physiological processes. The effects of lead on heme synthesis are considered to play a part in the development of anemia. Studies have associated PbB levels as low as 50 µg/100 g with lowered Hb levels. In particular, Tol's study, which showed a lowering of hemoglobin (Hb) over the length of lead exposure to 50 µg/100 g, and the work of the Mt. Sinai group in secondary smelters which demonstrated reduced Hb in 39 percent of the workers studied whose PbB levels ranged from 40 to 80 µg/100 ml, is considered by OSHA as strong evidence that lead does effect reduced Hb levels at this low PbB range. This implies that there is a lifetime alteration in the oxygen carrying capacity of the blood, in the blood viscosity and potentially in the cardiac work load.

In evaluating the effects of lead on heme synthesis, Piomelli suggested that effects on the blood forming system, such as the observed PbB levels below 20 µg/100 g, is considered by OSHA as strong evidence that lead does effect reduced Hb levels at this low PbB range. This implies that there is a lifetime alteration in the oxygen carrying capacity of the blood, in the blood viscosity and potentially in the cardiac work load.

Evidence indicates that there is disruption of heme synthesis in other tissues of the body following exposure to lead, and that this disruption results in alterations in the body's respiration. While this evidence relates lead's effects on heme synthesis to symptoms throughout the body is far from complete, it is, however, extensive enough to warrant a consideration with respect to the establishment of the standard. OSHA believes this evidence demonstrates that one stage of early lead disease is the disruption of heme synthesis and that the measurable effect of this disruption on the hematopoetic system parallels that which is known to occur in all body tissues at comparably low PbB levels, (below 40 µg/100 g). The disruption of heme synthesis is clearly not the only mechanism by which lead exerts its toxicological effect, but it is one mechanism of which we have substantial understanding and can measure.

In reference to the blood forming system, OSHA believes that the effects of lead are a complex progression which begins with discrete biochemical changes and proceeds to overt clinical symptoms. At increasingly higher PbB levels, a significant proportion of the population will suffer more extreme effects. At a PbB level of 40 µg/100 g, a sizable proportion of the population would show measurable disruption of heme synthesis in the hematopoetic system. A comparable degree of disruption of heme synthesis in the mitochondria would occur. OSHA believes the occurrence of such effects is an unacceptable health impairment.

Piomelli gave an excellent summary of the importance of lead's effects on heme synthesis stating:

It is my understanding that regulations have the purpose of preventing "material impairment of health". Alterations in heme synthesis do not produce subjective evidence of impairment of health, unless they reach the extreme depression in severe lead intoxication, when marked anemia occurs and the individual feels weak. However, it is not any longer possible to restrict the concept of health to the individual's subjective lack of feeling adverse effects. I believe that we now have the ability to detect functional impairments by appropriate tests, much before the individual can perceive any adverse effect. In fact, it is the duty of preventive medicine to detect these alterations which may precede frank symptomatology, and to prevent its occurrence. The alterations in heme synthesis caused by lead fulfill, in my opinion, the criteria for material adverse effects on health and can be used to forecast further damage. The depression of heme synthesis in all cells of the body is an effect of far reaching proportion and it is the key to the multiple clinical effects of lead toxicity, which becomes obvious as the exposure continues (Ex. 57, p. 21).

This does not in any way suggest that the lead effect on the body is the only mechanism of lead disease, but it does suggest that this effect is at least one of the important mechanisms in lead disease. An understanding of the spectrum of effects from subcellular to clinical symptoms is relevant not only to the occurrence of anemia but will also lead to the expected pattern in lead-induced neurological and renal disease.

OSHA believes that there is evidence demonstrating the impairment of heme synthesis and mitochondrial disruption in tissues throughout the body, and that these effects are the early stages of lead disease in these various tissues. The disruption of heme synthesis measured at low PbB levels is not only a measure of early hematopoetic effect, it is also a measure which indicates early disease in other tissue. The Agency believes that such a pervasive physiological disruption of processes of the body is unacceptable for protection of health and must be prevented. PbB levels greater than 40 µg/100 g should, therefore, be prevented to the extent feasible.
b. Neurological system. There is extensive evidence accumulated in both adults and children which indicates that the toxicity of lead is manifested in both the central and peripheral nervous systems. The neurologic manifestations of lead intoxication are variable, ranging from acute, chronic, or low level to massive. The location and degree of neurological damage depends on the dose and duration of exposure.

The record in this rulemaking clearly demonstrates that damage occurs in both the central and peripheral nervous systems at blood lead levels lower than previously recognized. Based on this record, OSHA has concluded that the earliest stages of central nervous system disease are recognizable as subjective CNS symptoms and behavioral disorders. These disorders have been documented in numerous scientifically sound investigations. Current information does not indicate a no-effect level. In adults, there is evidence of a dose-response relationship, but the no-effect level remains to be determined. Given the severity and potential nonreversibility of central nervous system disease, OSHA must pursue a conservative course of action.

A blood lead of 40 μg/100 g must be considered to be a threshold level for behavioral changes in adults, and to protect against long-term behavioral effects, blood levels should never exceed 60 μg/100 g. Some of the best and most extensive evidence in the rulemaking record are the data presented which confirm the existence of the earliest stages of peripheral neuropathy in workers exposed to lead levels below 70 μg/100 g. The evidence demonstrates that there is a statistically significant loss of motor nerve conduction velocity (MNCV) in lead-exposed adults. A dose-response relationship for the slowing of MNCV has been determined, and it appears that this slowing occurs in workers whose PbB levels are 50 μg/100 g and above. Whether there are effects as low as 40 μg/100 g is yet to be determined, although Repko does indicate a slowing of MNCV in the forties. Recently published research indicates edema appears to develop at the same time of onset of degeneration of myelin sheaths of nerve fibers which show reduced MNCV. This pathophysiological state will grow progressively worse with continued exposure even at PbB levels in the fifties. OSHA believes a clear deficit in the conduction velocity of more than one nerve is an early stage in the development of clinically manifest peripheral nerve disease and death (neuropathy). In order to prevent peripheral neuropathy as evidenced by a slowing in MNCV's, it is necessary to maintain PbB's below 50 μg/100 g, although if there is to be any margin of safety, a value less than this should be established. This is consistent with OSHA's overall goal of maintaining blood leads below 40 μg/100 g.

Recovery from the effects of chronic lead poisoning may be feasible in some cases. However, once nerve tissue is injured from the source of exposure and therapy is initiated immediately. There are instances, however, when complete recovery is impossible and the pathology is fixed. Even if the worker is removed from the source and therapy initiated, the worker may still experience impairment (Ex. 95 ref. Cantarow p. 135). In a recent paper describing his results, Dr. R. Baloh, a neurologist at UCLA, questioned the reversibility of nervous system damage:

Although there are isolated reports of significant improvement in lead induced motor neuron diseases and peripheral neuropathy after treatment with chelation therapy, most experts agree that risk of irreversible damage, and in the case of motor neuron disease, death has occurred despite adequate chelation therapy.

All of this data reinforces a disturbing clinical impression that nervous system damage from increased lead absorption is irreversible. OSHA agrees that increased lead absorption is a no-effect level, and in the case of motor neuron disease, death has occurred despite adequate chelation therapy.

OSHA agrees with the conclusions of Dr. Baloh and therefore must establish a standard which will prevent the development of nervous system pathology at its earliest stages.

c. Reproductive system. During the hearings, one of the most important contributions to the understanding of the adverse health effects associated with exposure to inorganic lead was the elucidation of evidence on kidney disease. In particular, the research of Wedeen and his coworkers, the health hazard evaluation by NIOSH at Eagle-Picher Industries, Inc., and the work of the Mt. Sinai group demonstrated that lead exposure is a key etiologic agent in the development of kidney disease among workers occupationally exposed to lead. Unlike the hematopoietic system where changes in heme formation can be detected at early stages, renal disease may only be detected through studies that have not been encouraged, since the heavy metal is bound by nervous tissue. Although further study is needed clearly needed, the major point I would like to make this morning is that there is strong evidence to suggest the only reliable way to treat nervous system damage from increased lead absorption is to prevent its occurrence in the first place. (Ex. 2777). p. 85.)

OSHA agrees with these concerns regarding irreversibility of neurological disease expressed by Dr. Baloh and therefore must establish a standard which will prevent the development of nervous system pathology at its earliest stages.

d. Renal system. During the hearings, one of the most important contributions to the understanding of the adverse health effects associated with exposure to inorganic lead was the elucidation of evidence on kidney disease. In particular, the research of Wedeen and his coworkers, the health hazard evaluation by NIOSH at Eagle-Picher Industries, Inc., and the work of the Mt. Sinai group demonstrated that lead exposure is a key etiologic agent in the development of kidney disease among workers occupationally exposed to lead. Unlike the hematopoietic system where changes in heme formation can be detected at early stages, renal disease may only be detected through studies that have not been encouraged, since the heavy metal is bound by nervous tissue. Although further study is needed clearly needed, the major point I would like to make this morning is that there is strong evidence to suggest the only reliable way to treat nervous system damage from increased lead absorption is to prevent its occurrence in the first place. (Ex. 2777). p. 85.)

OSHA agrees with these concerns regarding irreversibility of neurological disease expressed by Dr. Baloh and therefore must establish a standard which will prevent the development of nervous system pathology at its earliest stages.

OSHA agrees with Dr. Wedeen that:

- It is therefore the subclinical renal effects, and by subclinical, I mean effects that are not readily detected by the patient or the physician. It is therefore the subclinical effects of lead which should be detected and prevented, since this represents a material loss of functional capacity which has serious adverse health implications. (Tr. 1732) 40 μg/100 ml is the upper acceptable limit to prevent development of a hazardous body burden lead. (Tr. 1771)

There is conclusive evidence that lead crosses the placenta of pregnant women and enters the fetal tissues; maternal blood leads than did mothers with symptoms of renal failure during pregnancy. In fact, lead has been used as a abortifacient. In women exposed to lead, Phim has reported that the mothers of premature babies had significantly higher mean blood leads than lead mothers with normal pregnancies.

There is conclusive evidence that lead crosses the placenta of pregnant women and enters the fetal tissues; maternal blood leads that of the carrier's blood are comparable to concentrations in the umbilical cord blood at birth. A survey of fetal tissue demonstrated that the transplacental passage of lead becomes detectable at 12 to 14 weeks of gestation and may be sustained throughout pregnancy. Therefore, early in pregnancy the fetus may be adversely
affected by maternal lead exposure. Some investigators have suggested that the fetus is most vulnerable to lead during the first trimester. OSHA disagrees with this assertion, but rather believes the fetus is highly vulnerable whatever the stage of development. The fetus is particularly susceptible to neurological damage. In addition, there may also be heme synthesis impairment and renal damage in the fetus. In the newborn child, exposure to lead may continue through the secretion of lead in the mother's milk.

There is little direct data on damage to the fetus from exposure to lead but there are extensive studies which demonstrate neurobehavioral effects in children. OSHA believes that the fetus would be at least as susceptible to heme inhibition and neurological damage as would older children and therefore data on children is relevant to the fetus.

Behavioral disturbances, such as hyperactivity, have been associated with blood lead levels in children as low as 25 μg/100 ml. In general, mild CNS symptoms, behavioral problems, and other neurological signs and symptoms occur around 50 μg/100 ml but there is evidence of adverse effects at lower PbB levels.

An analysis of the data suggest that in order to protect against lead's adverse effects on the course of reproduction, blood lead levels should be maintained at or below 30 μg/100 ml. The Center for Disease Control, the Toxicology Committee of the National Academy of Sciences and the Environmental Protection Agency recommend that blood lead levels of children be kept below 30 μg/100 ml. Certainly the fetus and newborn should be similarly protected. OSHA recognizes that the PEL of 50 μg/m³ acting alone will not maintain blood lead levels of persons planning pregnancies or pregnant women below 30 μg/100 ml. When compliance is achieved, the mean blood lead level for the population of lead workers uniformly exposed to the 50 μg/m³ PEL will be approximately 35 μg/100 ml. OSHA believes that damage to the fetus represents impairment of the reproductive capacity of the lead exposed parent. While OSHA believes that a standard should be set which protects all persons—male and female workers, and the fetus—the agency is limited by the requirement that a standard be feasible. However, the standard minimizes adverse reproductive effects from lead by a variety of means including (1) establishing a 30 μg/m³ action level which will initiate biological and air monitoring, (2) utilizing the data of the medical surveillance section, including fertility testing, physician reviews, and medical removal protection to identify and perhaps remove workers who may wish to plan pregnancies or who are pregnant, and (3) insuring through the education and training provisions of the standard that workers are fully informed of the potential hazards from exposure to lead on their reproductive ability, during pregnancy and followup. Furthermore, in this respect these provisions of the standard should effectively minimize any risk to the fetus and newborn child, and thereby protect the reproductive systems of both parents.

The record in this rulemaking is clear that male workers may be adversely affected by lead as well as women. Male workers may be rendered infertile or impotent, and both men and women are subject to genetic damage which may affect both the course and outcome of pregnancy. Effective compliance with all aspects of these standard will minimize risk to all persons and should therefore provide equal employment for both men and women. There is no evidentiary basis, nor is there anything in this final standard, which would form the basis for not hiring workers of either sex in the lead industry.

During the hearings, industry representatives argued that lead exposed workers will not suffer material impairment of health if blood lead levels are below 80 μg/100 g. OSHA finds this argument to be unsubstantiated by scientific or medical evidence, and has concluded that it represents an incorrect assertion. It is not based on the sound evidence in the record which demonstrates adverse health effects as low as 40 μg/100 g. The record indicates that adverse signs and symptoms have been observed in workers who were exposed to lead for less than a year.

During the public hearings the vast majority of the physicians who testified supported the view that blood lead levels should be maintained at or below 40 μg/100 g in order to protect against the onset of the early manifestations of disease previously described as subclinical effects. The following physicians supported a PbB level of 40 μg/100 g: Dr. Lillis (Tr. 2709-01), Dr. Needleman (Tr. 1685-86; 1106-97); Dr. Epstein (Tr. 1051-52, 1058-65, 1067-68, 1072, 1073-74, 1104-65); Dr. Lancranjan (Tr. 1771), Dr. Wolfe (Tr. 4140), Dr. Tellitebaum (Tr. 374-78), Dr. Birdard (Tr. 1976-02), Dr. Fleishbein (Tr. 2690-61, 2669) and Dr. Fleishman (Tr. 2677).

In addition OSHA has carefully scrutinized the extensive evidence compiled by the Environmental Protection Agency (EPA) which led that Agency to establish a national ambient air quality standard of 0.5 μg/m³ designated to address the problem of lead in the urban environment. The EPA standard was based on the following considerations:

In establishing the final standard, "EPA determined that of the general population, young children (age 1-5 years) are most sensitive to lead exposure. In 1970, there were 20 million children in the U.S. under 5 years old, of whom 12 million lived in urban areas and 5 million lived in center cities where lead exposure is the highest. The standard is based on preventing children in the U.S. from exceeding a blood level of 30 micrograms per deciliter of blood. Blood lead levels above 30 micrograms are associated with an impairment in cell functional capacity, evident in the health of chronically exposed children. There are a number of other adverse health effects associated with blood lead levels above 40 micrograms per deciliter. EPA Press Statement, September 29, 1978.)

These conclusions are consistent with the testimony in this record including the policy statements of the Center for Disease Control (Ex. 2 (115)) and the National Academy of Sciences. These conclusions on exposure limits in the general population and children in particular are relevant to OSHA's final standard for a working population. The testimony of Dr. H. Needleman of Harvard University is relevant here.

I am one of those who believe that a substantial body of evidence is cumulative that the threshold for significant health effect depends on the avidity, sensitivity and sophistication with which we pursue it and that the lowering of acceptable health burdens in children and adults is scientifically and economically sound.

With the passage of time, the defined acceptable blood level for a child under six has moved from 60—when I began my training in pediatrics not too long ago—to 50 to 40 micrograms per deciliter. The CDC now begins to talk about 20 as the threshold for undue lead exposure. And Professor Zelhau and the Americans recommend an individual limits of 35 micrograms per deciliter and a group average of 20 micrograms per deciliter for children.

There are important differences during the time that the blood brain barrier is being laid down, that certain enzymes are being induced, but I think that the point that I was trying to generate in that argument, was that in my pediatric experience, when I started training in pediatrics, we said that children with blood leads over 80 were at high risk for the lead poisoning, and now we have been talking about children of 30, 40 or 45, and I think that same argument, deriving out of sharp and clear and experimental evidence, would apply to the worker that is, that if you look more carefully at the evidence of impairment, you are going to find it.

The fact that an adult worker will spill aminoadevulnic acid in his urine, at a blood
The Agency agrees with the conclusions of Dr. Needleman and emphasizes that overt symptoms of lead toxicity occur below 80 μg/100 g and in fact below 60 μg/100 g. OSHA is convinced by the record that large numbers of workers whose blood levels are above 40 μg/100 g and whose health will in all probability grow progressively worse, must be identified and protected.

### e. Air to blood relationships.

In order to establish a permissible exposure limit, OSHA was first required to determine the effect on blood lead levels of workers to changes in air lead exposure. OSHA believes this model represents the best approximation of the true air lead to blood lead relationship to date. It is superior to the short term studies in the record, insofar as it incorporates the best aspects of the studies in the model and also addresses the particular weaknesses of these studies, such as job tenure and particle size. OSHA has utilized the model in calculating the predicted blood lead distributions at various air lead levels and has determined the incremental benefits of the PEL to be discussed in the next section.

#### 3. Benefits of the PEL.

The dramatic reduction in the number of workers with blood lead levels over 40, 50 and 60 μg/100 g, is a measure of the incremental benefit derived from a PEL of 50 μg/m³. Ideally, it is desirable to express the benefits of a standard in terms of decreases in the incidence and severity of the various adverse health effects of lead exposure (e.g., neurological damage, kidney damage, etc.). However, the available data does not allow a meaningful quantitative estimation of the degree of prevention of damage which is likely to be achieved by lowering worker exposure and blood lead levels to specific levels. The record evidence allows estimates to be made of the blood lead levels which are likely to result from compliance with alternative air standards. In the absence of better epidemiologically determined morbidity and mortality data, the best judgment of the relative health benefits achievable under the different PEL’s which have been considered is based on the expected reduction in the number of workers with dangerously high blood lead levels.

The results are expressed in terms of the number of workers expected to fall into a particular blood lead range at any one time, after the establishment of long-term equilibrium, and without consideration of medical removal provisions. OSHA believes that this model will provide the best comparison of different assumed compliance levels. However, there are a number of inherent limitations in this approach which need to be clearly appreciated.

First, it should be understood that a change in air lead exposure causes a shift in the entire distribution of blood lead levels in the population:

![Figure 1](image-url)

Although the incremental benefits of standard No. 1 over standard No. 2 may be expressed in terms of the decrease in the number of workers (area under the curve) falling in each blood lead level range, the "benefits" of the standard are not really limited to workers who move across the lines. Under the lower exposure standard, all of the workers are expected, to some degree, to have lower blood lead levels, and therefore possibly some lower level of health risk. It should be noted that the comparison of differences in mean blood lead levels will markedly underestimate the benefits to a population of workers.

Second, it should be stressed that the measurement of benefits chosen represents a continuous "flow," not a "lock." As time passes and workers move into and out of employment in lead-related industries, the differences between compliance with various PEL’s continuously generate differences in the population of newly exposed workers. If two standards differ by 1,000 in the number of workers expected to be over 60 μg/100g at any one time, over a period of 10 years, the
difference is clearly 10,000 person-years at the higher blood lead level. This figure depends on the labor turnover in the industries concerned, the frequency with which workers change jobs (and hence exposures) within the industry, as well as other factors.

D. B. Associates has presented rough estimates of lead exposure in many industries. OSHA bases its assessments of the incremental benefits of the air lead standard on this data, as it is the most comprehensive compilation of exposure estimates. OSHA estimates based on DBA figures and other record evidence that overall, approximately 41,622 workers are currently exposed to time-weighted-average air lead levels of over 100 \( \mu g/m^3 \), and an additional 55,885 workers are exposed to air lead levels between 50 and 100 \( \mu g/m^3 \).

The following results are obtained by multiplying the appropriate exposure estimates by the estimates of the percentages of population expected to have blood levels in each range at any one time, following the establishment of long-term equilibrium. (See figure 2 and table 2.)
RULES AND REGULATIONS

BEST POINT ESTIMATES OF ULTIMATE EQUILIBRIUM BENEFITS
OF REDUCING AIR LEAD EXPOSURES UNDER
DIFFERENT BLOOD LEAD LEVEL VARIABILITY ASSUMPTIONS*

Blood Level Standard Deviation = 9/5 ug/100g

"Residual Health Hazard" (Number Remaining in Each Blood Level Range at Any One Time)
"Benefits of Regulation" (Number Prevented from Being in Indicated Blood Level Range at Any One Time, Compared to After Equilibrium) the "0" Compliance Level)

<table>
<thead>
<tr>
<th>Blood Level</th>
<th>Number of Workers (1,000's)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 60 ug/100g</td>
<td>80 + 70 + 60 + 50 + 40 + 30 + 20 + 10</td>
</tr>
<tr>
<td>50-60 ug/100g</td>
<td>70 + 60 + 50 + 40 + 30 + 20 + 10 + 10</td>
</tr>
<tr>
<td>40-50 ug/100g</td>
<td>60 + 50 + 40 + 30 + 20 + 10 + 10 + 10</td>
</tr>
<tr>
<td>Over 40 ug/100g</td>
<td>50 + 40 + 30 + 20 + 10 + 10 + 10 + 10</td>
</tr>
</tbody>
</table>

Number of Workers (1,000's)

80 70 60 50 40 30 20 10 10 20 30 40 50

<table>
<thead>
<tr>
<th>Blood Level</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 60 ug/100g</td>
<td>10</td>
</tr>
<tr>
<td>50-60 ug/100g</td>
<td>10</td>
</tr>
<tr>
<td>40-50 ug/100g</td>
<td>10</td>
</tr>
<tr>
<td>Over 40 ug/100g</td>
<td>10</td>
</tr>
</tbody>
</table>

*Computations based on air lead-blood lead relationships predicted by Bernard Model and Assumption C and OBA's best point estimates of exposure.

FEDERAL REGISTER, VOL. 43, NO. 220—TUESDAY, NOVEMBER 14, 1978
### RULES AND REGULATIONS

**BEST POINT ESTIMATES OF ULTIMATE EQUILIBRIUM BENEFITS OF REDUCING AIR LEAD EXPOSURES**

Blood Level Standard Deviation = 9.5 ug/100g

<table>
<thead>
<tr>
<th>Long Term Average Air Lead Exposure</th>
<th>Total Number of Workers</th>
<th>≥ 60 ug/100g</th>
<th>50-60 ug/100g</th>
<th>40-50 ug/100g</th>
<th>≥ 40 ug/100g</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>a.</em> Current Compliance Level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 100 ug/m³</td>
<td>41,622</td>
<td>27,652</td>
<td>8,508</td>
<td>4,166</td>
<td>40,326</td>
</tr>
<tr>
<td>50-100 ug/m³</td>
<td>55,885</td>
<td>5,125</td>
<td>14,379</td>
<td>19,732</td>
<td>39,243</td>
</tr>
<tr>
<td></td>
<td>97,507</td>
<td>32,777</td>
<td>22,887</td>
<td>23,898</td>
<td>79,569</td>
</tr>
<tr>
<td><em>b.</em> Compliance with 200 ug/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 100 ug/m³</td>
<td>41,622</td>
<td>9,340</td>
<td>13,569</td>
<td>11,958</td>
<td>34,867</td>
</tr>
<tr>
<td>50-100 ug/m³</td>
<td>55,885</td>
<td>5,125</td>
<td>14,379</td>
<td>19,732</td>
<td>39,243</td>
</tr>
<tr>
<td></td>
<td>97,507</td>
<td>14,465</td>
<td>27,948</td>
<td>31,690</td>
<td>74,110</td>
</tr>
<tr>
<td><em>c.</em> Compliance with 100 ug/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 50 ug/m³</td>
<td>97,507</td>
<td>2,562</td>
<td>14,041</td>
<td>32,870</td>
<td>49,475</td>
</tr>
<tr>
<td><em>d.</em> Compliance with 50 ug/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 50 ug/m³</td>
<td>97,507</td>
<td>498</td>
<td>5,373</td>
<td>22,729</td>
<td>28,599</td>
</tr>
</tbody>
</table>

**Incremental Benefits**

\[ \begin{align*}
\text{b over a} & = 18,312 - (5,061) = 13,251 \\
\text{c over a} & = 30,215 - 8,846 = 21,369 \\
\text{d over a} & = 32,279 - 17,514 = 14,765 \\
\text{c over b} & = 11,903 - (1,180) = 10,723 \\
\text{d over b} & = 13,967 - 8,961 = 5,006 \\
\text{d over c} & = 2,064 - 8,668 = -6,604
\end{align*} \]
The figure summarizes the best point estimates of the ultimate effects of achieving various air lead compliance levels (a-d). The left side of the figure shows the results of parallel computations of the number of workers in the various blood lead level ranges. The right side of the figure shows the incremental benefits (reduction of the number of workers in each blood level range) of the “b”, “c” and “d” compliance levels, compared to the baseline “a” compliance level which reflects the current distribution in the lead industry.

Assuming compliance with the present standard (the “a” compliance level), large numbers of workers could be expected to have potentially hazardous blood levels. At any one time, we anticipate that 37,777 workers would have blood lead levels over 60 µg/100 g, and 79,569 would have blood levels over 40 µg/100 g. In the absence of other remedial measures, Achievement of the “d” compliance level would reduce the number of workers over 60 µg/100 g, but would leave the number of workers in the 50-60 µg/100 g and 40-50 µg/100 g range substantially unchanged. Achievement of the “c” compliance level would be expected to reduce to about 2,500 the number of workers over 60 µg/100 g, and would be expected to produce reduction in the numbers of workers in the 50-60 µg/100 g blood lead level range to 14,900. The “d” compliance level would reduce the total number of workers over 40 µg/100 g to under 28,599, as compared to over 79,569 for the “a” scenario.

The incremental benefit of “d” over “a” in terms of the number of workers over 40 µg/100 g would be 50,970; for workers whose PbB levels would be over 60 µg/m³, the benefit would be 32,279. These are clearly substantial reductions in the number of workers with excessive blood levels and would represent marked benefits to lead-exposed workers.

4. Alternatives to the final PEL. During this rulemaking process, various parties advanced serious alternatives to the proposed OSHA standard. Since OSHA has adopted a PEL different from the proposal, this section will also discuss the proposed PEL of 100 µg/m³ as an alternative to the final one of 50 µg/m³. There were four alternatives proposed:

   (a) The LIA proposal. Adopt a standard which emphasizes biological indices and medical surveillance and which establishes an enforcement procedure directly utilizing these indices. OSHA has decided to place primary reliance on a PEL which is based on environmental monitoring of air lead levels and not on biological indices for the following reasons:

   1. Evaluation of the industrial environment by proven industrial hygiene techniques and measurement of the sources of lead exposure, adequacy of control technology, progress in implementation of engineering controls, and in general represents a continual check on lead exposure. Since OSHA believes that control of an air contaminant should be accomplished at the source, environmental monitoring is a direct measure of the control of lead exposure. Biological monitoring is designed to ascertain problems of individuals workers and is an indirect measure of the control of lead. In this regard environmental monitoring is better suited to serve as a basis for enforcement.

   2. Biological monitoring for compliance purposes is not feasible since there is no discrete value which could serve as the basis for citation. OSHA believes that based on consideration of health effects a PbB of 60, 70, or 80 µg/100 g would not protect workers’ health adequately. It is infeasible to require controls to maintain blood lead levels for all workers at the desired 40 µg/100 g and below. Rather, when all controls have been implemented, 30% of all workers’ PbB will range from 40 to 60 µg/100 g. Given the distribution of blood lead levels when compliance is achieved in a worker population, there is no discrete value which could serve as a maximum PbB. That is, OSHA believes that a PbB above 60 µg/100 g is excessive but a PbB between 40 to 50 µg/100 g may be the result of exposure or may represent the individual variation within a well controlled environment. Air lead determinations would differentiate between the two situations.

   3. A biological standard is not only infeasible it would provide inadequate protection since it would not immediately effect excessive blood lead levels. In fact, some workers’ blood levels might not rise to excessive levels for years, if at all, although their body burden would be increasing. Workers should not be expected to wait for protection until their blood leads become excessive. Air monitoring pinpoints overexposures immediately. This technique is preferable, therefore, for compliance purposes.

   4. Worker groups uniformly and vehemently oppose biological monitoring for compliance purposes. OSHA views this opposition seriously since workers would be the subjects of a compliance program based upon biological monitoring and their voluntary participation in such an invasive process would be crucial to its success.

5. Industry’s arguments that biological monitoring is preferred due to lack of an air lead-blood lead relationship are unsubstantiated. OSHA believes there is no doubt that an air to blood lead relationship exists and is best described in the CPA application of the Bernard model.

6. Although both biological and air monitoring are subject to errors, OSHA believes that the uncertainties associated with either measurement are not a sufficient basis for choosing one technique over the other. OSHA recognizes there are errors associated with air sampling, but nonetheless believes that evaluation of the plant environment is best and most directly accomplished through a comprehensive industrial hygiene survey as compared to biological sampling.

7. The record indicates that there are currently a significant number of industries which carry out biological monitoring. Given the current distribution of high blood lead levels throughout industry and the admitted lack of compliance with the current standard, other remedial measures. Achieving and maintaining the proposed PEL is designed to ascertain problems of individual workers and is an indirect measure of the control of lead. In this regard environmental monitoring is better suited to serve as a basis for enforcement.

4. Alternatives to the final PEL. During this rulemaking process, various parties advanced serious alternatives to the proposed OSHA standard. Since OSHA has adopted a PEL different from the proposal, this section will also discuss the proposed PEL of 100 µg/m³ as an alternative to the final one of 50 µg/m³. There were four alternatives proposed:

   (a) The LIA proposal. Adopt a standard which emphasizes biological indices and medical surveillance and which establishes an enforcement procedure directly utilizing these indices. OSHA has decided to place primary reliance on a PEL which is based on environmental monitoring of air lead levels and not on biological indices for the following reasons:

   1. Evaluation of the industrial environment by proven industrial hygiene techniques and measurement of the sources of lead exposure, adequacy of control technology, progress in implementation of engineering controls, and in general represents a continual check on lead exposure. Since OSHA believes that control of an air contaminant should be accomplished at the source, environmental monitoring is a direct measure of the control of lead exposure. Biological monitoring is designed to ascertain problems of individual workers and is an indirect measure of the control of lead. In this regard environmental monitoring is better suited to serve as a basis for enforcement.

   2. Biological monitoring for compliance purposes is not feasible since there is no discrete value which could serve as the basis for citation. OSHA believes that based on consideration of health effects a PbB of 60, 70, or 80 µg/100 g would not protect workers’ health adequately. It is infeasible to require controls to maintain blood lead levels for all workers at the desired 40 µg/100 g and below. Rather, when all controls have been implemented, 30% of all workers’ PbB will range from 40 to 60 µg/100 g. Given the distribution of blood lead levels when compliance is achieved in a worker population, there is no discrete value which could serve as a maximum PbB. That is, OSHA believes that a PbB above 60 µg/100 g is excessive but a PbB between 40 to 50 µg/100 g may be the result of exposure or may represent the individual variation within a well controlled environment. Air lead determinations would differentiate between the two situations.

   3. A biological standard is not only infeasible it would provide inadequate protection since it would not immediately effect excessive blood lead levels. In fact, some workers’ blood levels might not rise to excessive levels for years, if at all, although their body burden would be increasing. Workers should not be expected to wait for protection until their blood leads become excessive. Air monitoring pinpoints overexposures immediately. This technique is preferable, therefore, for compliance purposes.

   4. Worker groups uniformly and vehemently oppose biological monitoring for compliance purposes. OSHA views this opposition seriously since workers would be the subjects of a compliance program based upon biological monitoring and their voluntary participation in such an invasive process would be crucial to its success.

5. Industry’s arguments that biological monitoring is preferred due to lack of an air lead-blood lead relationship are unsubstantiated. OSHA believes there is no doubt that an air to blood lead relationship exists and is best described in the CPA application of the Bernard model.

6. Although both biological and air monitoring are subject to errors, OSHA believes that the uncertainties associated with either measurement are not a sufficient basis for choosing one technique over the other. OSHA recognizes there are errors associated with air sampling, but nonetheless believes that evaluation of the plant environment is best and most directly accomplished through a comprehensive industrial hygiene survey as compared to biological sampling.

7. The record indicates that there are currently a significant number of industries which carry out biological monitoring. Given the current distribution of high blood lead levels throughout industry and the admitted lack of compliance with the current standard, other remedial measures. Achieving and maintaining the proposed PEL is designed to ascertain problems of individual workers and is an indirect measure of the control of lead. In this regard environmental monitoring is better suited to serve as a basis for enforcement.

8. OSHA is concerned that a biological standard could impact negatively on workers with high blood leads and extended job tenure. Employers might terminate employment of these individuals to avoid citations for overexposure to lead. In addition, an employer could attempt to circumvent the standard by using respirators rather than implementing engineering controls. The use of respirators is not a satisfactory method for compliance. Indiscriminate use of respirators would be a confounding factor in ascertaining successful compliance with the standard.

Based on these considerations, OSHA will rely on determination of air lead level to ascertain compliance with the PEL.

b. The Proposal—100 µg/m³. The proposal would have established a PEL for airborne concentrations of lead at 100 µg/m³ as determined on an 8-hour time weighted average.

Based upon a thorough evaluation of the record, OSHA has reached the following conclusions which form the basis for establishing a PEL of 50 µg/m³ instead of 100 µg/m³. The health effects data indicates that to the extent feasible, blood lead levels should be kept at or below 40 µg/100 g. This contrasts with the proposal which set 40 µg/100 g as a mean, with 60 µg/100 g as a maximum. While feasibility limitations inhibit complete achievement of the goal of 40 µg/100 g as a maximum for all employees this goal can generally be achieved by setting the PEL at 50 µg/m³. Nevertheless, it forms an important foundation for OSHA’s decision to reduce the PEL.
to 50 μg/m². The CPA application of the Bernold model predicts a mean blood lead level of 34.6 μg/100 g at 50 μg/m² when compliance with the standard is achieved, compared to a mean PbB level of 40.2 μg/100 g at 100 μg/m².

The number of workers whose PbB levels were initially greater than 60 μg/100 g will be substantially reduced from 32,777 to 498 with compliance at 50 μg/m². For 100 μg/m², the benefits are also substantial, 32,777 to 2,562 with the incremental benefit for 50 μg/m² over 100 μg/m² being 2,064. There are 22,887 workers whose PbB are between 50 and 60 μg/100 g. Compliance with 50 μg/m² would reduce that number by 17,514, whereas at 100 μg/m², the number would be 8,846 with incremental benefit of 8,668 for 50 versus 100 μg/m². Between 40 and 50 μg/100 g there are 23,928 and compliance with 50 and 100 μg/m² results in a decrease of 10,141 and increase at 100 μg/m² of 5,872 with a benefit of 50 versus 100 μg/m² of 10,141. Lastly, there are 9,569 workers whose PbB levels are above 40 μg/100 g. Compliance with 50 μg/m² and 100 μg/m² respectively would reduce the numbers to 28,599 and 49,475 with an incremental benefit of 20,876 for 50 versus 100 μg/m².

SUMMARY

Incremental Benefit (by number of workers)

<table>
<thead>
<tr>
<th>PbB Level</th>
<th>50 μg/m²</th>
<th>100 μg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 μg/100 g</td>
<td>2,064</td>
<td></td>
</tr>
<tr>
<td>60-60 μg/100 g</td>
<td>8,668</td>
<td></td>
</tr>
<tr>
<td>40-50 μg/100 g</td>
<td>20,876</td>
<td></td>
</tr>
<tr>
<td>60 μg/100 g</td>
<td>1,169</td>
<td>32,777</td>
</tr>
<tr>
<td>60-60 μg/100 g</td>
<td>5,094</td>
<td>32,777</td>
</tr>
<tr>
<td>40-50 μg/100 g</td>
<td>9,569</td>
<td>32,777</td>
</tr>
<tr>
<td>60 μg/100 g</td>
<td>1,045</td>
<td>28,599</td>
</tr>
<tr>
<td>60-60 μg/100 g</td>
<td>4,964</td>
<td>28,599</td>
</tr>
<tr>
<td>40-50 μg/100 g</td>
<td>9,064</td>
<td>28,599</td>
</tr>
</tbody>
</table>

In summary, OSHA finds that 50 μg/m² will provide significantly increased protection to exposed employees over what would be achieved at 100 μg/m², and within the limits of feasibility provides substantial incremental benefits toward achieving a maximum of 40 μg/100 g.

(c) The LIA Second Alternative—200 μg/m². The LIA has proposed that if OSHA decides to retain a single air lead exposure limit as opposed to a standard with primary reliance on biological monitoring, the limit should not be lower than 200 μg/m².

The evidence of adverse health effects cited in the proposed lead standard and in this final standard demonstrates that a PEL of 200 μg/m² does not nor will not protect the worker in the lead industry from "material impairment of health or functional capacity." A PEL of 200 μg/m² would yield blood levels well above that which is deemed safe by OSHA in terms of both short and long-term exposure duration. Frank signs and symptoms of disease would be expected to occur at this level. The industry has argued that OSHA should not reduce the PEL from its current level of 200 μg/m² until compliance has been achieved at that level and medical evaluation has determined whether or not it is protective. OSHA agrees that the evidence already exists which demonstrates that 200 μg/m² is not protective and a delay in promulgating a new standard would place workers at severe risk to disease.

The benefits of compliance with 50 μg/m² versus the current level of compliance with 200 μg/m² were described in the benefits section and are substantial. The number of workers whose PbB levels are greater than 40 μg/100 g would be reduced from 79,569 to 28,599 and the number of workers whose PbB levels would be reduced below 40 μg/100 g is 50,970. To summarize:

Incremental Benefit of 50 μg/m² versus 200 μg/m²

<table>
<thead>
<tr>
<th>PbB Level</th>
<th>Number of workers removed:</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;60 μg/100 g</td>
<td>32,270</td>
</tr>
<tr>
<td>60-60 μg/100 g</td>
<td>20,876</td>
</tr>
<tr>
<td>&gt;40 μg/100 g</td>
<td>10,141</td>
</tr>
<tr>
<td>&gt;40 μg/100 g</td>
<td>2,562</td>
</tr>
</tbody>
</table>

It is important to note that the correct method of determining benefits is to compare a shift in the distribution of blood lead levels in the entire population. Comparison of the differences in average blood lead levels is irrelevant to an accurate understanding of the impact of the standard.

OSHA concludes that there are substantial benefits to be achieved from the promulgation of a 50 μg/m² standard and that the arguments set forth in favor of a 200 μg/m² alternative are not compelling.

(d) 40 μg/m².

The United Steel Workers of America proposed 40 μg/m² as an alternative to 100 μg/m² in the proposal.

OSHA has calculated the equilibrium distribution of blood lead levels assuming rigorous compliance with 40 μg/m² and has compared these results to a similar calculation for 50 μg/m². The results are as follows:

<table>
<thead>
<tr>
<th>Blood Lead Distribution (in Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;40 μg/100 g</td>
</tr>
<tr>
<td>40-50 μg/m², 50-60 μg/m², &gt;60 μg/m²</td>
</tr>
<tr>
<td>40 μg/m² (24.2%)</td>
</tr>
<tr>
<td>23.3%</td>
</tr>
<tr>
<td>5.5%</td>
</tr>
<tr>
<td>0.5%</td>
</tr>
<tr>
<td>50 μg/m² (29.3%)</td>
</tr>
<tr>
<td>23.3%</td>
</tr>
<tr>
<td>5.5%</td>
</tr>
<tr>
<td>0.5%</td>
</tr>
</tbody>
</table>

OSHA has determined that the incremental benefit of 40 μg/m² versus 50 μg/m² is negligible and in fact may be within the error of the measurements. While OSHA agrees with the goal that blood lead levels should be kept below 50 μg/100 g where possible, and in fact preferably below 40 μg/100 g, the levels required to achieve the latter value are clearly infeasible in the foreseeable future. Based on the conclusions OSHA believes the considerations which form the final standard are valid and the PEL of 50 μg/m² will be maintained.

C. MEDICAL REMOVAL PROTECTION

1. Introduction. The final standard includes provisions entitled Medical Removal Protection, Medical Removal Protection, or MRP, is a protective, preventive health mechanism integrated with the medical surveillance provisions of the final standard. MRP provides temporary medical removals for workers discovered through medical surveillance to be at risk of sustaining material impairment to health from continued exposure to lead. MRP also provides temporary economic protection for those removed. Temporary medical removal is mandated for any worker having an elevated blood lead level at or above 60 μg/100 g of whole blood, at or above 60 μg/100 g of whole blood average over the previous 6 months. Upon the effective date of the standard, temporary medical removal is also mandated for any worker found by a medical determination to be at risk of sustaining material impairment to health. In most temporary medical removals, the worker must be removed from any exposure to lead at or above the 30 μg/m³ action level, with return of the employee to his or her former job status when the temporary medical removal is no longer needed to protect the worker's health. During the period of removal, the employer must maintain the worker's earnings, seniority and other employment rights and benefits as though the worker had not been removed.

2. Importance of temporary medical removals. A central element of MRP is the temporary medical removal of workers at risk of sustaining material impairment to health from continued exposure to lead. This preventive health mechanism is especially well suited to the lead standard due to the reversible character of the early stages of lead diseases, and to the relative ease with which a worker's body may be biologically monitored for the presence of harmful quantities of lead. Temporary medical removal protects worker health both by severely limiting subsequent occupational exposure to lead, and by enabling a worker's body to naturally excrete previously absorbed lead which has accumulated in various tissues.

Temporary medical removal is an indispensable part of the lead standard for two significant reasons. Little margin for safety is provided by the final standard's 50 μg/m³ permissible exposure limit, thus it is highly likely that some small fraction of workers...
much less than 6 percent will not be adequately protected even if an employer complies with all other provisions of the standard. Temporary medical removal will be the only means of protecting these workers. Many segments of the lead industry are reluctant to adopt the standard's medical surveillance program. Medical surveillance, a major element of the inorganic lead standard because it is the only control mechanism which can serve the two preceding functions. Temporary removal is not an alternative means for an employer to control worker lead exposure, however, but rather a fall-back mechanism to protect individual workers in circumstances where other protective mechanisms were insufficient.

3. MRP as a means of effectuating the medical surveillance sections of the lead standard. Temporary medical removals depend on voluntary and meaningful worker participation in the standard's medical surveillance program. Medical surveillance, a major element of the Act's integrated approach to preventive health, can only function as intended where workers (1) voluntarily seek medical attention when they feel ill, (2) fully cooperate with examining physicians to facilitate accurate medical diagnoses, and (3) refrain from efforts to conceal their true health status. No one can coerce these qualities of worker participation—they will occur only where no major disincentives to meaningful worker participation exist. Absent these qualities of worker participation, medical surveillance will not be effective in identifying those workers who need temporary medical removals, and consequently the overall protection offered by the lead standard will be diminished.

Participation in medical surveillance offered under the lead standard will sometimes prompt the temporary medical removal of a worker.Absent some countervailing requirement, removal could easily take the form of a transfer to a lower paying job, a temporary lay off, or even a permanent termination. The possibility of these consequences of a medical removal present a dramatic and painful dilemma to many workers exposed to inorganic lead. A worker who fully participate in the medical surveillance program and risk losing his or her livelihood, or resist participating in a meaningless fashion, and thereby lose the many benefits that medical surveillance and temporary medical removals can provide. Convincing evi-

dence presented during the lead proceeding established that many workers will either refuse or resist meaningful participation in medical surveillance unless economic protection is provided.

Much of the evidence in the lead proceeding documents the extent to which worker participation is adversely affected by the fear that adverse employment consequences will result from participation in medical surveillance programs. This problem was emphasized by the testimony of many workers and worker representatives. The problem was seen as widespread throughout industry, and as having already seriously affected Act of participation in medical surveillance programs under several prior OSHA health standards which lack MRP benefits. Evidence concerning the issue of worker fears impeding participation and its consequences are furnished from worker representatives, but was verified by a wide variety of experts and industry representative as well. Current industry practices are such that genuine economic disincentives to participation exist. These disincentives will be intensified by the new lead standard, particularly as a result of the temporary medical removal provisions. Finally, OSHA's adoption of MRP as a means of effectuating medical surveillance has been significantly influenced by experience gained under the Black Lung Medical Surveillance and Transfer Program created by Section 203 of the Federal Coal Mine Health and Safety Act. Experience under this program reveals the extent to which economic disincentives adversely affect participation even in medical surveillance programs where job transfer and limited economic protection prevailed. For all of the preceding reasons, MRP was included in the final standard as a means of maximizing meaningful participation in medical surveillance provided to lead-exposed workers.

4. MRP as a means of allocating the costs of temporary medical removals. Temporary medical removal is fundamentally a protective, control mechanism, as is the elimination of air lead emissions through the use of engineering controls. The use of a temporary medical removal carries the possibility of dislocation costs to an employer through the temporary loss of a trained and experienced employee. And, a removed worker might easily lose substantial earnings or other rights or benefits by virtue of the removal. These costs are a direct result of the use of temporary medical removal as a means of protecting worker health. MRP is meant to provide workplace protection directly on the lead industry rather than on the shoulders of individual workers unfortunate enough to be at risk of sustaining material impairment to health due to occupational exposure to lead. The costs of protecting worker health are appropriate cost of doing business since employers under the Act have the primary obligation to provide safe and healthful places of employment.

One beneficial side-effect of MRP will be its role as an economic incentive for employers to comply with the final standard. Increasing public attention has been focused on the desirability of governmental regulations incorporating economic incentives to compliance, and though not adopted specifically to serve this purpose, MRP will nonetheless strengthen the protection afforded by the lead standard due to its inevitable impact on compliance. Employers who make good faith attempts to comply with the lead standard should experience only small numbers of temporary medical removals-removals which can be absorbed by available transfer alternatives. Employers who make only cursory attempts to comply with the central provisions of the standard will find that the greater the degree of noncompliance, the greater the number of temporary medical removals and associated MRP costs. MRP will serve as a strong stimulus for employers to protect worker health, and will reward employers who through innovation and creativity devise new ways of protecting worker health not explicitly contemplated by the formal standard.

5. Alternatives to MRP considered by OSHA. Before deciding to include MRP in the final lead standard, OSHA considered and rejected several possible alternatives. Mandating that employers compel all employees to participate in medical surveillance offered under the standard was rejected in part due to the fact that this approach would not be able to assure the voluntary and meaningful worker participation upon which success of the standard's medical surveillance program depends. Mere participation is not an end in and of itself. For example, no degree of compulsion can prevent workers form obtaining and misusing chelating agents so as to yield apparently low blood lead level results. No degree of compulsion can force workers to reveal subtle, subjective symptoms of lead poisoning which a physician needs to know as part of an adequate medical history.

In addition, OSHA declined to mandate worker participation in medical surveillance due to the substantial personal privacy and religious concerns involved in health care matters. Governmental coercion in this sensitive area could prove counterproductive to the goal of meaningful worker participation. Finally, the foregoing arguments against mandatory participa-
tion arise irrespective of whether or not MRP benefits are provided to removed workers. Thus, mandatory worker participation with MRP is no more satisfying as an alternative than mandatory worker participation without MRP.

A second alternative rejected by OSHA was to mandate that temporary medical removals occur only at the election of individual workers at risk of sustaining material impairment. Workers under this condition should have no reluctance to participate in medical surveillance since they would control the consequences of participation. This alternative would merely inform workers of their health status without providing affirmative protection to those who needed it. Workers who should be removed would far too often choose not to be in the absence of MRP economic benefits, and employers would even be prevented from utilizing removal in situations where it was imperative. These results are inconsistent with the preventive purposes of the Act, and thwart the level of health protection which temporary medical removals can provide.

A third alternative rejected by OSHA was to permit the use of respiratory protection in lieu of temporary medical removal. OSHA rejected this alternative because of the inherent limitations of respiratory protection. The need to temporarily remove a worker from lead exposure is a matter of medical necessity. Relying on a respirator to protect a worker from exposure beyond such a point is unacceptable in light of the numerous inadequacies of respiratory protection. OSHA does not intend, however, to preclude the use of respirators where appropriate as one means (in conjunction with other industrial hygiene measures) of seeking to assure in advance that no worker need ever be removed. The need to temporarily remove a worker due to medical reasons will rarely arise without advance warning, thus providing an advance opportunity to use respiratory protection where appropriate. If respirators prove to be effective in practice, then there will be no need to temporarily remove a worker.

6. Feasibility. MRP as structured in the final standard is a feasible regulatory device. Elevated blood lead levels will in practice be the primary basis for the temporary medical removal of workers. Blood lead level removal triggers are phased in over a 4-year period as follows: (1) Beginning upon the effective date of the standard, the temporary medical removal of those having blood lead levels at or above 80 μg per 100 g of whole blood; (2) beginning 1 year after the effective date of the standard, the temporary medical removal of those having blood lead levels at or above 70 μg; (3) beginning 2 years after the effective date of the standard, the temporary medical removal of those having blood lead levels at or above 60 μg; and (4) beginning 4 years after the effective date of the standard, the temporary medical removal of those having average blood lead levels over the past 6 months at or above 50 μg. This 4-year phasing in process has been designed such that employers have the available opportunity to reduce their current employees’ blood lead levels before particular blood lead level removal triggers come into effect.

Employers are required with the new standard should experience few temporary medical removals, and thus a minimal economic impact from MRP. The gradual phasing in schedule will enable employers to structure their production operations so that transfer opportunities are provided to all removed workers. Four years will allow collective bargaining relationships to be altered if necessary so that all removals can be accommodated. Once MRP has been fully phased in, and employers are fully in compliance with the new standard, only a small percentage of the exposed workforce (much less than 6 percent) should need temporary medical removals at any point in time. With experience, employers should acquire the capability to preclude even most of these temporary medical removals by removing sources of lead exposure which are causing the blood lead levels of particular workers to climb toward a removal trigger.

OSHA anticipates no substantially greater impact of MRP upon small employers than upon large employers.

The standard requires that an employee be temporarily removed from lead exposure whenever a final medical determination results in a medical finding, opinion, or recommendation that the employee has a detected medical condition which places the employee at increased risk of material impairment from exposure to lead. The term “final medical determination” refers to the outcome of the multiple physician review mechanism, or alternative medical determination mechanism, used pursuant to the medical surveillance provisions of the standard. Temporary removal based on medical determinations is included in MRP as a necessary complement to removal based on elevated blood lead levels. During the phasing in of MRP, workers experiencing adverse health effects from lead absorption deserve a temporary medical removal, even if the fact that their blood lead levels do not yet require a removal. Even after MRP has been fully phased in, situations may arise where lead poisoning occurs in a worker having a blood lead level below the removal criteria, or a worker may acquire a temporary nonwork-related medical condition which is worsened by lead exposure. In addition, temporary medical removal may in particular cases be needed for workers desiring to parent a child in the near future or for particular pregnant employees. Some males may need a temporary removal so that their sperm can regain sufficient viability for fertilization; some women may need a temporary removal to slightly lower their blood lead levels so that prior lead exposure will not harm the fetus.

A worker removed as a result of a physician determination must be pro-
vided reasonable follow-up medical surveillance during the period of removal. The worker must be returned to his or her former job status when a final medical determination indicates that the employee no longer has a medical condition which places the employee at risk of material impairment to health from exposure to lead. The standard does not explicitly define the phrase "material impairment to health" due to the innumerable contexts in which the temporary medical removal of a particular worker might be appropriate. Application of this phrase in a manner consistent with sound medical practice will result from the standard's physician determination mechanisms.

8. Removal from work or above the action level. In most cases where a worker is removed due to an elevated blood lead level or a medical determination, the standard provides that removal be from work having an exposure to lead at or above the 30 µg/m³ action level, having an exposure to lead at or above the action level refers to the worker's daily 8-hour time weighted average (TWA) exposure to lead. As in all cases where the term "action level" is used, exposure is to be computed without regard to the use of respirators. This job placement limitation for most removals was based first on the need to assure that a worker not be removed to work having lead exposure high enough to further increase risks to health. The second reason for this limitation was to assure that a worker be removed to work having lead exposure low enough to enable the gradual excretion of excess lead returned to his or her former job.

During the first year following the effective date of the standard, however, workers removed due to blood lead levels at or above 20 µg/m³ need only be removed from work having a daily eight hour TWA exposure to lead at or above 10 µg/m³. During the second year, following the effective date of the standard, workers removed due to blood lead levels at or above 30 µg/m³ need only be removed from work having a daily eight hour TWA exposure to lead at or above 50 µg/m³. These criteria were chosen consistent with the goal of effecting moderate worker blood lead level declines during the first 2 years of the standard's effect, while at the same time providing employers an opportunity to comply with the new lead standard and thereby avoid substantial MRP costs.

OSHA recognizes that situations may arise where removal to lead exposure just below the action level is inadequate to protect worker health. These situations can and should be dealt with on an individual basis in the course of a thorough medical examination conducted pursuant to the standard. The standard implies no unnecessary restriction on a physician's ability to recommend individual actions more protective than the standard's requirements. The standard does, however, embody the judgment that, at a minimum, it would be inappropriate to remove a worker from work having an exposure to lead at or above the action level.

9. Return of an employee to his or her former job status. The standard provides that once a period of removal or limitation has ended, an employee must be returned to his or her former job status. Former job status refers to the position the worker would likely be occupying if he or she had never been removed. If, but for a temporary medical removal, a worker would now be working at the same position held just before removal, then the employer may return the worker to that job. Otherwise, the employer may return the worker consistent with whatever job assignment discretion the employer would have had if no removal had occurred.

10. The implementation of temporary medical removals. It is OSHA's intention that employers implement each temporary medical removal in a manner consistent with existing collective bargaining agreements. MRP is meant to override existing contractual obligations only in the event that specific contract provisions directly conflict with the terms of MRP. MRP has been structured to guarantee maximum employer flexibility in effectuating MRP while minimizing the possibility of conflicts with existing collective bargaining agreements or other relationships. The standard does not specify what an employer must do with a removed worker; practically any action is permissible provided the worker is not exposed to lead at or above the action level. In most cases OSHA expects that a removed worker will be transferred to a low lead exposure position during the period of removal. OSHA intends that these transfers be to work that the removed employee is capable of performing and which is located in the same geographical area as the employee's normal job. Alternatively, the worker might work shorter hours in his or her current job or in a non-lead-related facility. OSHA's intention is that the choice between these or other alternatives be a prerogative of the employer unless this flexibility is abridged by specific work limitation obligations. A removed worker is provided no automatic right to veto an employer's choice which meets the standard, but similarly, the standard provides no right for an employer to simply override existing contractual commitments to either removed employees or to other employees.

Arguments have been made that MRP may create conflicts with existing collective bargaining relationships. To the extent conflicts exist, they should be easily resolved during the lengthy phase-in period for MRP. Worker transfer programs with economic protection have had longterm use throughout industry in a variety of contexts. These many programs have apparently melded quite well with collective bargaining relationships, and there is no evidence which suggests that the implementation of MRP will proceed any differently.

The mechanics of each temporary medical removal is a matter for the employer, the removed employee, and his or her collective representative, if any work out in the context of existing relationships. Some employers and unions may decide to modify their contractual agreements to specify how each removal will be accomplished, and the period during which MRP is phased in will provide ample opportunity for modifications to be made.

11. Employer flexibility pending a final medical determination. In some instances a dispute may arise between an initial physician, chosen by an employer, and a second physician, chosen by the employee, as to the appropriateness of removing or returning a particular worker. Pending the outcome of the standard's physician review mechanism, the standard provides that an employer may act in a manner consistent with the medical findings, opinions or recommendations of any of the physicians who have examined the employee, with two exceptions. First, if an employee was removed or limited as a result of a final medical determination, the employee's normal job. Alternatively, the worker might work shorter hours in his or her current job or in a non-lead-related facility. OSHA's intention is that the choice between these or other alternatives be a prerogative of the employer unless this flexibility is abridged by specific work limitation obligations. A removed worker is provided no automatic right to veto an employer's choice which meets the standard, but similarly, the standard provides no right for an employer to simply override existing contractual commitments to either removed employees or to other employees.

The mechanics of each temporary medical removal is a matter for the employer, the removed employee, and his or her collective representative, if any work out in the context of existing relationships. Some employers and unions may decide to modify their contractual agreements to specify how each removal will be accomplished, and the period during which MRP is phased in will provide ample opportunity for modifications to be made.

Arguments have been made that MRP may create conflicts with existing collective bargaining relationships. To the extent conflicts exist, they should be easily resolved during the lengthy phase-in period for MRP. Worker transfer programs with economic protection have had longterm use throughout industry in a variety of contexts. These many programs have apparently melded quite well with collective bargaining relationships, and there is no evidence which suggests that the implementation of MRP will proceed any differently.

The mechanics of each temporary medical removal is a matter for the employer, the removed employee, and his or her collective representative, if any work out in the context of existing relationships. Some employers and unions may decide to modify their contractual agreements to specify how each removal will be accomplished, and the period during which MRP is phased in will provide ample opportunity for modifications to be made.

11. Employer flexibility pending a final medical determination. In some instances a dispute may arise between an initial physician, chosen by an employer, and a second physician, chosen by the employee, as to the appropriateness of removing or returning a particular worker. Pending the outcome of the standard's physician review mechanism, the standard provides that an employer may act in a manner consistent with the medical findings, opinions or recommendations of any of the physicians who have examined the employee, with two exceptions. First, if an employee was removed or limited as a result of a final medical determination, the employee's normal job. Alternatively, the worker might work shorter hours in his or her current job or in a non-lead-related facility. OSHA's intention is that the choice between these or other alternatives be a prerogative of the employer unless this flexibility is abridged by specific work limitation obligations. A removed worker is provided no automatic right to veto an employer's choice which meets the standard, but similarly, the standard provides no right for an employer to simply override existing contractual commitments to either removed employees or to other employees.

Arguments have been made that MRP may create conflicts with existing collective bargaining relationships. To the extent conflicts exist, they should be easily resolved during the lengthy phase-in period for MRP. Worker transfer programs with economic protection have had longterm use throughout industry in a variety of contexts. These many programs have apparently melded quite well with collective bargaining relationships, and there is no evidence which suggests that the implementation of MRP will proceed any differently.

The mechanics of each temporary medical removal is a matter for the employer, the removed employee, and his or her collective representative, if any work out in the context of existing relationships. Some employers and unions may decide to modify their contractual agreements to specify how each removal will be accomplished, and the period during which MRP is phased in will provide ample opportunity for modifications to be made.

11. Employer flexibility pending a final medical determination. In some instances a dispute may arise between an initial physician, chosen by an employer, and a second physician, chosen by the employee, as to the appropriateness of removing or returning a particular worker. Pending the outcome of the standard's physician review mechanism, the standard provides that an employer may act in a manner consistent with the medical findings, opinions or recommendations of any of the physicians who have examined the employee, with two exceptions. First, if an employee was removed or limited as a result of a final medical determination, the employee's normal job. Alternatively, the worker might work shorter hours in his or her current job or in a non-lead-related facility. OSHA's intention is that the choice between these or other alternatives be a prerogative of the employer unless this flexibility is abridged by specific work limitation obligations. A removed worker is provided no automatic right to veto an employer's choice which meets the standard, but similarly, the standard provides no right for an employer to simply override existing contractual commitments to either removed employees or to other employees.

Arguments have been made that MRP may create conflicts with existing collective bargaining relationships. To the extent conflicts exist, they should be easily resolved during the lengthy phase-in period for MRP. Worker transfer programs with economic protection have had longterm use throughout industry in a variety of contexts. These many programs have apparently melded quite well with collective bargaining relationships, and there is no evidence which suggests that the implementation of MRP will proceed any differently.
12. Definition of MRP benefits. The standard requires an employer to provide MRP benefits to a worker on each occasion that the employer refuses to permit return from exposure to lead or otherwise limit. This requirement is defined as meaning that the employer must maintain the earnings, seniority and other employment rights and benefits of a worker, the worker being not been removed or otherwise limited. In most cases this will simply mean that an employer must maintain the rate of pay of a worker transferred to a low-lead-exposure job. The standard, however, uses the all-encompassing phrase “earnings, seniority and other employment rights and benefits” to assure that a removed worker suffers neither economic loss nor loss of employment opportunities due to the removal. The standard explicitly requires that an employer maintain the seniority of a removed worker due to the crucial role that seniority rights might play in defining a worker’s economic benefits. In addition, the standard by implication rejects industry suggestions that the provision of MRP benefits should be contingent upon the employer’s ability to locate an available transfer position. Such an available position precondition would end MRP’s role as a means of effectuating meaningful participation in medical surveillance. 

13. Duration of MRP benefits. The standard requires that up to 18 months of MRP benefits be provided to a worker on each occasion that he or she is removed from exposure to lead. The prime determinant of this figure is the rate at which workers will naturally excrete lead once removed from significant exposure. The vast majority of removals will be of shorter duration than 18 months, but some longterm leadworkers will likely require 18 months of removal.

14. Employees whose blood lead levels do not adequately decline within 18 months of removal. The standard establishes special procedures to apply in those rare situations where an employee’s blood lead level has not adequately declined during 18 months of removal. A medical examination must be made available to obtain a final medical determination as to whether or not the worker may be returned to his or her former job status. In some situations, continued removal may serve no major purpose since the damage done to the worker’s body is beyond the point of correction. In this event a physician might permit return of the worker to his or her former job status provided the worker’s blood lead level remains fairly constant. In other situations a physician might recommend several additional months of removal where a worker’s blood lead level is continuing to decline toward an acceptable level. In rare situations a physician might determine after 18 months that the worker’s blood lead level is so high that the worker will never be able to safely return to prior exposure. All of the preceding situations can best be evaluated and resolved by a final medical determination obtained pursuant to the standard.

Where the worker may not yet be returned to his or her former job status, the employer must provide MRP benefits until either the worker 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. The standard also provides that if a final medical determination returns a worker to his or her former job status despite what would otherwise be an unacceptable blood lead level, then any subsequent questions concerning removing the worker again shall be decided solely by a final medical determination. Automatic temporary medical removal due to an elevated blood lead level is no longer afforded to such a worker.

15. Follow-up medical surveillance during the period of employee removal or limitation. The standard provides that during the period of time that an employee is removed from exposure to lead or otherwise limited, the employer may condition the provision of MRP benefits upon the employee’s participation in reasonable follow-up medical surveillance. The standard does not mandate worker participation in follow-up medical surveillance, but rather permits the denial of economic protection to those unwilling to participate in procedures necessary for MRP’s smooth operation.

16. MRP and workers’ compensation claims. In rare situations, a removed worker might be eligible for temporary partial or total disability workers’ compensation payments for lost wages. Existing industry practices and the standard itself have provided the basis for prompt and effective responsive to these situations. If a removed worker files a claim for workers’ compensation payments for a lead-related disability, and an award is made to the worker for earnings lost during the period of removal, then the employer’s MRP benefits obligation is reduced by that amount. MRP benefits must be provided pending disposition of any filed claim subject to a credit or payback once an award is finally made.

17. Other credits. An employer should not have to provide MRP benefits which duplicate compensation which a removed worker is receiving from other sources for earnings lost during the period of removal. Accordingly, the standard explicitly provides that the employer’s obligation to provide MRP benefits to a removed worker shall be reduced to the extent that the employer receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or from employment with another employer made possible by virtue of the removal.

18. Voluntary removal or limitation of an employee. A final element of the standard with respect to MRP provides that where an employer, although not required 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 an employee’s medical condition, the employer shall provide MRP benefits to the employee. The purpose of this requirement is to avoid the possibility that some employers will attempt to evade the MRP program by voluntarily removing workers (without economic protection) shortly before the standard would mandate removal.

19. Legal authority for MRP. The Occupational Safety and Health Act contains ample legal authority for the adoption of MRP as a preventive health mechanism. OSHA’s legal authority to adopt MRP was perhaps the greatest source of controversy during the lead proceeding, with Industry representatives uniformly arguing that no legal authority for MRP exists. It is true that the Occupational Safety and Health Act contains no language which either explicitly requires or expressly authorizes the inclusion of MRP in OSHA health standards. The legislative history of the Act reveals no evidence that Congress gave any consideration to the appropriateness of MRP as a protective health mechanism. Though these factors are important, they are by no means dispositive of the legal authority. The Act does not constitute a rigid congressional codification of the only permissible devices OSHA can employ to reduce occupational injury and disease. Rather, the structure and specifics of the Act reflect the congressional decision to create an expert administrative agency with broad regulatory powers to fashion reasonable protective regulations concerning occupational injury and disease in light of agency experience and expertise. The legal authority issue depends on the purposes to be served by MRP, the extent to which MRP is reasonable response to a genuine problem, and the extent to which MRP is consistent with the Act’s grants of and limitations on rulemaking authority by OSHA.

As previously explained, MRP is a protective, preventive health mechanism carefully structured to (1) maximaze...
mize meaningful participation in the standard's medical surveillance program, (2) facilitate the use of temporary medical and (3) primarily allocate the costs of temporary medical removals. These functions are all directly related to the Act's purpose articulated in section 2(b) "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions * * *." MRP responds to genuine occupational health problems and substantially adds to the level of overall worker protection afforded by the final rule.

MRP flows directly from and is fully consistent with the Act's express language. Section 6(b) authorizes broad OSHA discretion in the promulgation of each occupational health standard, defined by section 6(b)(3) as a "standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." MRP meets this definition, and further satisfies the dictate of section 6(b)(5) that healthful working conditions be based on "experience gained under the Act and the laws." MRP is also a regulatory device which addresses the Congressional directive in section 2(b)(5) that healthful working conditions be provided "by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems." OSHA's adoption of MRP is a direct result of the proven value of this protective mechanism, and by adopting MRP, OSHA is following the Congressional mandate in section 2(b)(4) that worker health be provided "by building upon advances already made through employer and employee initiative for providing safe and healthful working conditions." MRP is needed to meet section 6(b)(5)'s requirement that health standards be made to protect all workers over entire working lifetimes because without temporary medical removals, it is doubtful that compliance with the remainder of the lead standard could achieve this mandated level of protection. MRP is also needed to achieve the benefits of medical surveillance envisioned by section 6(b)(7), and section 8(b)(2)'s grant of general rulemaking authority provides additional support for MRP's adoption. The preceding statutory provisions demonstrate that Congress intended OSHA to have broad flexibility in mandating remedial measures, and that MRP resides well within the scope of the flexibility Congress afforded.

The legal sufficiency of MRP's adoption is strengthened by comparable medical removal and economic provisions contained in the Federal Coal Mine Health and Safety Act of 1969, amended by the Federal Mine Safety and Health Amendments Act of 1977. MRP was proposed during the passage of the OSH Act, but this is hardly surprising in view of the Act's expansive coverage of practically every industry in the country. Congress promulgated a regulatory framework without attempting to identify and respond to individual problems of specific industries. The 1969 Coal Act, however, represents the culmination of decades of intense Congressional mandate in section 101 is expressed in various instances where Congress has considered the appropriateness of MRP in an occupational safety and health statute, Congress has tended to one of several possible health and safety regulations as detailed in any existing OSHA standard. In the context of its comprehensive review of coal mining, Congress considered the appropriateness of an OMR-type program with regard to coal mine workers pneumoconiosis. Congress responded by authorizing the adoption of MRP in this context to explicitly mandate the adoption of a MRP program. Authorization to adopt MRP with regard to other forms of mining was provided by Congress in 1977 as a response to the Coal Act. Thus, in both of the instances where Congress has considered the appropriateness of MRP in an occupational safety and health statute, Congress has tended to one of several possible health and safety regulations as detailed in any existing OSHA standard. This clear Congressional approval of MRP programs is indicative of how Congress likely would have acted had MRP been considered during passage of the Occupational Safety and Health Act.

Contrary to various suggested arguments, MRP does not violate section 4(b)(4)'s mandate that health standards not act "to supersede or in any manner affect any provisions of Federal, State, or Tribal law." MRP is intended to provide an interim exposure limit of 100 μg/m³ to industry during the passage of the OSH Act, but this is hardly surprising in view of the Act's expansive coverage of practically every industry in the country. Congress responded by authorizing the adoption of MRP in this context to explicitly mandate the adoption of a MRP program. Authorization to adopt MRP with regard to other forms of mining was provided by Congress in 1977 as a response to the Coal Act. Thus, in both of the instances where Congress has considered the appropriateness of MRP in an occupational safety and health statute, Congress has tended to one of several possible health and safety regulations as detailed in any existing OSHA standard. This clear Congressional approval of MRP programs is indicative of how Congress likely would have acted had MRP been considered during passage of the Occupational Safety and Health Act.

In setting standards for toxic substances, the Secretary is required to give due regard to the question of feasibility. Section 6(b)(5) of the Act mandates that the Secretary shall set the standard which "adequately assures employees' safety and health * * * to the extent feasible, on the basis of the best available evidence." Additionally, in the development of occupational safety and health standards, "considerations shall be given to all of the factors that are relevant to the safety and health of employees including the latest available scientific data in the field and experience gained under this and other health and safety laws."

OSHA has developed a rulemaking record which has enabled OSHA to promulgate a final lead standard which can confidently be considered "to the extent feasible, on the basis of the best available evidence." Additionally, in the development of occupational safety and health standards, "considerations shall be given to all of the factors that are relevant to the safety and health of employees including the latest available scientific data in the field and experience gained under this and other health and safety laws."

In setting standards for toxic substances, the Secretary is required to give due regard to the question of feasibility. Section 6(b)(5) of the Act mandates that the Secretary shall set the standard which "adequately assures employees' safety and health * * * to the extent feasible, on the basis of the best available evidence." Additionally, in the development of occupational safety and health standards, "considerations shall be given to all of the factors that are relevant to the safety and health of employees including the latest available scientific data in the field and experience gained under this and other health and safety laws."

The rulemaking record is comprised of studies and assessments of technological feasibility, cost data on various items of compliance, and economic impact assessments from the public participants as well as OSHA consultants. Most of the evidence assessed the feasibility of compliance with the proposed 100 μg/m³ standard although various alternatives received attention. On the basis of this information, OSHA has constructed a compliance scheme designed to provide optimal protection to workers, to allow for necessary technological change, and to...
encourage long run, cost-effective solutions to compliance problems.

In establishing the requirements of this standard, OSHA has identified affected industries and investigated potential compliance methods including the available technology in those industries. It has attempted to estimate the time necessary to implement the technology required, taking into account firms' need to plan, construct, test, and refine their efforts.

The implementation schedule also takes economic factors into account in that it incorporates time periods which OSHA expects will enable firms in each industry to comply with the standard without serious economic repercussions to the industry as a whole. Where specific costs of compliance could be assessed they are presented in the industry summaries.

1. Technological considerations. In general, inquiry into technological feasibility is only relevant to compliance with the exposure limits in the standard. It is clear that compliance with the 50 \( \mu g/m^3 \) PEL will be immediately feasible insofar as the standard permits respirators to be used where the exposure is above this level. The primary issue is whether the PEL and interim level can be achieved in the time set forth in the implementation schedule solely by engineering and work practices. OSHA has concluded that compliance in this manner is possible through the use of presently available process and control technology or foreseeable technological developments.

Testimony and comments from most of the engineers and industrial hygienists in addition to OSHA's past experience with other standards for toxic substances has led OSHA to conclude that rigorous and innovative application of known, conventional techniques for isolating workers from the sources of exposure to toxic substances will, in almost all cases, enable employers to comply with the standard. Compliance in this manner is predicted to be completed in 1 to 5 years depending upon the complexity and extent of change required.

In some cases where accurate identification of exposure sources is difficult or where conventional control techniques are ineffective, reliance on new technology (e.g., new types of control or process equipment or alterations to the production process itself) may be necessary.

OSHA has attempted to be sensitive to the complexities and various aspects of the process of technological change in its attempt to incorporate new technology into its compliance scheme for this standard. This has facilitated prediction of the kinds of technology likely to arise in response to the standard and the time period within which they might be expected, thus allowing OSHA to know, in general terms, what is feasible. It has also suggested different options as alternatives in designing the standard so as to achieve optimal compliance strategies in terms of protective capability and compliance cost.

The following is a summary of the discussion of the technological factors considered in the major industries affected by the standard. Attachment D to the preamble (feasibility) contains a full discussion of these factors including a process-by-process analysis of the problems raised and the range of possible technical solutions to those problems in the most impacted industries.

a. Primary smelting and refining. The primary lead industry ranks fifth (after iron, aluminum, copper, and zinc) in tonnage of metals produced in this country. Four companies—ASARCO, St. Joe Minerals, Amax and Bunker Hill—own the seven facilities that smelt and refine primary lead. Western smelters date from the early part of this century; smelters for the Missouri lead belt were built during the 1900's. An estimated 3,055 employees in the primary smelting sector are exposed to lead. (Ex. 26, p. 5-3.)

Primary smelting involves three basic steps—sintering, smelting, and refining. In sintering, a concentrate of galena ore (PbS) is mixed with fluxes and roasted to drive off sulfur dioxide. This operation produces a "sinter," a mixture of lead, lead oxide, and slag, which is smelted by a blast furnace at temperatures above 2,000° F. The blast furnace reduces the constituents of the charge (coke, fluxes, and recycled slag sinter) into molten lead and slag. Fifteen ton ladles on overhead bridge cranes transport the molten lead to open drossing kettles about 14 feet in diameter. These kettles rest in firebrick settings that keep the lead at the temperatures needed (700° to 1,200° F.) for drossing. During drossing, the molten lead from the blast furnace is stirred, and the impurities (dross) are skimmed. The impurities in lead ores vary. Colorado ore, unlike Missouri ore, has a high copper content. The lead is further refined through a soft roast of molten lead. Pyrometallurgy (the extraction of metal from ores by heat) requires extreme heat at variable temperatures, control of emissions in primary smelting has been difficult. For example, material that splashes or drips during transfer of molten lead collects and freezes at the rim and pouring lip of the ladle. These thick, lumpy accretions can interfere with a tight fit between hood and vessels. Ore with significant amounts of copper produces copper matte, which corrodes iron, steel, and most steel alloys. Further, the corrosive properties of the molten metal has prompted the use of open vessels and crude mechanichal methods. The nature and scale of primary smelting have made the application of standard engineering techniques difficult. While some problems are difficult, the hearing record indicates that, with new techniques and methods, they are surmountable.

After reviewing the record, OSHA has concluded that in all operations except perhaps maintenance work and where process upsets occur, the 100 \( \mu g/m^3 \) level is feasible within the 3-year time period in the implementation schedule through retrofitting and modification of existing processes. This conclusion is not in agreement with the conclusions of DBA and lead industry representatives. (Ex. 365, pp. 122-123.) After reviewing all the exhibits and testimony, OSHA is convinced that the reason for this disagreement is not so much a matter of differing professional judgment in what could be achieved, but in the interpretation of the term "feasibility." Industry representatives and DBA's claims of insurmountability of the 100 \( \mu g/m^3 \) level (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that for an exposure level to be feasible it must be attainable immediately and, in all operations, the PEL (and even the present 200 \( \mu g/m^3 \) standard) are, in part, based on the view that
possibly including alternatives to pyrometallurgy. OSHA believes that the 10 years provided in the implementation schedule represent reasonable flexibility for compliance by an industry which may need to rebuild in part or in whole to achieve a healthful workplace.

Hydrometallurgical production methods are likely to be commercially viable within the 10-year limit; however, less comprehensive forms of process redesign and/or adaptation of developmental projects discussed in the fessic hearing to put on specific operations may prove to be sufficient. (Tr. 1453.)

Witnesses at the hearing were optimistic about the development of new processes for primary smelting. Knowlton Caplan, president of IHE, while skeptical about the current technological feasibility of a 100 pg/m^3 standard, expressed faith in the future development of "more effective and less costly engineering systems." (Tr. 5723)

Frank Block, research director at the Reno Metallurgy Research Center for the Bureau of Mines, described one such potential development, a hydrometallurgical method for recovering lead from galena concentrate. (Ex. 128; Tr. 3386-34-17.) This process does not involve any sintering or smelting and may require no refining. It leaches galena concentrate in a hot solution of ferric nitrate to put on lead chloride, which, in turn, is electrolyzed to produce metallic lead. The new process generates no sulfur dioxide. It would be more economical than current techniques and could operate at smaller capacity. It could also be used with Missouri or Western concentrates.

b. Secondary smelting and refining. Secondary smelters produce much of the lead used in the United States. The industry, however, is poorly defined. The estimated number of smelters, for example, has ranged from 40 to 140. (Ex. 1308; p. 1). Secondary smelters recycle lead from discarded batteries and other waste materials. This recycling involves two phases: smelting of the old material to recover crude lead and, in some operations, refining of the crude lead to produce pure lead and alloys for use.

Secondary lead smelting plants take scrap lead material from many sources, but the majority (61 percent) comes from scrapped lead-acid batteries. Lead cable covers, linotype, and recovered fume and drosses are other major sources. Some scrap is reduced to remove lead from other materials. Battery plates and terminals, for example, are mechanically separated, and lead-copper cables are heated to melt off the lead. Materials containing lead oxide may be processed through a blast furnace to reduce the proportion of oxide to lead metal. Lead from the blast furnace and scrap containing lead metal may be melted in refining kettles and treated by dressing to remove copper and other impurities.

Following the dressing, the lead may be "softer" by removing antimony that has been previously added to give the lead hardness and strength. This removal is done by air oxidation in a reverberatory furnace or by oxidative slagging with sodium dioxide or sodium nitrate fluxes. Once the lead has been refined to a desired composition, it is cast into various shapes or fabricated into wires, pipes, sheets, or solders. (Ex. 26, p. 5-29.)

Approximately 4,400 workers in the United States work in secondary smelting facilities. (Ex. 26, p. 2-13) Exposure levels vary among different operations, with the highest occurring in blast furnace areas. DBA analyzed OSHA compliance data and found that prior to August 1976, 83 of 171 air lead samples exceeded 200 pg/m^3. Data after this date showed 102 of 129 air lead levels above 100 pg/m^3 and 87 of 129 above 200 pg/m^3. (Ex. 26, pp. 2-17, 2-18.)

The rulemaking record contains uncontroverted evidence that exposures in secondary smelting operations can be controlled below the 100 pg/m^3 interim level. Based upon its study of seven representative smelters, Dr. David Smith analyzed OSHA data that compliance by secondary smelters with a standard of 100 pg/m^3 is technologically feasible. (Tr. 798) One company, Keystone Resources, which operates five secondary smelters across the country commented "We feel that our controls are such that we feel we could also meet the action level (50 pg/m^3) specification" (Ex. 3(39)). Before the implementation of engineering controls, average air lead at Keystone Resources was 1,036 pg/m^3. The controls reduced the average to 126 pg/m^3. (Ex. 452, p. A-137) The results of a recent OSHA inspection at another secondary smelter indicate that it is presently in compliance with the 100 pg/m^3 level. (Ex. 26, p. 5-38; Tr. 956.)

Attaining these levels, however, may be in a few instances require extensive modifications of current processes. IBE, in a study for the Lead Industries Association, analyzed one plant in detail and concluded that conventional engineering techniques alone could not control battery breaking or scrap and slag handling to 100 pg/m^3 airborne lead. (Ex. 156D, p. 8) DBA doubted that manual battery breaking, slag and scrap handling, and some maintenance operations could be controlled without process redesign. (Ex. 26, p. 5-29.)

The rulemaking record describes new approaches that may be necessary to comply with the PEL. Michael Varner, corporate manager for ASARCO's Department of Environmental Sciences, and Melvin First, a professor of environmental health engineering at Harvard, discussed the possibility of innovations in dressing, such as continuous vacuum dressing. (Tr. 2387-80; Tr. 5142-5203.) Svend Bergsoe, president of Paul Bergsoe and Son of Glostrup, Denmark, described in detail his new technique for smelting scrap lead products. (Tr. 5142-5203.) His process eliminates one of the hardest to control processes, battery breaking, by using a new type of furnace that not only digests the entire battery, but also use the battery cases to supply 50 to 80 percent of the fuel required to run the furnace. (Tr. 5184.) In addition a flash furnace agglomerates the flue dust, and the process is entirely enclosed.

With the possible exceptions of installing afterburner and agglomerator systems on existing furnaces (Tr. 5177, 5192), the Bergsoe process would require construction of an entirely new smelting plant, estimated to cost $2.5 million for a 20,000-ton-per-year production, and would take 2 years for construction. (Tr. 5185.) It includes the scrap handling facility (Tr. 5199), furnace, afterburner, baghouse, refinery, and even canteen and washing facilities.

c. Battery manufacturing. The battery industry is the largest single user of lead in the United States. The industry produces both SLI (starting, lighting, ignition) batteries and industrial batteries, although the latter accounts for only 7 percent of the industry's production. 136 firms operate 200 plants, which vary tremendously in size and capacity. On one hand, the seven largest firms operate nearly 70 plants and account of over 90 percent of the batteries sold. On the other, 95 battery plants employ fewer than 20 people. Of the 16,000 persons employed by the industry, approximately 12,800, or 77 percent, are exposed to lead. (Ex. 26 p., 5-42.)

Manufacture of batteries begins with production of lead oxide, either by the Barton process, which oxidizes lead in the molten state, or more often, by the ball mill process, in which frictional heat generated by tumbling lead pigs or balls produces lead oxide. Lead oxide powder is mixed into a paste and pressed onto grids cast from lead. The pasted plates are cured, stacked by hand or machine, and connected with molten lead ('tubing') into groupings to form the individual cells of a battery.

All these processes, especially loading and unloading at each step, generate contamination. The racks that carry the pasted plates from one operation to another are additional sources
The record indicates that in the battery industry available methods can control employee air levels of lead below 50 μg/m³, as an 8-hour TWA, for all major processes. Indeed, more than 40 percent of employees exposed to lead in this industry may already have TWA exposures of less than 50 μg/m³. (Ex. 26, p. 5-45.)

Meier Schneider, an experienced industrial hygiene engineer testified that “with proper engineering control coupled with good maintenance and good work practices, proper design of process to minimize emissions, and education of workers and good hygiene that we can, today, achieve levels in the work area atmosphere of less than 50 μg/m³. (TR. 2065-2066). In his study of 17 plants, Bill Thomas of CAL-Osha concluded that “the general use of respirators should not be needed if a well-designed and managed lead storage battery plant.” (Ex. 101A) Similarly, Caplan, testifying on a detailed study of 12 plants IHE did for the Battery Council International ("BCI"), concluded that “technically, if all the things that we recommend were done and well done, it is our opinion that we would be able to control to 100.”

It is OSHA’s judgment that these systems proposed by IHE, combined with good work practices and administrative controls will be effective to control exposure below the PEL, primarily because they provide total control of the process and minimize the opportunity for fugitive emissions. As Dr. First stated, “The application of good control methods almost always results in air concentrations far lower than the standard for which they were designed.” (Ex. 276, p. 19.)

IHE’s specifications are designed primarily for larger operations. They assume that production is continuous and that operators remain at each work operation for a full shift, assumptions that do not hold for small plants. Thus, the engineering controls designed by IHE will be effective but may not be appropriate for small plants. The record suggests that less complex controls may be feasible and effective for small plants. Good housekeeping appears especially important. Both Meier Schneider and Albert Stewart, an industrial hygienist who formerly conducted lead inspections for OSHA, testified that control costs might be held down by approaching problems on a case-by-case basis and by emphasizing the use of good housekeeping and techniques for handling materials along with imaginative engineering to minimize the need for ventilation. (Tr. 2057-2077.) Dr. Mirer, the UAW’s industrial hygienist, noted that of 30 plants surveyed by the UAW, the one with the lowest lead exposures had only nine workers. (Tr. 106.)

Testimony of small battery plants also stressed good housekeeping and work practices. For example, Don Hull, president of Dynolite Corp., a plant that employs fewer than 20 people, testified that he gives priority to housekeeping and personal hygiene. (Tr. 1246; see also Tr. 3561.) When OSHA took a series of readings in his plant at the stations for grid casting, stacking, element assembly, battery assembly, and battery filling, only one reading at one location, element stacking, exceeded 100 μg/m³, and its was just slightly over, 110 μg/m³. (Tr. 1247-48.)

Some operations with high exposures are done only intermittently in small plants. Small battery plants, for example, may paste plates only once or twice a week. (Tr. 3465; Tr. 1259) To meet the PEL as an 8-hour time weighted average may not be practical. Employees in small plants do not work exclusively at one station. As Stuart Manix of Lancaster Battery Co. explained, “most people try to do a little bit of everything.” (Tr. 3465.) Thus, rotation of employees to positions with higher exposures for less than 8 hours per shift may also reduce 8 hour TWA averages. That is, four employees could each work 2 hours pasting plates.

New approaches may also offer small plants an alternative to IHE’s engineering controls. Two firms, APSSE, Inc., and Kermatrol, Inc., testified that they could provide the technology for compliance at sharply reduced cost. (Tr. 2801.)

The new approaches might aid large as well as small plants in meeting the 50 μg/m³ standard. Some operations in either large or small plants will quickly be able to achieve the 50 μg/m³ standard. The UAW asserted that aggressive implementation of such conventional control techniques as enclosure, ventilation, and process redesign can achieve the 50 μg/m³ level. (Tr. 5278.) At the same time, the UAW recognized that, until innovative processes are introduced, some operations will require respirators as well as ventilation to meet the 50 μg/m³ standard. (Tr. 5053.)

Brass and bronze foundries. The load content of copper based alloys, i.e. brass and bronze, may amount to as much as 20 percent by weight of the metal core. (Tr. 2786) The load content of copper based ingots average 5 percent. (Ex. 26, p. 5-73.) Over 1820 foundries cast brass and bronze at least occasionally; in approximately 770 foundries brass and bronze are the primary raw materials. Most of these foundries are small, 75 percent employing fewer than 50 people. Although small, most of these foundries make a diverse range of products of varying price, size, and composition. (Ex. 26, p. 5-73.) An estimated 26,000 employees are exposed. Exposure to airborne lead results from insufficient control of fumes from the melting or pouring of alloys. In copper-base alloy foundries, approximately 15 percent of the particulate matter in furnace stack gases from the melting of red and yellow brass is lead oxide, and up to 50 percent of the particulate matter has been shown to be lead oxide when the alloy has a high lead content. Any attempt to reduce the fugitive emissions from baghouse dust collectors may be subject to inhalation of lead containing fumes. New approaches to the control of fugitive emissions may also include areas where castings are cut or finished and areas where scrap is received or stored. Levels of exposure are highly variable and depend on the amount of general and local ventilation, the lead content of the alloy, the type of furnace, and the quality of housekeeping procedures. (Ex. 26, pp. 5-73, 5-75.)

The hearing record indicates that brass and bronze foundries can achieve an exposure level of 100 μg/m³ within one year. DBA concluded that feasible engineering controls are available to met this level. (Ex. 26, p. 5-73, Tr. 800.) They pointed out that most plants did not use baghouses and the majority do not even provide local make-up air. Gary Mosher, representing the American Foundrymen’s Society, explained that “exhaust systems have been devised and designed that will close capture 95% of fumes right at the ladle and the furnace.” He further testified that such methods are effective in bringing exposure below 200 μg/m³, but did not express an opinion as to whether such techniques are effective in bringing exposures below 100 μg/m³. (Tr. 2861.)

OSHA, however, has concluded that conventional technology in the industry has been shown effective for lowering exposures from melting and pouring to 100 μg/m³. Refinement and development of these technological changes should permit, over time, compliance with the PEL. Examples of these controls include: 1) The adoption of electrical induction furnaces
with local exhaust ventilation installed during the initial furnace installation; (2) covered ladles; (3) segregated melted; (4) use of the Hayle Trav-L-Vent; and (5) increased use of dilution and directional ventilation during pouring. Compliance will, of course, also require comprehensive housekeeping, maintenance employee training, work practices, and personal hygiene. Further, administrative controls such as worker rotation may prove effective in reducing exposures in many small firms.

c. Pigment manufacturing. Of the 114 plants that manufacture pigments in the United States, approximately 25 produce pigments containing lead. Pigment products include red lead (or, litharge), lead sulfates, lead carbonates, lead silicates, lead oxides and lead chromates. Inorganic pigments are a prime component in surface coatings and important components in other products such as inks, paints, rubber and plastics, inks, ceramics, and paper coatings. Litharge is used principally in the manufacture of products other than paint, i.e., ceramic glazes, batteries, glasses, and vitreous enamels.(2) The number of production employees in lead pigment manufacturing is estimated to be 2,000. DBA's survey of several plants indicated that 90 percent of the workers were exposed to levels of lead above 100 \( \mu g/m^3 \). (Ex. 26, p. 5-95.) The manufacture of pigments involves a number of different processes. Only pulverizing and grinding processes for reducing the particle size are common to all members in the class. Inorganic pigment manufacturing is a combination of chemical-physical processes involving both wet and dry reactions, including precipitation, filtering, washing, fusing, calcining, etc. The process carried out over a batch system, as continuous production, or as a combination of the two.

Pig lead is often the basic raw material in inorganic lead pigment. Litharge and other lead forms, however, are sometimes used. Because litharge is a powder, it presents the potential for lead exposures at every transfer point. Filtering, drying, grinding, sizing, grading, blending, and bagging are all considered to be areas of potential exposure to lead. Cross contamination between operations also occurs.

Most pigment plants are older. All but five plants visited by DBA were at least 50 years old. One plant was said to be 129 years old. (Ex. 26, p. 5-95.) Because of the age of the facilities, retrofitting may not achieve levels below 100 \( \mu g/m^3 \), although such methods have reduced air-levels to 200 \( \mu g/m^3 \). However, redesign of the process, including "total enclosure of certain steps and/or automation" is expected to be able to reduce levels to a 100 \( \mu g/m^3 \) level. (Ex. 26, p. 5-98.) The same conclusion applies to the 50 \( \mu g/m^3 \) PEL. As Dr. First explained, "every operation that can be mechanized and automated is capable of being enclosed by tight physical barri der s and placed under slight negative pressure to prevent outleakage of dust or fume-laden air to the workroom." (Ex. 270, pp. 29-30.) While such technology may require time and money to install, it is available and adaptable to the pigment industry.

Using substitutes for lead pigments, such as organic pigments, would eliminate exposures. While substitutes may not exhibit all the properties of lead, such as resistance to corrosion and weathering, they would nonetheless be adequate in many cases. Such substitution would also reduce or eliminate exposures in all the industries that involve lead pigment—wallpaper manufacturing, glove manufacturing, pottery manufacturing, ink manufacturing, paint manufacturing, shipbuilding, and automobile manufacturing.

1. Other industries. For the 11 other industries that were discussed in the DBA report or its supplement (Ex. 65- 67), technological considerations are detailed in the attachment. OSHA found the PEL to be generally feasible within 1 year from the effective date by use of engineering and administrative controls. For a few operations, particularly in the shipbuilding and automotive manufacturing industries, airline hoods or other supplementary personal protective equipment may be necessary on a periodic basis.

Other industries were assessed for technological feasibility in the Short report, (Ex. 22). They were generally found to have very low lead exposure and any compliance activities will only require very simple engineering controls.

2. Economic considerations. OSHA has attempted to determine, for all affected industries, the costs of compliance of the final standard and to assess the economic impacts in terms of plant closures, industry competition, product prices, employment, and other economic factors. In many respects accurate and reliable cost estimates were difficult to determine for several reasons. OSHA and industry consultants who performed economic impact analyses found it difficult to avoid the "double counting" of costs. Almost all of the information came from the regulated industries unverified by objective sources, and financial data, necessary to analyze the impacts, were not made available by the affected firms.

In attachment D to the preamble, OSHA has made a detailed examination of the cost estimates of its constructor (DBA) and those of the principal industry consultants (CRA). Differences in estimates are discussed and reconciled wherever possible. In several instances, OSHA has reduced the estimates where obvious methodological errors required that such revisions be made. It should be noted that both of these studies attempted only to assess the cost of reducing exposures, by means of retrofit technology, from current levels to the proposed 100 \( \mu g/m^3 \) standard.

OSHA has concluded that the record contained adequate cost information for most industries. In addition, review of the record revealed that compliance with the PEL will be below 100 \( \mu g/m^3 \). Further, in several industries, require extensive technological development for which long periods of implementation time would be required, thus precluding meaningful quantification on the cost. However, the record was sufficient to predict that compliance within the times given would not result in undue economic hardship on those industries. This impact analysis is based on the record evidence concerning the financial and technical resources available to the various industries, the certainty of product and factor (production inputs) markets, and the availability of most cost-effective alternative methods of compliance.

The implementation schedule, itself, represents a merging of both economic and technological factors used to evaluate feasibility. Firms can choose from an array of technical solutions over a time frame allowing the long-run economic optimization. Since all firms in each industry face the identical PEL and time constraints, the process of the internalization of the cost of compliance acts on the decision-making process of the firm and the industry in the same manner as any other market signal. Depending on how firms judge a number of long-run factors including product demand, amount of investment sunk in the existing physical plant and managerial expertise, and alternative rates of return available on the necessary capital, some firms may choose to exit the market and invest in alternative ventures. Of course, other firms with different long-run expectations may choose to enter the market.

A brief review of the major affected industries follows:

a. Primary smelting and refining. In all operations, except maintenance and maintenance work and where process upsets occur, compliance with the 100 \( \mu g/m^3 \) level by engineering controls and work practices is feasible within the 3 year implementation period through the use of conventional control techniques as well as some modification of existing processes. Attainment of the PEL may require the development and im-
implementation of substantial technological change, possibly including alternatives to pyrometallurgy which are now considered only in experimental stages. Ten years for this goal is considered by OSHA to be sufficient to encourage commercially viable technological solutions for this industry.

Given the earlier discussion about the unreliability of cost estimates, OSHA has determined that the capital expenditure to meet the 100 µg/m³ interim level is in a range between $32 million and $47 million (in 1976 dollars). The total annualized cost at the 100 µg/m³ level is estimated to range between $11,927 and $15,641 million. After-tax cost, figured on the corporate rate of 48 percent, should then be between $8.202 and $8.133 million. Based on total 1976 industry production, this would be equivalent to $0.004 to $0.006 per pound. OSHA has reached the following conclusions regarding economic impact in this industry:

1. The primary smelting companies will probably be able to raise the price of refined lead as much as 1¢ per pound in order to pass compliance costs to consumers of its product. This increase will be passed forward to consumers in the incremental costs of meeting the 100 µg/m³ interim level. DBA and CRA concluded that it would not be possible for firms to increase the price of lead. CRA attributes this to the high elasticity of foreign supply (Ex. 127, pp. 2-51 to 2-56), and DBA concludes that high elasticity of the demand for lead will have the same effect (Ex. 26, p. 6-28). CRA's and DBA's conclusion is somewhat doubtful for several reasons. First, given OSHA's revision of estimated costs to the industry, the necessary price increase would be smaller than predicted by CRA and DBA. Second, the demand for lead in the long run, in the event that the 100 µg/m³ price increase, and possibly inelastic in the short run, thereby allowing a short-run price increase, and possibly inelastic in the long run if one or more of several possible factors materialize. At least one major producer, Amax, is confident that the industry will be able to absorb the costs of the standard "without adding to the price of our final product which in turn will have to be passed on to the consumer." (Ex. 3(67), p. 5.)

2. Compliance costs can, in part, be shifted backward to suppliers of ore. CRA concluded that costs could be shifted, in part, backward onto suppliers through a reduction in the price paid for ores and concentrates (Ex. 127, Exec. Summ., pp. 8-10). DBA did not evaluate backward shifting of costs. The extent to which this could be accomplished minimizes the cost impact on the primary producers. OSHA has concluded that the limits on the backward shifting of costs are not as severe as indicated in the CRA analysis. The increasing price of lead has improved the marginal conditions of several mines by CRA. Further, the incentive to ship abroad that the costs of the standard "would certainly add to the price of our final product which in turn will have to be passed on to the consumer." (Ex. 3(67), p. 5.)

3. The demand for lead will probably be substantially price inelastic in the long run. CRA's studies over the past 10 years, Dr. Burrows' of CRA) repudiation of Helmeke's work (the basis of the DBA analysis), and OSHA's evaluation of Helmeke's conclusions supports this. Therefore, demand factors should not play a significant role in the industry's pricing decisions. With respect to supply, the factors affecting the long-run behavior of firms are numerous. The increasing cost of producing lead (absent new discoveries) may impact on foreign producers sufficiently in the short run to reduce the incentive to shift production to the U.S. Market. Foreign governments may follow the U.S. lead and compel similar environmental and occupational health constraints on their industry. Trade barriers or trade agreements limiting foreign imports may be adopted.

These factors affecting supply are highly speculative and no firm conclusions can be drawn other than that foreign supply is probably price inelastic in the short run, thereby allowing a short-run price increase, and possibly inelastic in the long run if one or more of several possible factors materialize.

4. If primary smelting firms were forced to absorb all the costs of compliance in the short run, they would nevertheless remain profitable and competitive. To the extent that increased costs cannot be passed back to suppliers or forward to consumers, the primary lead producers must absorb them internally, i.e., pay for them out of profits. From the record evidence as a whole, it appears that each of the affected firms can shift or absorb compliance costs of the interim level and remain profitable and competitive. Of all the primary producers, only Bunker Hill's profitability is in question and the cost impact should be such that OSHA costs alone would not threaten the company's economic viability.

OSHA's conclusions regarding Bunker Hill are misleading because its calculations are based upon cost estimates.
that are significantly overstated. The cost estimates it used for the Bunker Hill smelter showed the impact on Gulf Resources to be a reduction in the rate of return on total assets from 13.34 percent to 6.28 percent. (Ex. 26, p. 6-13.) This, however, is based on compliance costs at least double those which OSHA has determined to be reasonable. Similarly, the percentage decrements for the other firms, St. Joe (1.56 percent), ASARCO (1 percent), and Amax (0.3 percent) would be even smaller if adjustments were made using the revised cost estimates. The same is true in the percentage decrements predicted for value of the firms' common shares. The result is that DBA's conclusion that Bunker Hill would have to shoulder an inordinate compliance burden compared to the other firms is weakened. Gulf Resources' return on assets will decrease more than the other firms', but it will still have a rate higher than ASARCO and Amax.

The steelworkers asserted that each of the four firms could pay for all the capital improvements estimated by CRA out of 1976 profits alone. (Ex. 343, p. 172.) Their calculations showed that compliance costs as a percentage of 1976 profits were as follows:

<table>
<thead>
<tr>
<th>Company</th>
<th>Capital costs</th>
<th>Annual costs</th>
<th>Capital costs (percent)</th>
<th>Annual costs (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASARCO</td>
<td>45.6</td>
<td>12.3</td>
<td>45.6</td>
<td>12.3</td>
</tr>
<tr>
<td>Amax</td>
<td>5.4</td>
<td>1.7</td>
<td>5.4</td>
<td>1.7</td>
</tr>
<tr>
<td>St. Joe</td>
<td>15.1</td>
<td>4.5</td>
<td>15.1</td>
<td>4.5</td>
</tr>
<tr>
<td>Gulf</td>
<td>54.3</td>
<td>15.9</td>
<td>54.3</td>
<td>15.9</td>
</tr>
</tbody>
</table>

CRA evaluated each firm's profitability and their ability to shift costs back to suppliers of ore. They concluded that Bunker Hill, with the heaviest costs of compliance and little chance to shift cost back to suppliers, might prove unable to operate without capital resources to continue to operate. Initially, production at Bunker Hill is expected to increase (Ex. 343, p. 173), thereby lowering the cost per pound, but more important, the cost attributable to the OSHA standard is less than 1 cent per pound. (0.95 cent by CRA's calculations.) This is only 0.23 cent in excess of the 0.72 cent per pound that CRA estimates Bunker Hill can pass back to the mines under the best conditions. (Ex. 127, p. 2-73.) Under the worst conditions, the differences would be 0.8 cent (Ex. 127, p. 2-74.) The firm would have to absorb between $0.379 to $2.016 million in compliance costs.

Looking then at profitability, CRA concluded that if Bunker Hill was forced to absorb between $2.3 to $3.9 million, the consequences would be "severe." However, Bunker Hill's 1976 profit was $8.2 million. Its average profit between 1970 and 1975 was $10.646 million overall and about $5.528 million from lead operations. Absorbing costs of $0.579 to $2.016 million will cut into profits, but those costs are only 5 to 19 percent of the firm's average profits. This mitigates CRA's conclusion.

In fact, the division of the management of Gulf Resources on whether or not to make the investment required at Bunker Hill will be determined by its assessment of the long-run profitability of the industry. Profits in 1975 were reduced because of production restrictions related to air quality problems since alleviated. Also, as noted earlier, the price of lead is almost double its 1975 level.

The degree of concentration in primary refined lead production is already potentially high enough to assure the monopolistic result as a consequence of the mutually recognized interdependence of the four large producers. This could occur without the necessity of resorting to overtly collusive conduct.

That this result is not presently attained is due to forces being exerted from outside the primary lead segment of the market, viz., from secondary lead, refined lead imports, and the threat of entry. These forces would still be operating no matter what the degree of concentration in primary refined lead.

The compliance schedule for meeting the 50,000 pg/m² standard assures economic viability. The 10-year period set forth in the methods of compliance section is based primarily on technological factors. This time should be sufficient for firms to complete necessary capital planning. Any premature determination of the temporal level to be attained as a result of the standard would be premature. (Ex. 3(103), p. 5) or to construct new capacity.

This extended compliance period also assures economic viability of the PEL. Production efficiencies may arise from new processes, such as hydrometallurgy, sufficient to offset EPA and OSHA costs. Retrofit technology may be refined that will effect control at a lower cost. Such an event would take 2 to 3 years and may provide a more cost-effective alternative to present technology.

(b) Secondary smelting and refining. Compliance with the interim level in 3 years and PEL in 5 years appears feasible since extensive process modification is as well as refinement of recent technological developments may be necessary for some firms. In addition, the Bergsoe melting process, a cleaner, more fuel efficient smelting technology used for many years outside the United States, is available for either partial adaptation to existing facilities or total and the necessary facilities are built. Construction of new plants employing this technology would take 2 to 3 years and may provide a more cost-effective alternative to present technology.

Capital costs for compliance by means of retrofit controls with the interim level have been estimated to range from $34.1 to $51.1 million. Pretax annualized costs associated with these estimates are $10.9 million and $28.5 million, respectively. After taxes, the figures range from $9.8 to $14.8 million. The annual cost of the best estimate is equal to $0.013 per pound of 1975 production.

The cost of attaining the PEL of 50 pg/m² cannot be ascertained precisely because the industry faces several options for long-run compliance. However, an upper limit (the cost of completely rebuilding the industry with the latest available smelting technology) is determinable. To completely rebuild with the Bergsoe process would cost...
The battery industry is essentially an oligopolistic industry with a fringe of small independent producers who compete in regional or specialty markets. This means that the battery industry is somewhat more competitive than the lead industry. OSHA estimates the capital cost of achieving a PEL of 50 µg/m³ is likely to be in the range of $250.1 to $230 million excluding land costs. OSHA has concluded that compliance with the PEL will not be possible for all producers, particularly for the smaller producers. OSHA estimates that compliance will cost approximately $80.6 million excluding land costs. Following the implementation schedule for this industry is feasible through the use of conventional engineering and industrial hygiene techniques, although significant modifications may be required in the production processes. Cost estimates appear to be possible for small producers, including the use of employee rotation. OSHA estimates the capital cost of meeting the PEL for 100 plants to be in the range of $205.1 to $230 million with annualized costs of $25 to $28.1 million.

Thirty firms operating 100 plants will remain, and the capacity of the 5 largest firms, whose costs exceed the average, would increase a few percent. Competition from the smaller firms has little or no effect on the price of batteries, which is set by the major producers, except in those "interstices" of the market where they may choose to operate. OSHA has estimated that the average compliance cost will be $0.74 per battery, except for the five major producers, who will have compliance costs of about $0.74 per battery. Battery prices will increase as a result of the pass-through of compliance costs. The industry price setters, the five major producers, will have compliance costs of about $0.74 per battery. OSHA estimated that a cost passthrough of $0.74 will result in a retail price increase, due to markups in the distribution chain, of about $1.75 per battery. The small producers will be able to pass through some of the cost increases to the distributors and to the retailer. OSHA estimates that the net gain in employment, if production remains at the prestandard level, will be approximately 2,000 employees. Productivity, therefore, would decrease by just over 9 percent. OSHA's evaluation of the technological changes required to achieve the interim level of 100 µg/m³, although further refinement, additions, and modifications may be necessary. The compliance schedule requiring engineering controls and work practices to be used to reach 100 µg/m³ in 2 years and the PEL in 5 years is based on the time it should take to implement the relatively conventional control methods required. Largely independent producers would have little problem meeting the costs involved, especially since they will be able to pass on all of the increased costs of production to consumers. However, small producers might take advantage of economies of scale in increasing production, e.g., expanding a one-shift operation to a two- or three-shift operation.

Some of these small firms will probably exit the market irrespective of the OSHA standard. There has been a trend toward consolidation. Large firms (95 firms have less than 20 employees and a total of 2 percent of the market) leaving the industry because of unprofitability. They have discovered shrinking markets for their products; an inability to compete with larger companies because size is related to production efficiency. Most of the new plants in the industry have been quite large. OSHA has concluded that even if the questionable DBA and CRA predictions that approximately 100 small manufacturers would exit the market are true, the standard is nonetheless feasible for the battery industry. OSHA estimates that if 100 small businesses would have a minimal impact on the competitive structure of the industry.
ing their inordinately excessive estimates of compliance cost. Where capital acquisition problems are encountered in meeting the implementation schedule, the flexibility in the compliance scheme for the standard should, under certain conditions, enable employers to spread compliance costs over 5 years.

(c) 

(d) 

Brass and Bronze Foundries. Compliance with the interim level of 100 mg/m³ in 1 year is feasible in this industry with presently available technology. The flexibility in the compliance scheme with the PEL may require some further development and refinement of the same technology. 

Cost estimates for compliance with the interim level are $161 million for capital expenditures and $41.2 million in after-tax annualized costs. Costs of compliance will be passed on to the purchasers of castings, and DBA estimates that price increase would be equivalent to a percentage of the cost of casting. This assumes that industry profit rates will be maintained since it is double the price necessary for full cost recovery. Some small firms with higher than average costs of compliance may leave the industry thereby reducing competition, and even substitutes for brass and bronze castings exist for some uses total industry output may fall. The industry association which testified at the hearings indicated the effects did not lead to economic hardship.

(e) 

Pigment manufacturing. Control of employee exposure in pigment plants to comply with the implementation schedule will probably require extensive modification of the present production processes. Substitution of other materials for lead is also possible for some uses of pigment.

Cost estimates for this industry for the interim level are between $17.6 million and $21.1 million and $6.4 million in annualized costs. These costs are for replacement of about 60 percent of the enterprise and may not be adequate to comply with the PEL. If compliance with the PEL requires the redesign of the production process, the capital costs for the industry may be in the area of $109 million with after-tax annualized costs of $21.8 million.

DBA concluded that almost all costs of production would be passed on to the consumers, and competition in the industry would decrease slightly as marginal firms exit. The DBA analysis was based on estimates of the cost of totally rebuilding the industry ($109 million—capital; $14.8 million—annual). Given the product substitution option, OSHA doubts that such estimates would ever be realized. However, if such sums are ever spent, they would be expended to comply with the PEL over a 5-year period. OSHA's revised estimates of the cost to achieve the 100 mg/m³ interim level would require a price increase of 1.7-3.7 percent instead of the DBA prediction of 16.6-21.5 percent. This would substantially mitigate the impact on marginal firms.

(f) Other industries. At least 33 other industries have been identified as having some lead exposure. In almost all cases control of lead levels below the PEL should be feasible within 1 year using conventional methods, but in some operations, such as solder grinding and paint spraying, elaborate, personal protective equipment may be necessary to comply with the PEL.

(g) Aggregate economic impacts. While the costs of compliance are significant for some industries and the employment impacts may have regional significance, the aggregate impacts are minimal. The effect of costs associated with the interim level is estimated to increase the Consumer Price Index by only 0.02 to 0.03 percent.

IV. SUMMARY AND EXPLANATION OF THE STANDARD

The following sections discuss the individual requirements of the standard. Each section analysis of the record evidence and the policy considerations underlying the decisions adopted pertinent to specific provisions of the standard. To the extent appropriate, the requirements in this standard are similar to requirements in other OSHA health standards and reflect OSHA's regulatory policy for comprehensive health protection of workers.

Each provision is an integral part of the comprehensive health program contained in this standard and as such provides a discrete but necessary contribution to the overall objective of the standard. Because of this, the benefits attributable to any specific provision can not be quantified and compared to its costs. For example, the training and education provision provides an essential function in assisting workers to recognize hazards and to minimize lead absorption by means within their control, i.e., better hygiene and work practices. This provision does not, however, provide any quantifiable benefits apart from the complex of other provisions which also contribute to the overall objective of the standard because the contribution of poor hygiene or work practices, as percentage of total absorption, varies among individuals and is thus not determinable.

On the other hand, OSHA has assessed the costs of individual provisions (see Ex. 26; Ex. 22; Ex. 127) and has minimized costs to the extent possible without compromising the level of health protection and the integrity of the standard. OSHA has accomplished this by decreasing the frequency of periodically recurring requirements (e.g., air monitoring) or by providing a certain condition at which the obligation begins (e.g., an action level, the PEL, or a minimum duration of exposure).

In many cases, the standard does not create new costs for employers because the obligations already preexist the standard (e.g., current OSHA standards for respirators, personal protective equipment, hygiene facilities, engineering controls (29 CFR Part 1910)) or because employers have voluntarily instituted them as part of a comprehensive industrial hygiene program. OSHA thus believes the standard has been constructed in the most cost efficient manner and that the cost burdens imposed on employers are reasonable.

A. SCOPE AND APPLICATION: PARAGRAPH (a)

This standard for occupational exposure to lead is applicable to all employees and places of employment over which OSHA has statutory jurisdiction and in which lead, in any amount, is present in an occupationally related context. Exposure of employees to the ambient environment which may contain small concentrations of lead is not subject to this standard; however, where the source of lead is employment related, all exposure to lead is covered by the standard. The lead in which this standard applies is defined to include metallic lead, all inorganic lead compounds, and organic lead compounds. All of these substances are covered within the scope of a single standard because they generally react in a chemically and toxicologically similar manner in the human body.

On the other hand, most organic lead compounds, except for organic lead compounds, have varying degrees of toxicity or have toxicological properties different than the inorganic group, and thus are excluded from the scope of this standard. Some of these excluded compounds are covered by existing OSHA standards, and others will be treated in separate standards to be developed in the future.

Some covered compounds may be covered by this and one or more other OSHA standards. Lead chromate, for example, is covered under this comprehensive standard for lead as well as...
under the permissible exposure limit for chronic acid and chromates in Table 2 of 29 CFR. Lead arsenate is covered under this standard and the standard for inorganic arsenic, S1910.1018. The requirements of each standard would apply to the extent applicable.

It should be recognized that although this standard may have general applicability to a particular employer or workplace, almost all of the obligations in the standard are predicated on an initial determination of certain minimum lead exposure conditions. For example, the requirements for periodic environmental monitoring and medical surveillance apply only if employees are exposed to airborne lead in excess of the action level (30 µg/m³). Employers whose employees are exposed below the action level are not required to conduct periodic monitoring or medical surveillance or to comply with most other provisions of the standard. This distinction is made in order to differentiate between more hazardous and less hazardous work operations and obligations concerning the degree of hazard present. For a more complete discussion of each particular requirement, see following paragraphs (C) through (E).

The notice of proposed rulemaking stated that the standard would apply to all industries covered by the Act, including general industry, construction and maritime and that corresponding standards for maritime industries are the infeasibility (technical and economic) of compliance with certain provisions of the standard and the apparent purposelessness of others given the facts that the nature of construction work (1) often exposes employees to lead for very brief periods of time; (2) requires the employees to move from place to place, resulting in varying exposure conditions; and (3) has a high number of temporary employees. These factors are claimed to impact on the construction industry's ability to comply with the standard's provisions in the following ways:

1. Exposure determinations and environmental monitoring. Environmental monitoring is not claimed to be infeasible other than where the length of the job could be shorter than the time it could take for air samples to be taken and analyzed (Tr. 7293-7309; Ex. 3(64), p. 3). It is claimed, however, that the mobility of the worker and the impermanence of the worksite renders the environmental monitoring requirements useless in the construction context because the value of air monitoring, beyond use as a historical record of exposure, is primarily based upon "the degree to which the results of the monitored activity can be related to some future repetition of that activity," (Ex. 3(30), p. 3) In a construction environment, the contaminated source and exposure levels are often unique in any given task at any given time, and the air monitoring data derived from it is primarily for the purpose of evaluating the need and efficiency of engineering controls and other protective measures triggered by the result of air monitoring.

2. Methods of compliance. Engineering controls are contended to be inherently not feasible for certain construction activities, such as abrasive blasting or certain mobile activities. It is also claimed that on short-term jobs amortization of some controls, e.g., a conditioned-air ventilation system, would not be economically feasible. Technological and cost considerations aside, the time to design, procure and install such a system might exceed the entire time to complete the whole construction job. (Ex. 3(64), p. 4; Ex. 3(30), p. 4–6.)

3. Hygiene facilities. On remote construction sites, minimal amounts of water and sanitation may be available, and the use of mobile, self-contained facilities providing lockers, change rooms, showers, etc. would probably be economically prohibitive, especially for short duration jobs. (Ex. 3(64), p. 7.)

4. Medical surveillance and MRP. Medical monitoring, medical removal and MRP requirements are also claimed as unworkable. Because initial medical surveillance and periodic follow-up is predicated upon air monitoring results, the shortcomings of air monitoring for the construction industry

---

Footnote:

Construction work has a high turnover rate (300-650 percent (Tr. 7292; Ex. 3(30), p. 11), and construction subcontractors commonly hire local craftsmen through local unions for brief, specified periods. (Tr. 7297, 7301.)

"The Council of Construction Employers states that "lengthy procedures using air monitoring techniques to determine toxic concentrations of airborne contaminants. There is no doubt that such techniques are available but they provide valuable information . . ." (Ex. 3(64), p. 2)
The PEL is an eighth-hour average of exposure for any work day. If respiratory protection is permissible being used, the employee shall not be exposed to the PEL and all of the requirements relating to selection, fitting, and maintenance of respirators are met, the employee needs to wear the respirator only for a period of time that, when averaged with periods of time the respirator is worn will result in a TWA exposure below permissible limits. For this purpose, the employee's exposure level when a respirator is worn may be considered to be the airborne concentration, without regard to their sp, permissible level protected by the protection factor of the respirator. For example, if an employee is exposed to 100 µg/m³ for 8 hours with no respirator, he would have to wear a respirator with a protection factor of 10 for about 4.4 hours or with a protection factor of 60 for about 4.1 hours, in order to comply with the PEL.

Of course, a class of respirator more protective than required by paragraph (f) may be selected, and if selected, would reduce the amount of time a respirator would need to be worn.

OSHA recognizes that workshifts can extend beyond the regular 8-hour period as a result of overtime or other alterations of the work schedule. This extension of worktime also extends the time during which the employee is exposed. The effects of this additional exposure time must be considered when determining the permissible level of exposure. For the purpose of calculating such a level, the relationship of concentration and length of time of exposure has been assumed to be linear. As the exposure time increases, the factor of concentration multiplied by time (C×T) should remain constant. As a result, it is believed that by equating exposure with the 8-hour time-weighted average, reasonable assurance of maintaining a safe exposure level is retained.

The final standard contains a formula by which adjustments to the permissible exposure limit can be made due to overtime. For example, if an employee is exposed to lead for 10 hours, the permissible limit, as a 10-hour average, would be 400/10 or 40 µg/m³.

The proposed standard expressed the PEL as an 8-hour, time-weighted average "based on a 40-hour week." This has been deleted to avoid ambiguity since it was misconstrued by some commenters as an extension of the PEL to a 40-hour average.

Information was also presented during the rulemaking proceeding regarding the variation in solubility and toxicity of different lead compounds. (Ex. 3 (4), (57), (59), (103), (107); Ex. 38; Ex. 294(16); Ex. 294(22); Ex. 247 A and B; Ex. 311A.) The key issue which emerged is whether the final standard should differentiate between different lead compounds in the establishment of permissible exposure limits.

Stanley D. Korems, Deputy Assistant Secretary of the Interior, advocated the tolerance of some lead compounds at higher airborne concentrations. Lead compounds, particularly lead sulfide, which is common to the majority of lead ores, are virtually insoluble in biological tissue. He calls it "inconsistent" to institute the same low exposure limit for lead, coding to Bissonnette, "would not result in excess blood lead" (Ex. 3 (57), (4)) as the others which would result in elevated blood leads.

D. A. Bissonnette, corporate industrial hygienist for PACCAR, Inc., advanced precisely the same complaints about the proposed lead standard. Bissonnette said the standard failed to take into account the different degrees of toxicity of lead in its different forms, e.g., from ores to lead compounds used in paint pigments. He stated that this explains why painters highly exposed to lead still exhibit normal blood lead levels. (Ex. 3 (59), (4.)

Most of the other arguments presented on this point reflected the view expressed by St. Joe Minerals Corp. that lead sulfide is absorbed little by man, if at all. St. Joe's D. E. Berlstein claimed that lead sulfide "does not pose a significant adverse health problem and should be specifically exempted" from the lead standard. (Ex. 3 (107), (1.)

After evaluating industry claims that solubility and other factors of lead toxicity should be incorporated into the PEL, OSHA does not believe that the final standard poses what Bissonnette called "an unnecessary administrative and economic burden" on the less toxic lead compound industries. (Ex. 3 (50), (2.) Several factors lead to this conclusion. Decreasing the airborne exposure reduces the amount of lead available for ingestion. Second, with the exception of lead sulfide, all other lead compounds are encapsulated in the paint mist rendered much less toxic than lead fumes or dust, according to Bissonnette. He stated that this explains why painters highly exposed to lead still exhibit normal blood lead levels.
RULING AND REGULATIONS

Administration and are not covered by
OSHA standards. Only the few em-
ployees involved in the handling of ore
and concentrates of at least smelters
will be exposed to lead dusts and many of
them may also be exposed to other,
more soluble forms of lead such as re-
cycled flue dusts, drosses, etc. (Ex. 26,
p. 5-3.) With regard to paint, not
enough is known about the biological
response to paint particulates (Tr.
1203) for OSHA to assume that ex-
sposure to lead-based paints are less tox-
ic. Bissonnette's suggestion that painters'
lead blood levels are normal despite
high air lead levels because of lower
toxicity is perhaps better explained by
the fact that painters always wear res-
pirators as protection from toxic
vapors of solvents in the paint. (Tr.
1200.)

Another factor suggested by partici-
pants is the particle size of the lead
aerosol. Particle size affects the respira-
tibility and hence absorption of lead
into the blood. However, nonrespirable
particles will be deposited on the skin
and absorbed by the body through direct
ingestion or from swallowing nonrespired
particles trapped on the mucous membranes
in the respiratory tract. (Ex. 439A, p.
3-12.) The location in which lead is
clearly different than in the lung.
OSHA agrees that particle size is rele-
ant to the determination of a PEL
and accounted for particle size in de-
veloping its air-leed to blood-leed rela-
tionship.

D. EXPOSURE MONITORING: PARAGRAPM (d)

The monitoring requirements of the
final standard are imposed pursuant to
section 6(b)(7) of the Act which
mandates that standards promulgated
under section 6(b) shall, where appro-
priate, "provide for monitoring or
measuring of employee exposure at
such locations and intervals, and in
such manner as may be necessary for
the protection of employees." The pri-
mary purpose of monitoring is to iden-
tify the sources of lead emission and
to determine the extent of employee
lead exposure. This will enable the em-
ployer to select and apply control
methods and to evaluate the effective-
ness of the selected methods. Addi-
tionally, monitoring enables employers
to notify employees when their ex-
posure levels exceed permissible limits,
as required by section 6(c)(3) of the
Act, and provides information neces-
sary to the examining physician.

Paragraph (d) of the regulation con-
tains provisions for monitoring em-
ployee exposure to airborne lead with-
out regard to the use of respirators.
The final standard is essentially un-
changed from the proposal except for
tree differences: (1) the initial deter-
imination of employee exposure must
be based, at least in part, on air sam-
ppling and analysis, (2) periodic moni-
toring must include full-shift personal
samples, and (3) the monitoring fre-
quency is reduced.

The proposed standard would have
required employers to make an ini-
tial determination of whether any em-
ployee might be exposed to lead in
excess of the action level. The basis of
this determination for most employers
did not include exposure monitoring.
Only employers who were known to
have high lead exposure would have been
required to monitor. The purpose of this requirement was
to minimize the burden on employers
where limited exposure to lead exist-
ed.

OSHA has reassessed this provision
and decided that employers in all in-
dustries where lead is present in an oc-
upational context should perform a
minimal amount of exposure monitor-
ing because it is the only precise
method of determining lead-in-air con-
centrations and because it cannot be
confidently predicted that lead expos-
ures exceed the action level in only
certain industries.

In its criteria document on lead,
NIOSH identified 113 occupations or
trades in which exposure to inorganic
lead is possible. (Ex. 1, p. x-3.) The
preliminary technological feasibility
and economic impact analysis identified
and collected information on 46 indus-
tries, representing at least 75 SIC
codes, where employee exposure to
lead is believed to occur. (Ex. 22.)
However, because of the changing
usage of lead in industry and the
widely varied trades where exposure
occurs, there is no reporting system
in the United States to analyze the prev-
ance of lead poisoning and no precise
measure of the extent of lead expos-
ure. (Ex. 1, p. III-1.) For these rea-
sons, it is important for the employer,
in whose workplace lead is present or
used in an occupational context, to
make an initial determination of po-
tential employee exposure based on a
reliable and accurate method. To ex-
clude all employers except those in
traditionally high exposure industries
from initial monitoring (as the pro-
posed standard would have done) is to
fail to recognize the need to accurately
identify and measure all occupational
sources of lead exposure.

The initial monitoring requirement
is minimal in that it only requires
monitoring of a representative sample
of the employees believed to have the
highest exposure levels. If these mea-
surements indicate exposure below the
action level, no further monitoring is
required except where subsequent
process or control changes would trig-
ger a redetermination pursuant to
paragraph (d)(7). If any employee is
detected to have the permissible ex-
posure level, then full-scale repre-
sentative monitoring for all exposed em-
ployees is required.

In conducting the monitoring of em-
ployee exposures, the standard does not
require that each individual em-
ployee's exposure level be measured.
Although individual measurement is
the ultimate indicator of an employ-
ee's exposure, OSHA believes that
the requirement for individual meas-
urement may be too burdensome, and
that representative monitoring will ade-
quately insures that the worker's ex-
posure is maintained within the re-
quirements of this standard. In estab-
lishments having more than one work
operation involving the use of lead, in
order for monitoring to be representa-
tive, it must be performed for each
type of employee exposure within each
operation. It should be noted that the
requirement for representative
monitoring does not preclude an em-
ployer from taking individual expo-
sure measurements of each of his em-
ployees; individual measurements are
certainly considered to be representa-
tive; however, representative monitor-
ing merely establishes the minimum
that the employer must meet.

OSHA disagrees with testimony
which suggests that little or no confi-
dence can be placed in determinations
of employee exposure which are not
based on an actual measurement of
the exposure of each individual em-
ployee. (Tr. 6073.) If the representa-
tive employee chosen is, in fact, rep-
resentative and a sampling protocol uti-
lizing full-shift samples is used, OSHA
believes this will be adequate in ascer-
taining employee exposure without
being unduly burdensome. (Tr. 91-92.)
Accordingly, the standard requires
that the measurements be made by
monitoring which is representative of
each employee's exposure to lead over
a full shift period without regard to
the use of respirators. A full-shift
sample is considered to be at least 7
hours long; this provides a sufficiently
long sampling period while allowing
time for equipment set-up and calibra-
tion. (Ex. 3 (12), p. 4; Tr. 3626)

The objective of environmental mon-
itoring is twofold: first, full shift per-
sonal sampling will enable the em-
ployer to determine an individual em-
ployee's exposure to airborne concentra-
tions of lead.4 Individual monitoring
information combined with biological
monitoring data and clinical evalu-

1OSHA recognizes that there will be day-
to-day variability in airborne lead exposure
experienced by a single employee. The per-
missible exposure limit is a maximum al-

FEDERAL REGISTER, VOL. 43, NO. 220—TUESDAY, NOVEMBER 14, 1978
tion form the basis for ascertaining the lead-related health status of an individual worker.

For example, if a worker had high blood lead level but a low air lead exposure as determined by individual sampling, other sources of lead exposure (injection, non-occupational sources, etc.) would be suspected. The physician could make use of this information to ascertain and correct the associated problem.

Second, thorough environmental monitoring enables the employer to determine the source of lead emission, the efficacy of control technology, and progress achieved during implementation of controls. In industries with high lead exposure, a comprehensive industrial hygiene survey may be required to determine the nature and extent of the lead exposure problem. This survey may require far more than a single full shift personal sample. Multiple area and personal samples may be necessary and a variety of sampling times may be needed to determine precisely the source of emission. Short-term samples may determine ceiling values in a markedly fluctuating environment, whereas continuous area sampling may be required in relatively stable situations.

Thus environmental monitoring serves two different but related functions. The monitoring requirements of this section also facilitate these different goals. The requirement of full shift personal sampling is mandatory for two reasons: First, it enables the employer to determine whether he is in compliance with the action level and/or the PEL, and second, to obtain data on the individual employee which may be used in conjunction with biological monitoring to better insure that an individual suffer no loss of health from other sources of lead.

The standard also requires that air monitoring data obtained to define the sources of emission and to assist in the development of the compliance plan be contained in the compliance plan. This data is necessary, however, to determine what environmental controls will be required to achieve compliance and will enable OSHA to fully evaluate the proposed compliance plan.

The final standard reduces the frequency of periodic monitoring from monthly to quarterly when the PEL is exceeded and from quarterly to semiannually when the action level is exceeded. This was favored by both industry (Ex. 4, p. 83-84) and labor (Ex. 5, p. 83-84) representatives. OSHA believes that accurate and representative sampling can be achieved by this schedule while reducing the economic costs of sampling between 50 percent and 66 percent.

Finally, the standard requires that the initial determination be made within 30 days of the effective date and the initial monitoring to be conducted and the results obtained within 90 days of the effective date of the standard. OSHA believes that these periods, in addition to the 90 day delayed effective date, is sufficient to enable employers to secure sampling equipment, take sufficient samples and obtain the results. Moreover, the standard permits employers, who have monitored within the last year as many have (Ex. 3(1), p. 1) to utilize these measurements for purposes of compliance with the initial monitoring requirements, provided that the sampling and analytical method used meets the accuracy and confidence levels of this standard and provided that the employer maintains a record of these measurements and notifies employees of their exposure levels.

E. METHODS OF COMPLIANCE: PARAGRAPH (e)

The final standard requires employers to institute engineering controls and work practices, including administrative controls, according to a specific timetable. Depending on the interim period before full compliance with the PEL in this manner is required and thereafter where engineering controls and work practices are not sufficient to comply with the PEL, they must be supplemented with appropriate respiratory protection. The standard also requires the employer whose initial monitoring reveals that employee exposure exceeds the PEL to develop a written compliance plan which is intended to promote rational planning and implementation of the employer's compliance efforts within the time permitted. The written plan also will enable OSHA and affected employees and their representatives to monitor the employer's progress toward compliance. Finally, if mechanical ventilation or administrative controls are used, some specific requirements are set forth.

In order to comply with the PEL, an employer will need to conduct an industrial hygiene survey, including environmental sampling, to identify sources of lead exposure and then devise methods to reduce employee exposure to within permissible limits. Employees covered by this standard are generally exposed to airborne lead particulate either when it is generated or released into the air directly from a production process or work operation or when it is dispersed after settling on floors, rafters, or other surfaces, including the worker's body and clothes. Methods commonly employed by industrial hygienists to control these exposures fall into three basic categories: engineering controls, work practice controls, including administrative controls, and personal protective equipment.

Several comments, including one from California's Occupational Safety and Health Administration, suggested that the terms "engineering controls," "work practice controls," and "administrative controls" are not understood by many employers and employees and need definition. (Ex. 3(3)) These terms admittedly do not have precise meaning and often overlap. The best way is to accomplish as simply as the employee's body and clothes. Methods commonly employed by industrial hygienists to control these exposures fall into three basic categories: engineering controls, work practice controls, including administrative controls, and personal protective equipment.

Finally, personal protective equipment is a method of exposure control that isolates the employee from the emission source. Respirators are the primary type of personal protective equipment used when the concern is protection from an inhaled air contaminant.

The priority of control methods required by this standard, i.e., use of res-
piratory protection only as a supplement to engineering controls and work practices or as an interim measure while engineering controls and work practices are being implemented and supported by evidence from the record and is consistent with the policy approach taken in all prior air contaminant standards promulgated by OSHA. Almost all representatives of the lead industries, including ILA and BCI, concurred with this approach provided engineering and work practice controls were feasible. (Ex. 342, p. 6; Ex. 356; Ex. 341, p. 12). The rationale behind this approach is based primarily on two principles. One is that protection of the employee is most effectively attained by elimination or minimization of the hazard at its source, which work practices and engineering controls are both designed to do, and the other is that methods which depend upon the vagaries of human behavior are inherently less reliable than well-maintained mechanical methods. The validity of these generalizations has been borne out by agency experience obtained throughout OSHA's existence and has been reiterated by many professional industrial hygienists for the lead record. (Tr. 2068.) Engineering control is unquestionably the best method for effective and reliable control of employee exposure to lead. (Tr. 1366; Ex. 270, p. 20.) It acts on the source of the emission and eliminates or reduces employee exposure without reliance on the employee to take self-protective action. This method encompasses product substitution, process or equipment redesign, exhaust or dilution ventilation, and employee isolation (e.g., a standby pulpit, but not personal protective equipment). Once it is implemented, it protects the employee permanently, subject only, in some cases, to periodic preventive maintenance. Work practices also act on the source of the emission, but rely upon employee behavior, which in turn relies upon supervision, motivation, and education to make them effective. For this reason, work practices are not as desirable a method as engineering controls, but because the two methods often must be employed together to make either one effective (Ex. 270, pp. 22-23; Tr. 2069) and because they are the only methods that act to eliminate or reduce the hazard at its source, they have been given equal status in the compliance priorities of the final lead standard.

Administrative control, as a type of work practice, is also included in the group of primary methods of exposure control that must be used before respiratory protection. This modifies the approach in the proposed standard in which engineering controls were to be given priority over work practices, and reference to administrative controls was omitted. The approach in the final standard is based on the result of recognizing the important role of work practices and clarifying the definition of the term "work practices" to include "administrative controls." These terms have been somewhat ambiguous in that administrative controls has been commonly thought to include employee rotation or other administrative types of control. However, OSHA's policy has generally been to dignitize the use of administrative controls (while still approving of other work practices) because they not only fail to eliminate the hazard but they expose more workers to the contaminant, albeit for shorter periods of time. The latter reason makes administrative controls unacceptable when the contaminant is one for which no effect levels are known, e.g., carcinogens. (See preamble to standard for asbestos and inorganic arsenic, 43 FR 19617, May 5, 1978.) In the case of lead, however, the PEL is based on dose-response data and although administrative controls do not eliminate or reduce the hazard as engineering controls and other work practices do, they can be a relatively safe and effective means of maintaining TWA levels below permissible limits.

Respiratory protection is relegated to the bottom of the compliance priority list because it is an administrative, unreliable, and unsafe method of reducing employee exposure. The Council on Wage and Price Stability (Ex. 224) and some industry representatives (e.g., Ex. 3107) suggested a control strategy which would permit employers to place principal reliance on respiratory protection where employers determined that it was a "less costly method of achieving the same level of worker health." (Ex. 224, p. 13.) It is true that respirators are usually less costly than engineering controls, hence CWPS's and employers' eagerness to prefer them as the solution to control problems, but it is also true that respirators are not comparable alternatives to engineering controls, work practices, and administrative controls because they do not eliminate the source of the exposure, are generally not capable of providing the protection required, and create additional hazards by interfering with vision, hearing, and mobility. (Tr. 1967; 1462.) Some employees develop skin rashes where the facepiece makes contact with the skin, and some employees with cardiopulmonary impairment, otherwise able to work, cannot safely work with a respirator placing stress on their breathing. It may be difficult to fit some employees with unusual facial configurations since respirators are manufactured with males as standards. (Tr. 1360.) The OSH Act places the primary burden of compliance on the employer, to shift it to the employee, as respirators do, is, according to NIOSH, inappropriate (Tr. 1462) and is contrary to established OSHA policy. (See preamble to cotton dust standard, 43 FR 27384, June 23, 1978.)

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 the proper ones selected for the environmental in which the employee will be working, properly fitted to the employee, maintained and cleaned periodically, and worn by the employee when required.

It is clear from the discussion on feasibility (attachment D) that compliance with the PEL solely by means of engineering controls and work practices is feasible in all the affected industries, although in certain cases major process and control modifications may be required. The steelworkers noted that "the question of feasibility is basically one of length of time necessary for any plant to achieve compliance. . ." (Tr. 4634.) Dr. Frist also agreed that "stringent limits for lead exposure should be treated as goals to be reached over reasonable time periods." (Ex. 270, p. 18.) The Court of Appeals for the Third Circuit in its review of the asbestos standard also recognized the need to allow "sufficient time to permit an orderly industry-wide transition. . ." (IUD v. Hodgson, 499 F. 2d 467, 479 (3d Cir 1974).)

The time necessary to implement these modifications will vary from industry to industry according to the magnitude of the modification required, but essentially it is based on the time necessary to acquire, install, and test them. OSHA has taken these factors into account by developing an implementation schedule for compliance solely by the use of engineering controls and work practices. This schedule represents OSHA's best estimate of when each industry as a whole can feasibly come into compliance. This approach was what the third circuit apparently expected when it remanded the asbestos standard for clarification of why interindustry distinctions were not recognized in establishing the effective date for the two fiber PEL (499 F. 2d at 479-81). The rationale for the times chosen for each industry is contained in the discussion of feasibility in attachment D.

The language of paragraph (e)(1) is intended to impose on the employer the affirmative obligation to comply with the implementation schedule.
solely by means of engineering and work practice controls. This obligation has been determined to be feasible (see attachment D) and thus the obligation in the proposal to implement only "feasible" controls has been deleted in the final standard. OSHA's intent is to preclude individual employers from being able to escape the defense of infeasibility of compliance in an enforcement action and having citations vacated. OSHA has established industrywide feasibility and does not believe that any individual employer should be able to escape obligations that the industry as a whole can meet. On the other hand, OSHA will take individual claims of infeasibility into account through abatement programs tailored to meet the needs of individual firms and their employees.

In addition, where an employer needs more time to comply with the implementation schedule and a temporary variance under section 6(b)(6)(A) of the Act is appropriate, it should be sought. Similarly, the mandatory nature of these requirements is intended to discourage or inhibit the development of different, equally effective means of providing the required protection. The variance provisions of section 6(d) of the Act, and the implementing regulations in Part 1905 of this title, provide a mechanism for employers to obtain variances from the provisions of this section where the employer has developed alternative procedures which are as safe and healthful as those required by this section. The variance provisions of the Act permit the flexibility which contributes to efficient compliance with the standard. OSHA encourages interested employers to utilize the variance provisions of the Act where equally safe and healthful protective means are available.

Additionally, since the standard has been deemed to be feasible in all industry segments, the standard establishes an employer's failure to meet the exposure levels in accordance with the implementation schedule as a prima facie violation of paragraph (c)(1). However, the preamble recognizes that engineering and work practice controls may not be adequate or appropriate at certain times (e.g., unexpected process upsets) or for some job tasks which are performed in locations which are not predeterminable (e.g., repair, non-routine maintenance) or inaccessible (e.g., lead burning in ship hulls). In these and other cases, it should properly be the employer's burden to prove impossibility or technological infeasibility of compliance. The employer is familiar with his workplace and is informed of the state of the art of work practices and control technology available to his industry and should properly bear the responsibility of proving an inability to comply.

The standard also has a requirement for the development and implementation of a written compliance plan where the employer has employees exposed to lead, without respect to respiratory protection. In excess of the PEL. The purpose of the written strategy for achieving compliance with the implementation schedule solely through the use of engineering and work practice controls, and must incorporate all relevant information that relates to those goals so that in an examination of the plan, one could determine whether the employer reasonably analyzed the problems and their solutions, including alternatives that were developed in the plan in accordance with its schedules.

This plan is required primarily to promote systematic and rational compliance by employers and to assist OSHA in its enforcement function by involving compliance personnel to monitor employers' compliance activities.

The standard requires the employer to have the written plan completed and available as of the date it issues the enforcement action to the employer. This plan must be consistent with the interim levels of the Final Standard. The plan must be consistent with the interim level, taking into account the time allowed for each industry to achieve compliance, and the interim level is intended to be compatible with the Final Standard.

Upon examining the employer's written plan, OSHA will determine whether the plan is consistent with the interim level and whether the plan will take into account the time allowed for each industry to achieve compliance. OSHA will determine whether the plan is consistent with the interim level and whether the plan will take into account the time allowed for each industry to achieve compliance. OSHA will determine whether the plan is consistent with the interim level and whether the plan will take into account the time allowed for each industry to achieve compliance.

The standard permits employers to implement interim levels in cases where the compliance program does not project the implementation of these controls by that date, or where it appears that the schedule for implementation in the interim level is extended such as to make it impossible to achieve the controls and the process could achieve compliance with the interim level. This level will take as much as five or more years, compliance with 100 μg/m² as an intermediate milestone is required because it will assure a greater measure of employee protection than might otherwise be provided if no intermediate goal were specified. OSHA recognizes that in some limited cases ultimate compliance with the PEL may not be achieved at the time indicated as an intermediate milestone until ultimate compliance with the PEL is achieved. The time allowed for each industry to comply is based on record evidence of the speed at which the action required in each industry and the time reasonably necessary to accomplish it. Since ultimate compliance in several industries will take as much as five or more years, compliance with 100 μg/m² as an intermediate milestone is required because it will assure a greater measure of employee protection than might otherwise be provided if no intermediate goal were specified. OSHA recognizes that in some limited cases ultimate compliance with the PEL may be achieved by retrofitting an antiquated production process with expensive dust control devices, but only removal of those devices and costly redesign and modernization of the process could achieve compliance with the PEL. If the employer's compliance program contemplates achieving the PEL within the schedule, the employer can demonstrate why compliance with the interim level is inconsistent with the Final Standard. The plan must be consistent with the Final Standard.
RULES AND REGULATIONS

spection of the compliance plan if appropriate.

The final standard retains the requirement that where mechanical ventilation is used, quarterly measurements of the system's effectiveness must be made. Some parties claimed that this was too costly, but OSHA believes that periodic checks are absolutely necessary to insure the integrity of a ventilation system. It should be noted that the three measurements listed in the regulation are only examples. Any measurement which assures the system's effectiveness will comply with the standard. In addition, because of the cost and minimal utility, the requirement that a record of these measurements be kept has been deleted.

The proposed standard prohibited the recirculation of workspace air. However, as Dr. First explained during the hearings, "energy conservation by recirculation of industrial exhaust ventilation systems is a highly desirable goal" if "a system of that type would be sufficiently reliable given the general degree of maintenance and repair of air control equipment that we see in industry." (Tr. 2320; Tr. 5310)

The evidence of the hearings is that safe recirculation is technologically feasible and economically desirable for dry, particulate dusts. The post-hearing brief of the Steelworkers concluded from the hearings that "it is now possible for plants to operate recirculation systems safely with the advent of sophisticated backup equipment." (Ex. 343, p. 129) The National Advisory Council on Occupational Safety and Health agreed. (Ex. 342, p. 7) IHE performed cost calculations with and without recirculation in its cost study of 12 battery plants to illustrate the fuel savings. (Ex. 26[29A]).

Caplan testified that the capital cost of installing a safe recirculation system could be paid for by the savings in fuel. (Tr. 3718-19) OSHA thus has permitted recirculation of air under conditions which will provide cost savings to employers and fuel efficiency with adequate protection of employees.

Finally, the fiscal standard requires that when administrative controls are used to lower employee exposure, a rotation schedule is to be kept and followed and made a part of the written compliance plan. This will enable OSHA and affected employees to determine the effectiveness of the administrative control program.

F. RESPIRATORY PROTECTION: PARAGRAPH (F)

This section contains specific requirements for the usage, selection, maintenance, and fitting of respirators. It is, in essence, unchanged from the previous regulations. Some minor changes have been added to account for the possibility that substantial reliance may be placed on respirators to achieve permissible limits while engineering and work practice controls are being implemented. As a general matter, few objections to the proposed respirator provision were made; specific ones are discussed below.

The final standard, like the proposal, requires that respirators be used during the time period necessary to install or implement engineering and work practice controls, when engineering and work practice controls are not sufficient to reduce exposure to the permissible exposure limit, or when ever an employee requests a respirator. This last requirement is to provide protection for those employees who wish to reduce their lead burden below that which is required in the standard. For example, male and female workers whose blood lead levels are in the 50-50 µg/100g range may desire increased protection, especially if they intend to parent in the near future.

With respirators the most satisfactory means of exposure control, they are capable of providing protection if properly selected, fitted, maintained, replaced when they cease to provide adequate protection, and worn when required. While it is theoretically possible for all of these conditions to be met, it is often the case that they are not, and as a consequence, the protection of employees by respirators is not always as effective. Further, employees with impaired respiratory function may not be able to wear certain types of respirators, such as those operating in the negative pressure mode.

Several witnesses addressed the difficulty in obtaining a proper fit in some employees. Robert Schutz, of NTOSH's Testing and Certification Branch, noted that respirators have traditionally been designed for fit men and only recently has OSHA proposed regulations to amend Subpart K of Part 11, 30 CFR, for dust, flame and mist respirators, to include a test panel composed of women test subjects. (Tr. 1459).

Edward Baler, Deputy Director of NTOSH, further emphasized that while respirators are not suited to women's faces, they are also not suitable for persons wearing a beard or mustache. For instance, there are more problems associated with the use of respirators than those of fit. Fatigue and reduced efficiency occur more rapidly among workers wearing respirators due to increased breathing resistance, hearing stress and reduced vision. (Ex. 91) The inherent difficulties presented by respirators must be considered. (Ex. 91) Respirators may limit vision, which is a significant factor where numerous physical hazards exist and the employee's ability to see is important. Speech is also limited. (Ex. 91) Voice transmission through a respirator can be difficult, annoying and fatiguing. (Tr. 5871, 6619) Communication may make the difference between a safe, efficient operation and a hazardous operation, especially in dangerous jobs. Entanglement of hoses of air respirators as well as limited mobility due to hose lengths, are problems in heavy industrial environments. (Ex. 91, Tr. 4014).

Self-contained breathing apparatus have the double problem of restriction of motion and necessity for carrying around heavy weight. (Ex. 91)

Despite the inherent difficulties associated with respirator use, they remain the only viable form of protec-
tion when engineering and work prac-
tice controls are not adequate to
achieve permissible limits. Witnesses
for NIOSH, labor and industry agreed
that respirators are only acceptable as
an interim measure (Tr. 1459; Tr.
2594-95; Tr. 6455; Tr. 6476; Tr. 1313;
Tr. 1561; Tr. 1240-41; Tr. 1966; Tr.
5612; Tr. 5821; Tr. 5508), and OSHA
emphasizes that respirators are not to be
used as a primary method of control. However, because
of the lengthy compliance periods re-
quired by some industries to imple-
ment engineering controls and work
practices, respirators will be necessary
in the interim as the only available
protective method.

A daily limit on duration of respira-
tor usage (e.g., Tr. 1459; Tr. 5801-11;
Ex. 343, p. 118) has been considered by
OSHA, especially for those industries
which presently have high lead exposure and will require a year
or more to reduce levels to permissible
limits. In most cases respirators will
not be required to be worn for a full
day; the employer has the flexibility
and discretion to determine the time
period for respirator usage. This period
of time is not to exceed the PEL.

OSHA anticipates that there will be
workplace situations where respirators
will be required for long periods of time.
Because of the discomfort and haz-
ards associated with wearing respira-
tors, coupled with the possibility of
long-term use in some industries,
OSHA has recommended that respira-
tor usage be limited to 4.4 hours per
day, the respirator need be worn only
a little more than 4 hours. (See paragraph
(C)(3) of the regulation and discussion
in paragraphs C and D of the Summary
and Explanation.)

The evidence in the record on the in-
adequacy, discomfort, and hazards as-
ociated with respirator usage support
some limitation of full-shift wearing of
respirators for long periods of time.
(Ex. 155, p. 9) Four industries (secor-
dary lead production, battery manufac-
turing, pigment manufacturing, and
nonferrous foundries) are not required
to meet the PEL for five years; one in-
dustry (primary lead production) is not
required to meet it for 10 years.

OSHA has concluded that for these in-
dustries the time for compliance with
the interim level of 100 \(\mu g/m^3\) should
begin a limitation for respirator usage
for employees. Accordingly, the final
standard limits for 4.4 hours the
amount of time an employee may be
required to wear a respirator after 3
years in primary smelting, secondary
smelting, and pigment manufacturing;
after 2 years in battery manufacturing
and after 1 year in nonferrous found-
ries. The time limit is based on the
maximum amount of time an employ-
ee would have to wear a respirator (as-
suming a protection factor of 10) if the
employer has complied with the inter-
im level, and as such, imposes no addi-
tional burden on the employer. If the
interim level of 100 \(\mu g/m^3\) is not
achieved within the compliance dates
specified, the employee will not be
required to wear respirators more than
4.4 hours per day, and the employer
will be required to make quarterly
means, for example, worker rotation, to
achieve compliance with the PEL of 50
\(\mu g/m^3\). OSHA anticipates that some
firms will not attempt to achieve the
interim 100 \(\mu g/m^3\) PEL but will devel-

ume should be required to
bear the burden of the continued high
lead levels by being required to wear
respirators 8 hours per day. OSHA has
attempted to provide a great deal of
flexibility in the methods of compli-
ance in order to reduce the burden to
the employer without compromising
the health of the employees. The em-
ployees cannot be expected to accept
these more flexible compliance provi-
sions if they are to bear the brunt of
the effects of that flexibility by being
required to wear respirators continu-
ously. Worker acceptance toward respi-

tors is well documented in the rule-
making records of this and other
OSHA standards and in addition the
agency is concerned that respirator
usage for extended periods of time may
result in health risk to individual employees, especially
those with cardio-respiratory disor-
ders.

Because of the discomfort and haz-
ards associated with negative pressure
respirators, coupled with the possibil-
ity of long-term use in some industries,
OSHA has recommended that respira-
tors be properly cleaned and fil-
tered before use, especially for use
with systemic poisons. (Tr. 1459; Tr.
5821; Tr. 5508). and the employer
will be required to ensure on an annu-
al basis that respirators are properly
fit tested, and that respirators be pro-
vided to workers as soon as practicable.

In order to insure that the employ-

ee's respirator fits properly and that
facepiece leakage is minimized, there
was agreement by Industry, govern-
ment and labor that fit testing should
be done. (Tr. 1554, 1556, 1966, 2311,
3203-04, 4721, 4935, 6480, 2401, 2311;
Ex. 91) A quantitative fit test on nega-
tive pressure respirators is required by
the standard because it is more ac-
curate and provides greater assurance
that the respirator is providing proper
protection to the employee than any
other type of fit testing. (Tr. 3203-4;
1554-56; 2311; 4721; 1966) Whereas the
quantitative fit test is subjective, rely-
ing upon the employee's sense of smell, the quantitative fit test uses in-
sertion testing to determine the integrity of the seal.

FEDERAL REGISTER, VOL. 43, NO. 220—TUESDAY, NOVEMBER 14, 1978
One type of quantitative fit test involves using a simple hood, sodium chloride vapor, and automated instrumentation. It can be performed rapidly and easily. The cost of the quantitative fit testing equipment is substantial, but since the standard only requires it to be done twice a year and since some employers will be wearing respirators for only a few months during the year, the costs involved may be less than the benefits. NIOSH has concluded that good respirator fit must be assured and that the benefit of quantitative fit testing far outweighs the costs involved. NIOSH confirmed the feasibility of such testing (Tr. 1566), and the costs for small employers can be minimized because the testing equipment is mobile and could be brought to the workplace on a fee basis. (Tr. 1555; 4722)

In addition, the standard requires that employees be properly trained in the use of respirators. (Ex. 91) The employee must be properly trained to wear the respirator, to know why the respirator is provided and the limitations of the respirator. (Tr. 4010, 4011, 4085; Ex. 91) An understanding of the hazard involved is necessary to enable the employee to take steps for his or her own protection. The respirator protection program implemented by the employer must conform to the program set forth in 29 CFR 1910.134.

The standard requires that the employer shall provide respirators at no cost to the employee. This has been added to make explicit what was implicit before and has been common practice in all industries. Allocation of respirator costs to the employer was made in the EIS (Ex. 26).

G. PROTECTIVE CLOTHING AND EQUIPMENT: PARAGRAPH (g)

This paragraph contains requirements that the employer provide employees with protective clothing and equipment that are appropriate for the hazard. The purposes are to protect employees from lead compounds which may cause skin or eye irritation (e.g., lead arsenate, lead oxide) and, for employees who are exposed to lead above the PEL, to assure that clothing, shoes, and equipment on which lead dust can accumulate during the work shift are not worn home or in the lunchroom. Wearing contaminated clothing outside the work area where exposure controls are operating will lengthen the duration of exposure through both inhalation and ingestion routes. In addition, lead dust will accumulate in employees' cars and homes exposing other family members to the hazard. (Tr. 4146)

These provisions generally met with approval by all participants to the rulemaking, and in fact, several employers are presently providing clothing and equipment at no cost to employees. (Ex. 26, pp. 5-11, 5-35, 5-68; Tr. 2215, 3788, 4078, 4147, 5055, 5283, 5554, 5656, 6156, 6256, 6257, 6267, 6306, 6510, 6939).

The purpose of the frequency with which work clothing must be provided. OSHA has determined that if clean work clothing is provided at least weekly to employees whose exposure levels are above the PEL and daily for those above 300 µg/m², adequate protection will be afforded and unnecessary costs minimized.

The final standard also emphasizes the need to assure that contaminated clothing is stored, cleaned, or disposed of in a safe manner. It requires that contaminated clothing be stored in sealed containers prior to laundering or disposal so that contamination in the change room is minimized and that employees who later handle the clothing are protected. The latter group are further protected by the requirements to put warning labels on the containers and to provide written warning of the hazards of lead. These practices commonly occur in the lead industries today, and do not impose significantly new obligations on employers. (Tr. 1253, 1556)

Some confusion arose over the language in the proposal that "the employer shall launder, maintain, and dispose of all protective clothing." (Paragraph (h)(2)) This was interpreted by some employers as requiring the employer to operate his own laundry facilities. This was not OSHA's intent, and the final standard attempts to make clear that the employer may utilize commercial laundries by stating that the "employer shall provide for the cleaning, laundering, or disposal..." Some witnesses testified that discarded and dirty uniforms should never leave the workplace. (Teildebaum, Tr. 530), but OSHA believes that the labelling and warning requirements of the standard will minimize exposure outside the plant.

H. HOUSEKEEPING: PARAGRAPH (h)

The final standard requires that all surfaces be maintained as free as practicable of accumulation of lead dust. This is to be accomplished primarily by vacuuming of floors, rafters, and other surfaces or by methods equally effective in preventing the dispersal of lead into the workplace. This is an exceptionally important provision because it minimizes additional sources of exposure that engineering controls are generally not designed to control. All participants to the rulemaking agreed to the need for scrupulous housekeeping: (Ex. 335, p. A-9; Ex. 270) Donald Hull, president of a small battery manufacturing company, testified that the success of his industrial hygiene program to a primary emphasis on housekeeping. (Tr. 1246)

The proposed language for this provision required "surfaces to be maintained free of accumulation of lead which, if dispersed, would result in airborne concentrations above the permissible exposure limit." (Paragraph (i)(7)) This requirement would be very difficult for the employer to comply with and OSHA to enforce because it would be nearly impossible to objectively determine when the condition in the standard would occur. (Ex. 3(71), p. 13) OSHA's view is that a rigorous housekeeping program is absolutely necessary to keep airborne lead levels below permissible limits but that the obligation should be measured by a standard of practicability. (Tr. 5747)

This contemplates a regular housekeeping schedule based on exposure conditions at a particular plant and the capability for emergency cleanup of spills or other unexpected sources of exposure.

Vacuuming is considered by all experts to be the most reliable method of cleaning surfaces on which dust accumulates (Tr. 2379; 2069) but equally effective methods may be used, for example, a wet floor scrubber. (Tr. 2072) Dry or wet sweeping, shoveling, or blowing with compressed air may not be used except where vacuuming or other equally effective methods have been tried and do not work. (Tr. 2198; 2079).

1. HYGIENE FACILITIES: PARAGRAPH (i)

This provision requires employers to provide hygiene facilities and to assure employee compliance with basic hygiene practices which are recognized industrial hygiene tools for minimizing additional sources of lead absorption from inhalation or ingestion of lead that accumulates on a worker's clothes or body. No later than one year after the effective date of this standard, the employer must provide adequate shower and washing facilities, (Ex. 335, p. A-9; Ex. 270) Donald Hull, president of a small battery manufacturing company, testified that the success of his industrial hygiene program to a primary emphasis on housekeeping. (Tr. 1246)

The proposed language for this provision required "surfaces to be maintained free of accumulation of lead which, if dispersed, would result in airborne concentrations above the permissible exposure limit." (Paragraph (i)(7)) This requirement would be very difficult for the employer to comply with and OSHA to enforce because it would be nearly impossible to objectively determine when the condition in the standard would occur. (Ex. 3(71), p. 13) OSHA's view is that a rigorous housekeeping program is absolutely necessary to keep airborne lead levels below permissible limits but that the obligation should be measured by a standard of practicability. (Tr. 5747)

This contemplates a regular housekeeping schedule based on exposure conditions at a particular plant and the capability for emergency cleanup of spills or other unexpected sources of exposure.

Vacuuming is considered by all experts to be the most reliable method of cleaning surfaces on which dust accumulates (Tr. 2379; 2069) but equally effective methods may be used, for example, a wet floor scrubber. (Tr. 2072) Dry or wet sweeping, shoveling, or blowing with compressed air may not be used except where vacuuming or other equally effective methods have been tried and do not work. (Tr. 2198; 2079).

1. HYGIENE FACILITIES: PARAGRAPH (i)

This provision requires employers to provide hygiene facilities and to assure employee compliance with basic hygiene practices which are recognized industrial hygiene tools for minimizing additional sources of lead absorption from inhalation or ingestion of lead that accumulates on a worker's clothes or body. No later than one year after the effective date of this standard, the employer must provide adequate shower and washing facilities, clean rooms for changing clothes, and filtered air lunchrooms for employees who have exposure above the PEL. In addition, employers must assure that employees use the facilities as required by the standard as well as observe prohibitions on tobacco, food, and cosmetics in contaminated areas. OSHA expects that strict compliance with these provisions will virtually eliminate several sources of lead exposure which substantially contribute to increased lead absorption.

Several of these facilities and practices are already required under current OSHA standards for General Environmental Controls in Subpart J of 29 CFR Part 1910. For example, §1910.141(e) requires the employer to provide change rooms with separate storage facilities for street and work
clothing, and section 1910.141(g) requires the employer to prohibit the consumption of food and beverages in areas where there is exposure to toxic substances. The provisions of this standard are intended to augment Subpart J with additional requirements which are specifically applicable to lead exposure and to consolidate all related provisions under one standard.

Many firms affected by this standard have already instituted facilities similar to those required in the final standard. (Tr. 1231; 2176; 2995; 2943; 3655; 3785; 4395; 4397; 4844; 4875; 5651; 5855; 6154; 6259) Employers have suggested, because employees are in a better position to impose and enforce work rules or practices. OSHA does however believe that employees will have a responsibility to act consistent with the objectives of the standard and to comply with all reasonable work rules designed to implement them.

Employers generally conceded the authority to impose and enforce reasonable work rules or practices. OSHA believes that employees have a responsibility to act consistent with the objectives of the standard and to impose such rules.

The proposed standard contained provisions for a medical surveillance program which combined periodic biological monitoring with preplacement and followup medical examinations. In general, the proposed standard contained provisions for a medical surveillance program which combined periodic biological monitoring with preplacement and followup medical examinations. OSHA believes that this program is necessary to detect early medical effects associated with exposure to lead. The final standard requires employers to provide persons working in lead areas with filtered air lunchrooms which are readily accessible. Employers must also assure that employees wear protective clothing, unless cleaned beforehand. OSHA finds that employees have a clean place to eat, free from the toxic substance with which they work all day. Filtered air lunchrooms shall shield employees from the dangers of food which would otherwise become contaminated by lead dust, mist or fume. (Tr. 2074) Employees are required to wear clothing, unless cleaned beforehand, that maintains provisions for a medical surveillance program.

The final standard requires employers to provide persons working in lead areas with filtered air lunchrooms which are readily accessible. Employers must also assure that employees wear protective clothing, unless cleaned beforehand. OSHA finds that employees have a clean place to eat, free from the toxic substance with which they work all day. Filtered air lunchrooms shall shield employees from the dangers of food which would otherwise become contaminated by lead dust, mist or fume. (Tr. 2074) Employees are required to wear clothing, unless cleaned beforehand, that maintains provisions for a medical surveillance program.

Employers are required to prohibit smoking, eating, applying cosmetics and the presence of tobacco products, food stuffs, or cosmetics in all work areas except those designated. (Tr. 6459) This prohibition will prevent unnecessary contamination of food or tobacco products caused by exposure to lead dust or fumes within the work area. It also decreases the likelihood of lead absorption in employees due to ingestion or inhalation of products contaminated with lead within the work environment.

The standard reiterates specifications in section 1910.141 pertaining to the type of change room an employer must provide. OSHA believes it is essential that employees have separate storage areas for street and work clothing to prevent cross-contamination between the two. This provision coupled with showering and the prohibition on wearing work clothing home will minimize employee exposure to lead after the work shift ends because it reduces the period in which work clothes coated with lead dust may be worn.

Employers are also required to assure that employees exposed to lead during their work shift shower before leaving the plant and do not leave wearing work clothing. Showering reduces the worker's period of exposure to lead and removes lead particles which accumulate on the skin and hair. Employees are not permitted to leave the plant wearing any work clothes, including shoes and undergarments, because this practice would negate any advantage gained by showering.

During the hearings, some employers protested that this provision is impractical because it would require close supervision of employees, but none work all day. Filtered air lunchrooms and wash facilities have already instituted facilities similar to those required in the final standard. (Tr. 1231; 2070; 2943; 2959, 6583, 6585) The standard's primary mechanisms of reduction of airborne concentrations of lead and sources of ingestion, by facilitating the early detection of medical effects associated with exposure to lead. Control of airborne lead below the permissible exposure limits 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 many years working in the lead industries, (2) who have additional, uncontrolled sources of lead exposure, (e.g., non-occupational), (3) who exhibit abnormal variation in lead absorption rates, or (4) who have specific 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, and periodic medical surveillance of individual workers may help detect those failures.

The proposed standard contained provisions for a medical surveillance program which combined periodic biological monitoring with preplacement and followup medical examinations. OSHA has reviewed all the rulemaking evidence on this subject and has concluded that the final standard, while similar to the proposal, contains a medical program that is reasonably necessary and appropriate for the early detection of the effects associated with overexposure to lead. OSHA has deleted the unnecessary or objectionable aspects of the proposal and supplemented it with only those medical tests and procedures which the lead record documents are necessary to identify early indications of lead-related disease in the affected systems. The final standard also contains provisions which will maximize voluntary and willing participation and will foster employee confidence in the program, both of which are often lacking in current industrial medical programs (Ex. 343).

The employer's obligation to commence a medical surveillance program for an employee is triggered by a determination that the employee's exposure exceeds the action level for more than 30 days a year. Some firms in the primary smelting industry claimed that all employees working with lead should be subject to periodic medical surveillance without regard to air lead.
levels. (Ex. 3(67); Ex. 3(103), p. 59; Ex. 3(71), p. 15.) This may be desirable for lead industries where lead exposure is so pervasive, but the OSHA standard applies to many industries in which lead exposure is relatively low, infrequent, or incidental. OSHA believes there is no need or justification for employees whose TWA exposure levels are below the action level, or above the action level for less than 30 days a year, to undergo medical surveillance or for their employers to bear the related costs.

Upon completion of initial air monitoring, the employer must begin the medical surveillance program for all covered employees. The standard does not make participation in the medical surveillance program mandatory for the employee. The employer's obligation is to "provide" and "make available" the medical tests and procedures as required. Where employee confidence in the medical program exists, refusal to participate should be minimal. (See discussion of mandatory medical examinations in the MRAP Attachment.)

Initial biological monitoring and medical examinations must be completed no later than 180 days from the effective date thus allowing 90 days from the completion of air monitoring. (See paragraph (r) of the regulation.) In most cases, this extended startup date should compensate for the predicted short-run unavailability of medical and technical personnel, and OSHA believes the problems will be minimal since some type of medical surveillance program is commonplace in most industries where lead is handled, even in the smallest firms.

The standard requires that priority for medical surveillance be given to employees who are at the greatest risk from continued exposure. This determination should be made on the basis of the air monitoring results, along with any other information the employer may possess, such as past medical or air monitoring records, employees' job tenure in the lead industries, etc. This should assure that those employees most in need of medical surveillance obtain it as soon as possible so that remedial action may be taken if necessary.

Biological monitoring required by the final standard is somewhat different than that in the proposal. The proposal would have combined blood lead level monitoring (PbB) with monitoring of urine lead levels (PbUr) or urine ALA levels (ALAUr); urine measurements have been deleted and replaced by monitoring of zinc protoporphyrin (ZPP) levels. The preamble to the proposal expressed the medical community's doubt about the usefulness of urine monitoring; with a few exceptions (Tr. 4356), the consensus in the record was in favor of deleting urine measurements and adding ZPP monitoring. (Tr. 1309, 1311-12, 2555, 2732, 2771, 2877, 4358, 4735.) PbB's have been the traditional means of biological monitoring in the lead industries. It is a relatively accurate measurement of current absorption, and almost all dose-response studies of lead-related disease have used PbB's as an index of exposure dosage. (Tr. 1311.) Hence, OSHA has had to rely on PbB's to establish the PEL and now retains PbB's as an essential part of the biological monitoring program. (Ex. 284A, p. GL1.) However, the advent of simplified ZPP monitoring through the use of the hematofluorometer has convinced OSHA that ZPP monitoring, in concert with PbB's, will provide, at minimal cost, a greatly improved biological monitoring program over PbB's alone. PbB measures only absorption on day 1; ZPP gives an indication of the biological effect of absorption on heme synthesis.

Heme is the basic component of both hemoglobin, which functions in the transport of oxygen from the lungs to the body cells, and the cytochromes, which function in the respiration of the individual cells. Therefore, any interference with heme synthesis may create a considerable adverse health hazard. (Tr. 429.) Lead is one substance known to produce such interference, causing changes, not only in heme production, but also in the level of some of the circulation intermediate metabolites formed during heme synthesis. These metabolites include delta-aminolevulinic acid dehydratase (ALAD), delta-aminolevulinic acid (ALA), coproporphyrin, and zinc protoporphyrin (ZPP). (Ex. 275.) Zinc protoporphyrin is actually the result of the inhibition of an enzyme, ferrochelatase, which catalyzes the insertion of an iron molecule into the protoporphyrin molecule, which then becomes heme. If hindered, then, the iron molecule, zinc protoporphyrin, and then, having a great affinity for protoporphyrin, takes the place of the iron, thus forming ZPP. (Tr. 435.) Whereas the heme molecule serves in a very necessary body function, ZPP is useless to the body, but it is the most easily measured heme metabolite. (Tr. 436; Ex. 343.)

Measuring the level of ZPP in the blood is one means of determining the external toxic effect of lead absorption, relative to heme synthesis impairment. In fact, the level of ZPP is a far superior indicator of lead toxicity than the level of blood lead itself, which actually only measures the level of indirect exposure. (Tr. 343) Furthermore, an elevation in the level of circulating ZPP may occur at a very low blood lead, i.e., 20-30 µg/100 g in some workers. (Ex. 262.)

Eventually, the blood lead level has reached 40 µg/100 g, however, there is a precipitous rise in the ZPP value from its normal range of less than 100 µg/100 g whole blood. (Ex. 105E) As the evidence within the record indicates, there is a strong correlation between the level of ZPP and other biological parameters, blood lead and ZPP. In fact, it has been shown that after the blood lead level reaches 40 µg/100 g, any arithmetical increase in blood lead will correspond to an exponential increase in ZPP. (Ex. 105E; Ex. 23(30); Tr. 438.) It is possible that the ZPP test may be the key to the multiple clinical effects of lead toxicity on several body systems, which become apparent as the exposure continues. (Tr. 466; Tr. 2432.)

Substantiation for this is demonstrated by the correlation between elevated ZPP and other measurable biological parameters, including blood lead. For instance, it is reasonable to expect a lowered hemoglobin level as ZPP values increase, and significant correlations have been found between reduced hemoglobin and elevated ZPP. (Ex. 118C; Ex. 105E; Ex. 23(39).) Elevations in blood urea nitrogen (BUN) and serum creatinine (S-Creat) have also been found to correlate well with increased ZPP levels. Since both BUN and S-Creat are biological indicators of kidney damage, the monitoring of ZPP may serve as an early herald of renal toxicity. (Ex. 23(39).) There is also some evidence available that elevated ZPP values are found in workers with peripheral neuropathy and CNS symptoms. (Ex. 23(14); Tr. 2432; Ex. 23(39).)

The accumulation of ZPP in the red blood cells quite clearly indicates a chronic interference by lead with heme synthesis. (Ex. 24(2).) In practice, the monitoring of ZPP on a bi-monthly basis will provide an index of lead effect, as well as lead exposure. (Tr. 1312.) Moreover, in contrast to blood lead, the ZPP test is a quick, efficient, economic and safe means of monitoring workers. By utilization of the hematofluorometer, the ZPP test can be conducted at the worksite, and the workers can almost instantly see accurate test results. (Ex. 343; Tr. 433; 609.)

Finally, as the result of the variability of lead absorption and its subsequent distribution within the body, blood lead levels fluctuate over short time spans, whereas ZPP levels remain relatively stable. (Ex. 343; Tr. 2445.) For example, ZPP, once it becomes the heme substitute has been shown to remain there for the lifetime of the red blood cell (about 120 days). The
rate of production of ZPP is, however, a function of the concentration of lead within the bone marrow—the primary site not only of heme synthesis, but of the blood cells themselves. (Tr. 2445.)

During their testimony NIOSH discussed some of the weaknesses of the ZPP method:

One of the major problems with ZPP is that this is a very recently developed test and only limited data are available on blood lead-ZPP correlations. Further, ZPP may not detect elevated levels if they occur. NIOSH could increase costs to the employer and fail to protect the employee. Testimony in the record reflects the participants' concern that NIOSH Insure that blood lead levels are determined accurately. LIA stated: "Laboratory control and certification procedures are essential." (Ex. 335, p. 88) and similarly, the USWA argued:

Testimony at the hearings strongly suggests significant discrepancies in blood lead results depending on who is conducting the biological monitoring. While it is impossible to police all biological monitoring, some further beefing up of the "Accuracy" language is warranted to cut down on any attempts at cheating. Accordingly, we suggest that, at a minimum, blood lead samples be analyzed in established laboratories which are certified by the Center for Disease Control. (Ex. 452, pp. 52, 61.)

In addition, testimony from the Motor Vehicle Manufacturers Association (Ex. 402, p. 10), Drs. Wolfe (Tr. 3805-07) and Teltiebaum (Tr. 330-92) and the Amalgamated Clothing and Textile Workers Union (Tr. 7280) supported the recommendation that laboratory certification should be required. OSHA is concerned about the evidence which demonstrates the inadequacies in the proficiency records in blood lead determinations, and therefore based on the recommendations cited in the record will require blood lead samples be analyzed in laboratories which are licensed by the Center for Disease Control or which have received satisfactory grades in proficiency testing by CDC in the previous year. The accuracy requirements in the proposal will be adjusted to coincide with the accuracy requirements of CDC, i.e. 15 percent or 6 \( \mu g/100 \) ml, whichever is greater.

The standard requires medical examinations to be provided to employees only if they are in the process of being exposed to lead. If the employee has developed symptoms commonly associated with lead-related disease, or if an employee desires advice concerning the effects of lead on reproductive capacity, or if a pregnant or breathing when wearing a respirator. Additional examinations must be made available when an employee is removed from exposure or otherwise limited under paragraph (k) of the regulation. The content and frequency of these examinations is to be at the discretion of the physician. Upon request of an employee, however, a pregnancy test or male fertility test (at a minimum, analysis of sperm motility, and morphology) must be provided. These tests will facilitate the protection of reproductive capacity.

The medical surveillance provisions of the final standard contain a multiple physician review mechanism which gives workers an opportunity to obtain a second and possibly third opinion regarding the medical determinations
made pursuant to the standard. An employee may designate a second physician to review any findings, determinations or recommendations of an initial physician chosen by the employer. Efforts are to be made to resolve any disagreement which may arise between the two physicians. Should they be unable to agree, a third physician they select will resolve the disagreement. OSHA’s reasons for the provision of this review process are two-fold: first, to broaden and strengthen the basis for medical determinations in situations where a worker questions the results of the initial examination or consultation; and second, to assure employee confidence in the soundness of medical determinations made pursuant to the standard. OSHA views the multiple physician review mechanism as an important element of the lead standard’s medical surveillance program both due to the importance attached to medical surveillance by the Act, and due to the crucial role medical surveillance will play in the operation of the standard’s medical removal protection program.

Medical surveillance pursuant to section 6(b)(7) of the Act must be provided by employers without cost to employees. Since the multiple physician review mechanism will be one means by which medical surveillance is provided to an employee, employers must bear the expense of this mechanism when it is used. In practice, the costs of this mechanism will not be burdensome, particularly since employers will have substantial control over the frequency of its use. Where employers carefully structure and administer medical surveillance programs which engender, merit and maintain worker confidence, workers will see no need to seek a second medical opinion.

OSHA’s first reason for the provisions of a physician review opportunity is to strengthen and broaden the basis for medical determinations made under the standard in situations where a worker questions the results of an initial medical examination or consultation. The education and training provisions of the lead standard should assure that workers become knowledgeable in the nature and symptoms of the numerous lead-related diseases. Thus, when a worker disputes the results of an initial medical examination or consultation conducted by an employer-retained physician, adequate justification will exist for seeking a second medical opinion.

Two medical doctors testified in the lead proceeding that multiple physician review is a desirable diagnostic device as a general matter (Tr. 7375-7376; 7978-7980) for such reasons as the inherent biological variability of disease. (Tr. 7393-7394) The Black Lung medical surveillance and transfer program of the 1969 Coal Act includes multiple physician review of X-rays in all cases to improve the quality of medical diagnosis. (Tr. 7781-7782; 7786-7787; 7992-7993; Ex. 795A(2), p. 31) In light of the high percentage of trained and experienced occupational physicians in this country, and the number and varied nature of lead-related diseases, no one medical specialty is uniquely suited to provide error-free diagnoses under the lead standard. Accurate medical determinations under this standard are vital due to the interdependence between medical surveillance and the preventive medical removal protection program. Additionally, the facts that the standard’s PEL is not a completely safe exposure level, that many lead workers have years of substantial prior exposure to lead, and that some lead-related diseases are reversible if detected at an early stage, support a conclusion that physician review would be appropriate in all cases of medical surveillance under the lead standard.

Rather than add the additional opinions in all cases, however, OSHA has limited the opportunity for physician review to situations where a worker questions the findings, determinations or recommendations of the initial physician. OSHA’s choice of a multiple physician review mechanism, as opposed to some other mechanism, is based on the common and increasing use of multiple physician participation in the formation of medical determinations. A formal physician review process is incorporated not only in the Coal Act program but in at least two other federal programs. A multiple physician review mechanism appears in physical qualifications and examinations regulations concerning motor vehicle drivers subject to the Federal Motor Carrier Safety Act. (Tr. 8098; Physical Qualifications and Examinations, 49 CFR sections 391.41-391.49 (1977)) A similar review process operates under medical care and surveillance regulations of the Longshoreman’s and Harbor Workers’ Compensation Act. (Medical Care and Supervision, 20 CFR sections 702.401-702.422 (1977)) In addition, recent congressional attention has been focused on the benefits to be gained from review as to the advisability of surgical procedures. (Quality of Surgical Care: Hearings before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, 95th Cong., 1st sess. (1977)) The Department of Health, Education, and Welfare strongly promotes the use of second medical opinions in this regard (Hearings before the Subcommittee on Oversight and Investigation, supra, pp. 227-232 (statement of Halle Champion, Department of Health, Education, and Welfare Undersecretary)), and in recent weeks has launched a national campaign to urge patients to get a second doctor’s opinion before surgery. (Washington Post, Sept. 14, 1978, p. A17, col. 2)

Multiple physician review mechanisms are also widely used in the private sector. This mechanism frequently appears in conjunction with physical examination requirements contained in collective bargaining agreements (Ex. 365, p. 37), and commonly occurs in the determination of a worker’s eligibility for a disability pension. (Tr. 7652, 7664-7666; Ex. 418C, pp. 11-12) The lead record contains some twenty specific examples of multiple physician review mechanisms. (Tr. 8224; Ex. 157, pp. 10-11; Ex. 158, p. 75; Ex. 365, pp. 15-16; Ex. 369, p. 18; Ex. 379A, Att. 1; Ex. 404B, p. 4; Ex. 404B (D-2), pp. 18-17; Ex. 404B (D-4), pp. 26-27; Ex. 404B (D-5), p. 53; Ex. 404B (D-7), p. 13; Ex. 404B (D-9), p. 132; Ex. 415A, p. 23; Ex. 415B, p. 74; Ex. 426, pp. 18-19; Ex. 427, p. 59; Ex. 430C (D-1b), Sections 70B-79; Ex. 430D (D15), Art. 27; Ex. 430H, pp. 64-65) The multiple physician review mechanism adopted by the lead standard incorporates characteristics common to many of these private sector and federal programs: The worker has an opportunity to select a second examining physician if dissatisfied with the results of the first examination, and if the two physicians disagree, he chooses a third physician to resolve the differences of opinion. OSHA is convinced that the use of this multiple physician review mechanism will significantly improve the quality of the medical determinations provided under the lead standard. OSHA’s second reason for the provision of a physician review opportunity is to assure employee confidence in the soundness of the medical determinations made pursuant to the lead standard. Considerable evidence in the lead record documents the fact that workers question the objectivity of some employer-retained physicians. Furthermore, since there is documentation in the lead record of specific abuses by a portion of employer-retained physicians, OSHA has concluded that the problem cannot be ignored in the context of this standard.

Attachment C to the standard concerning Medical Removal Protection discusses the major importance of meaningful worker participation in the medical surveillance program created by this standard. The standard’s ability to prevent material impairment to worker health and functional capacity—particularly with respect to reproductive health, and the health of the long term lead worker—will significantly depend on workers trusting and
confiding in examining physicians. OSHA adopted the multiple physician review mechanism as a means of providing workers with an opportunity to obtain independent review of the determinations of physicians they do not trust. More importantly, use of this review mechanism should serve to engender worker trust in the process of correcting inadequate medical determinations and to expose a major deficiency in the employer's medical surveillance program.

A substantial body of testimony in the lead proceeding focused on the lack of worker trust and confidence in some company doctors. (Tr. 2210-2211, 4254, 4255, 6217-6219, 4284, 4285, 7976-7979, 7642, 7661-7692, 7976-7978, 8053, 8096, 8221-8223, 8241-8245; Ex. 167, pp. 2-4; Ex. 343, pp. 91-97, 103-104; Ex. 393, p. 6, Ex. 450B, pp. 3-5; Ex. 452, p. 66. The company doctor does not have the same power as the employer's agent of the employer, as not a neutral physician maintaining a close doctor-patient relationship with the employee. (Tr. 4284, 4780-4782, 4851, 5088-5090, 6032-6033, 7267-7279, 7623, 8053, 8223, 8240, 8245-8247; Ex. 393, p. 6; Ex. 450B, pp. 3-5.) The company doctor is sometimes viewed as an employer representative charged with minimizing the costs of successful workers' compensation claims, the opposite of a neutral physician who is bound to devote work health to the employee. (Tr. 4284, 4809-4811, 7276-7279, 8096; Ex. 379A, p. 12; Ex. 411H(4), p. 5-6.) The lead record contains numerous reports of employer physicians refusing to divulge to an employee his or her blood lead level (Tr. 2569, 4775-4774, 4854-4855, 8076; Ex. 167, pp. 2-4; Ex. 450B, p. 5; See also, Tr. 4811), as well as numerous reports of employer physicians making gross misrepresentations of the toxic properties of lead—for example, statements to the effect that one is not lead-poisoned until one's teeth fall out, or Blacks are not susceptible to high blood lead levels, or a lead level of 20 is not lead-poisoned until irreversible nervous system damage occurs. (Tr. 533-535, 2169-2172, 4178-4179, 4757-4759, 4773-4774, 4806-4807, 5094-5095; Ex. 167, pp. 2-4.) Additionally, there was testimony of employer physicians reporting the results of medical examinations not to the worker, but directly to the employer such that the worker learned of his or her health status from the company's medical director rather than from the examining physician. (Tr. 4833, 8096.) Finally, evidence in the record points to a practice of some employer physicians failing to report crucial adverse health effects information either to affected employees or to the broader medical community. (Tr. 5007-5008, 5644-5647; Ex. 379B, p. 4.)

In addition to the above, the lead record documents numerous instances of the practice by employers of prophylactic chelation, a grossly improper medical procedure dependent upon the active participation of the employee-retained physician. (Tr. 222, 225-240, 539-532, 1111-1112, 1272-1273, 2169-2172, 2200-2201, 2537-2539, 2542, 2876-2881, 2983(12)-2983(17), 4009, 5002, 5022, 6026, 6043-6045, 6878-6879, 6861; Ex. 20; Ex. 84, p. 9; Ex. 86H; Ex. 117A; Ex. 118D; Ex. 165; Ex. 167, pp. 5-7; Ex. 246A.) The practice has been condemned for several decades by the LLAMA. (Ex. 4780-4782, 7276-7279, 8096, 8221-8223, 8241-8245; Ex. 167, pp. 2-4; Ex. 343, pp. 91-97, 103-104; Ex. 393, p. 6, Ex. 450B, pp. 3-5; Ex. 452, p. 66. The company doctor does not exercise a power to the same extent as the employer-retained physician, then workers will be much more likely to trust the company doctor in the future. If the choice of a second and third physician repeatedly results in medical determinations greatly at variance with that of the employer-retained physician, then the multiple physician review mechanism will have served the beneficial purposes of (1) correcting inadequate medical determinations, and (2) exposing a major deficiency in the employer's medical surveillance program.

The preceding paragraphs explain in some detail OSHA's reasons for the inclusion of a multiple physician review mechanism in the lead proceeding. See the new component of OSHA health standards. (See, Medical Requirements, 40 FR 37650, 37658 (July 22, 1977), 29 CFR, §1910.411(f); Taylor Diving and Salvage Co., v. Department of Labor, Civ. No. 77-2875 (D. D.C., filed Sept. 16, 1977.) The discussion concerning the Inclusion of this mechanism, however, is not implicit criticism of the general medical community. Based on the lead record, OSHA has no cause to conclude that a majority of employer-retained physicians are not sincerely devoted to worker protection. Even worker representatives most critical of some "company doctors" agree that this mechanism is an important component and concerned corporate physicians. (Tr. 4281, 5088-90.) The multiple physician review opportunity contained in the final standard addresses problems presented by a minority of physicians. The record is convinced that there are situations where employer-retained physicians have a close doctor-patient relationship with lead exposed employees, and the employer-retained physician gains a close relationship of trust and confidence from a company official, not from the employee concerned. (Tr. 4281, 5088-90.) The multiple physician review mechanism operates in a simple and straightforward fashion. It is important initially to stress that this mechanism is meant to apply to all forms of medical surveillance provided under the standard. If an employee's past, present, or future exposure to lead is a relevant consideration in the examination of the surveillance program, then the opportunity for an additional medical opinion must be provided.

The multiple physician review mechanism commences after an initial medical examination or consultation provided by a physician chosen by the employer. OSHA recognizes the value to employers and employees' alike of the mechanism operating in an expeditious fashion, and thus has established an explicit criteria for the beginning of the process. After an initial physician conducts an examination or consultation pursuant to the standard, the employer must promptly notify the employee of his or her right to seek a second medical opinion. This notification need be no more than an oral reminder of the existence and content of this multiple physician review mechanism. After this notification has been given, the employee must condition its participation in, and payment for, the
rules and regulations

mechanism upon the employee acting within 15 days after receipt of the foregoing notification, or receipt of the physician's written opinion, whichever is later. Before or within this 15-day period the employee may seek a second medical opinion. The employee shall also assure that efforts are made for the two physicians to resolve any disagreement. OSHA expects that the two physicians would as a professional matter communicate with each other to resolve their differences, but it would make this expectation explicit. This professional interaction among peers should in most cases resolve any differences between the two physicians. The preceding elements of the multiple physician review mechanism assure that if differences of opinion remain, these differences are likely to be genuine and substantial.

Where the first two physicians have been unable to quickly resolve any differences of opinion with respect to an employee, then it is necessary for a third qualified physician to resolve the dispute. It is important that this third physician be competent to resolve the dispute, thus the standard provides that the third physician shall be designated by the employer and the employee jointly through their respective physicians. It is the responsibility of the employer and the employee to assure that a third physician is selected, but the selection is to be made by the two prior physicians. Since the third physician is chosen by the joint endorsement of the two prior physicians, the professional competence of the third physician will be assured.

The standard provides that the third physician have a full opportunity to review the findings, determinations, and recommendations of the two prior physicians by conducting such examinations, consultations, and laboratory tests as the third physician deems necessary. The standard incorporates the expectation that the third physician will consult with the two prior physicians, and upon request the employer must supply the same information to the third physician, given to the initial physician. The third physician is responsible for making a medical determination, his opinion to the employer, which will operate to resolve the disagreement between the earlier physicians. The standard finally requires that the employer act in a manner consistent with the findings, determinations, and recommendations of the third physician, and if the employer clearly acts to frustrate the resolution of the multiple physician review mechanism, the employer may safely assume that the employee no longer desires the peer review process to continue.

Employer representatives raise in the lead proceeding a wide variety of objections to the multiple physician review mechanism. (Tr. 7461-7462, 7481-7482, 7527-7528, 7543-7546; Ex. 354(F), p. 3; Ex. 354(II), p. 3; 354(O), pp. 3-4; Ex. 354(V), p. 4; Ex. 354(W), p. 1; Ex. 354(Y), p. 5; Ex. 354(AA), pp. 13-18; Ex. 354(FF), p. 3; Ex. 354(GG), p. 2; Ex. 354(HH), p. 1; Ex. 356, pp. 13-14; Ex. 356A, pp. 4-5; Ex. 453, pp. 32-36; Ex. 457, pp. 35-36; but see, Tr. 8460-8461, Ex. 354(P), p. 3; Ex. 354(II), p. 3; See also, Ex. 354(M), p. 2) Worker representatives, with one exception, strongly endorse adoption of the
mechanism. (Tr. 7202-7205, 7246-7247, 7264, 7609-7610, 7691-7692, 7976-7980, 8072-8074, 8224-8226; Ex. 35(A)(D), p. 5; Ex. 372, pp. 8-9; Ex. 374, pp. 139-140; Ex. 375, pp. 4-5; Ex. 450B, pp. 5-10; Ex. 452, pp. 63-68; contra, Ex. 395, p. 3; See also Ex. 464B, p. 2) Many of the employer objections have been dealt with by the preceding paragraphs explaining the justifications for, and operation of, the multiple physician review mechanism. The thrust of most employer objections was that this review process is unworkable and unduly burdensome. Were the physician review process adopted by the final standard a completely new and untried concept, then it would be appropriate for OSHA to discuss at greater length each specific criticism. As discussed earlier, however, the multiple physician review mechanism as adopted by this standard is currently in widespread use by a variety of collective bargaining units. No evidence was offered suggesting that any of these existing mechanisms have proven unworkable or overly burdensome. In view of this, OSHA rejects employer criticisms of the final standard’s peer-review process as being mere allegations unsupported by concrete evidence—evidence which employers could easily have brought forward had it existed. OSHA is convinced that the multiple physician review mechanism can and will substantially add to the health protection afforded workers by this lead standard, and thus included this mechanism in the final standard.

The medical surveillance section of the standard includes a provision stating that the employer and employee or authorized employee representative may agree upon the use of any expedient alternate physician determination procedure which is not founded upon an employer’s unilateral choice of the examining physician. (Tr. 8243-8244, 8271-8272; Ex. 40(CD); Ex. 452, p. 68) For example, the Parke Davis & Co. formula that some employers and unions may decide in cases of dispute over the use of the multiple physician review mechanism in lieu of the multiple physician review mechanism can and will substantially add to the health protection afforded workers by this lead standard, and thus included this mechanism in the final standard.

The medical surveillance section of the standard includes a provision stating that the employer and employee or authorized employee representative may agree upon the use of any expedient alternate physician determination procedure which is not founded upon an employer’s unilateral choice of the examining physician. (Tr. 8243-8244, 8271-8272; Ex. 40(CD); Ex. 452, p. 68) For example, the Parke Davis & Co. formula that some employers and unions may decide in cases of dispute over the use of the multiple physician review mechanism in lieu of the multiple physician review mechanism can and will substantially add to the health protection afforded workers by this lead standard, and thus included this mechanism in the final standard.

The medical surveillance section of the standard includes a provision stating that the employer and employee or authorized employee representative may agree upon the use of any expedient alternate physician determination procedure which is not founded upon an employer’s unilateral choice of the examining physician. (Tr. 8243-8244, 8271-8272; Ex. 40(CD); Ex. 452, p. 68) For example, the Parke Davis & Co. formula that some employers and unions may decide in cases of dispute over the use of the multiple physician review mechanism in lieu of the multiple physician review mechanism can and will substantially add to the health protection afforded workers by this lead standard, and thus included this mechanism in the final standard.

The medical surveillance section of the standard includes a provision stating that the employer and employee or authorized employee representative may agree upon the use of any expedient alternate physician determination procedure which is not founded upon an employer’s unilateral choice of the examining physician. (Tr. 8243-8244, 8271-8272; Ex. 40(CD); Ex. 452, p. 68) For example, the Parke Davis & Co. formula that some employers and unions may decide in cases of dispute over the use of the multiple physician review mechanism in lieu of the multiple physician review mechanism can and will substantially add to the health protection afforded workers by this lead standard, and thus included this mechanism in the final standard.

The medical surveillance section of the standard includes a provision stating that the employer and employee or authorized employee representative may agree upon the use of any expedient alternate physician determination procedure which is not founded upon an employer’s unilateral choice of the examining physician. (Tr. 8243-8244, 8271-8272; Ex. 40(CD); Ex. 452, p. 68) For example, the Parke Davis & Co. formula that some employers and unions may decide in cases of dispute over the use of the multiple physician review mechanism in lieu of the multiple physician review mechanism can and will substantially add to the health protection afforded workers by this lead standard, and thus included this mechanism in the final standard.

The medical surveillance section of the standard includes a provision stating that the employer and employee or authorized employee representative may agree upon the use of any expedient alternate physician determination procedure which is not founded upon an employer’s unilateral choice of the examining physician. (Tr. 8243-8244, 8271-8272; Ex. 40(CD); Ex. 452, p. 68) For example, the Parke Davis & Co. formula that some employers and unions may decide in cases of dispute over the use of the multiple physician review mechanism in lieu of the multiple physician review mechanism can and will substantially add to the health protection afforded workers by this lead standard, and thus included this mechanism in the final standard.

The medical surveillance section of the standard includes a provision stating that the employer and employee or authorized employee representative may agree upon the use of any expedient alternate physician determination procedure which is not founded upon an employer’s unilateral choice of the examining physician. (Tr. 8243-8244, 8271-8272; Ex. 40(CD); Ex. 452, p. 68) For example, the Parke Davis & Co. formula that some employers and unions may decide in cases of dispute over the use of the multiple physician review mechanism in lieu of the multiple physician review mechanism can and will substantially add to the health protection afforded workers by this lead standard, and thus included this mechanism in the final standard.
Penicillamine or Cuprimine also has some very serious adverse effects which include the nephrotic syndrome and aplastic anemia. It should not be given to patients allergic to penicillin because of cross-sensitivity between penicillin and penicillamine. Penicillamine has a plethora of other potential adverse effects detailed in the package insert which comes with capsules of Cuprimine. In part, that insert warns against its use during pregnancy because of penicillamine's affinity for metals and cystine and its effect on collagen. Also, it advises performing routine urinalyses, white and differential counts, hemoglobin determinations and direct platelet counts as well as frequent liver and kidney function tests during therapy. Penicillamine causes allergic skin reactions, including urticaria and may cause eye cataracts. Other adverse reactions that have been reported include hepatic dysfunction, tinnitus, falling hair, thrombocytopenia, thrombotic thrombocytopenic purpura, bone marrow hypoplasia, leukopenia and granulocytopenia ranging in severity from asymptomatic and reversible to agranulocytosis with fatalities. Thrombocytopenia, pancreatitis, central nervous system manifestations, sometimes with ulceration of the mucous membrane; polyneuropathy; mammatory hyperplasia; peptic ulcer; myasthenia; cholestasis performed anomalies have been reported but are unusual. A syndrome closely resembling disseminated lupus erythematosus and periarteritis nodosa, as well as severe and ultimately fatal glomerulonephritis and intraalveolar hemorrhage (Goodpasture's syndrome). Iron deficiency anemia has also been reported but is unusual. Reversible optic neuritis and chellosis, possibly connected to younger men who have nuclear inclusion bodies in their renal table lining cells. These data suggest that chelation therapy reduces the ability of the kidneys to protect themselves against the toxic effects of lead by virtue of the action of chelating agents in removing the lead-induced inclusion bodies. This conclusion is further supported by observations that renal tubular dysfunction may follow EDTA administration in lead poisoned children. (Ex. 86 H, p. 7, 8)

Liis and Fishbein, in their review, also evaluated the effects of CaEDTA. They noted the side effects associated with the use of this drug but concluded that most of these effects could be avoided if the drug was used appropriately. They stated:

"Edetate disodium calcium has been shown in terms of lead elimination and excretion, to be superior to both dimercaprol and penicillamine. The mobilization as a noninvolvement of calcium, and the maximum effect is reached six hours after intravenous administration, when 95 to 98% of the total amount has been excreted. When the therapeutic dosages of 50 mg/kg/day are not exceeded, the rate of administration is less than 20 mg/min, and the course of therapy restricted to five to seven days, practically adverse side effects are not observed.

Renal damage is the most important side effect associated with edetate disodium calcium chelation therapy; a small number of cases of acute tubular necrosis were described in the early days of edetate disodium calcium therapy. Most of these were due to very large doses, rapid administration, or severe preexisting renal disease (such as hypercalcemia and multiple myeloma).

Various mucocutaneous lesions have been described in patients after prolonged administration of disodium edetate and edetate disodium calcium; one possible explanation considered was zinc depletion.

Treatment of lead poisoning with edetate disodium calcium therapy in five-day courses, with dosage and rate of administration not exceeding those previously mentioned and repeated if necessary after a free interval of two to five days, has been successful and has not been associated with clinically significant side effect. (Ex. 118D)

Wedeen concurred with Liis' and Fishbein's conclusions concerning the acceptability and appropriateness of chelation therapy when administered therapeutically for treatment of lead poisoning. (Tr. 1745-1746)

The decision to use chelating agents involves a weighing of the risks of the adverse effects of use against the benefits of use. The medical community has defined three categories of instances under which chelation might be used and has generally established what is acceptable practice in each. "Therapeutic" chelation is the use of chelating agents for the treatment of the frank symptoms of lead poisoning. "Diagnostic" chelation is the use of chelating agents to assist in making the diagnosis of lead poisoning or lead induced disease. "Prophylactic" chelation was defined by Bridbord and Blejer "both as the routine use of chelating or similarly acting drugs to prevent elevated blood lead levels in workers who are occupationally exposed to lead or as the use of these drugs to routinely lower blood lead levels to predesignated concentrations believed to be safe." (Ex. 86 H, p. 19)

OSHA agrees with this definition and emphasizes that an employer who hospitalizes an asymptomatic worker and has chelation carried out by a physician solely to reduce the worker's blood lead level will be performing prophylactic chelation. The use of a hospital and a physician is not the definition of therapeutic chelation. Routine chelation to reduce blood lead level is unacceptable whatever the setting.

The risks and benefits vary with the circumstances of use. Thus, in different circumstances the use of chelating agents might or might not be considered medically appropriate. With reference to therapeutic chelation, Bridbord and Blejer stated in their review that: "Most authorities agree that chelating or similarly acting agents have a proper place in the therapy of the acute symptomatology of severe lead intoxication, a condition accompanied by pronounced gastrointestinal, neurologic and other symptoms and signs." (Ex. 86 H, p. 1)

Those who testified were generally in agreement with this statement though there were some variations as to what witnesses felt was the degree of severity of symptoms necessary for instituting chelation therapy. It was also generally agreed that chelation must be done only under careful medical supervision involving specific monitoring to minimize the risks involved.

Blejer testified extensively concerning the circumstances under which therapeutic chelation should occur:

The therapeutic use of chelating agents on occupationally exposed individuals is warranted only when there is frank and, in my opinion, severe symptomatology of lead intoxication such as anemia, lead encephalopathy and the still-common lead colic. In most cases, it is my professional opinion that the health risks of administering che-
lating agents far outweigh the benefits of relieving mild to moderate symptomatology. In such cases, “natural detoxing,” i.e., removal from exposure, plus symptomatic/supportive treatment will achieve the same end results more safely and probably just as quickly.

Moreover, as demonstrated and published recently by Fishbein, Mirer, and Bridbord, defined by OSHA and recommendations for lead abatement, toxicology should therefore be used in the absence of overt symptomatology. In all of these instances, however, the affected worker must be monitored closely by physicians expert or competent in the treatment of lead poisoning, with the treatment administered in appropriate medical facilities and, in the case of intravenous CaEDTA administration, on an in-patient basis. Needless to add, any such treatment would be thoroughly unproductive and essentially wasted if the worker is allowed to return to an uncontrolled lead exposure at the workplace. As stated previously—and it bears repeating—the treatment will only constitute secondary rather than primary prevention.” (Ex. 53, p. 13, 14)

Fishbein took a position similar to Blejer's stating:

Chelation therapy should be resorted to only in cases of acute exacerbations in the course of chronic lead poisoning, such as encephalopathy, lead colic, or rapid and threatening increase of blood lead levels, and should always be done under careful medical supervision and after cessation of lead exposure. (Tr. 2643)

The use of chelating agents as a test for the existence of lead induced kidney disease as described by Wedeen, is a new and experimental diagnostic use of chelating agents. Blejer discussed a more conventional use of these agents for diagnostic purposes and suggested that in many cases diagnosis is possible without resort to the risks of chelation. (Ex. 53, p. 12-13) OSHA concurs in the view that in appropriate circumstances chelation may be used for therapeutic and diagnostic purposes.

The third type of use of chelating agents is “prophylactic” use. Prophylactic chelation is prohibited by the standard.

There was a remarkable degree of consensus in the testimony concerning this aspect of the proposal. Condensation of prophylactic chelation was virtually universal. (Ex. 343, p. 91; Ex. 335, p. 88; Ex. 290A, p. 105; Ex. 353, p. 10-12, 11; Ex. 82, p. 12; Ex. 284A, p. 577; Ex. 53, p. 14)

The health effects related to the use of chelating agents have been described above in some detail. With reference to the prophylactic use of these drugs, it is important to note certain particular effects. While the PbB levels are lowered by chelation, various authors have noted that in prophylactic chelation “effect” measures are not lowered to a comparable degree. Selander (Ex. 118D, ref. 12) noted that oral CaEDTA had little effect on ALA-U levels. The results of Fishbein et al. suggested that prophylactic chelation did not lower ZPP levels to a degree comparable to PbB levels. The study results of Fishbein et al. also suggested that workers who had been chelated prophylactically were not protected from neuropathy or lead colic-effects. Thus they concluded that “without such cessation of exposure, chelating drugs may be ineffective, or even deleterious.” (Ex. 105 D)

Similarly, Dr. Finklea has stated that:

We in the National Institute for Occupational Safety and Health also strongly oppose this practice. Prophylactic treatment of workers with chelating agents while failing to control the source of lead exposure in effect places workers in double jeopardy, by virtue of the potential harmful effects particularly on the kidneys combined with continued excess exposure to lead, a known renal toxin. (Ex. 246A)

Blejer testified that:

Prophylactic administration of CaNa2EDTA by whatever route under conditions of continued lead exposure is judged to be particularly hazardous. Use of chelating agents is not an adequate substitute for engineering controls and proper industrial hygiene practices. Both lead and CaNa2EDTA in sufficient dosages are established to be toxic to the kidneys. Prophylactic chelation may decrease the ability of the kidneys to protect themselves against the toxic effects of lead. A recent mortality study of workers exposed to lead conducted by Cooper and Gaffney, (Ex. 6273), for example, demonstrated an increase in deaths from end-stage renal disease. In conclusion, prophylactic use of chelation to control lead absorption represents an unacceptable medical practice that cannot be conditioned. (Ex. 6 (19), p. 20)

Lils and Fishbein reviewed the effects of prophylactic chelation and similarly concluded that:

Oral prophylactic treatment with chelating agents such as edetate disodium calcium or penicillamine is contraindicated for the prevention of lead poisoning in workers exposed to lead. Among the reasons are the poor absorption of edetate disodium calcium from the gastrointestinal tract, the concomitant, possible increased absorption of ingested lead, and the unsatisfactory effect of oral administration of edetate disodium calcium on blood lead, urinary coproporphyrin, and amino-Javelinic acid indicating a failure to prevent adverse metabolic lead effects. These constraints explain the repeated failures of oral chelation therapy with symptomatic lead poisoning developing in some workers in spite of the prophylactic treatment.

Further, the effect of long-term chelation therapy on serum iron, copper, magnesium, and zinc levels and the interference with metal-dependent enzymatic activity adds to the disadvantage of this treatment, as do the side effects of penicillamine, such as renal damage, leukopenia, agranulocytosis, eczennphilia, and decreased serum iron levels.

Finally, it may not be unimportant that alteration of biological measurements used to estimate the current extent of absorption of lead has occurred and is bound to make the clinical management of lead disease more difficult and confused.

Adequate control of occupational lead exposure cannot and should not be replaced by inappropriate and potentially hazardous attempts at prophylactic treatment. (Ex. 118D)

Moreover the membership of the American Occupational Medical Association at a general session in 1976 approved and adopted a statement of ethical which in essence stated that “the use of chelating agents as a prophylactic measure to prevent lead intoxication among workers in place of environmental controls would be considered as unethical practice of medicine and the subject physician would be subject to censure.” (Tr. 291)

In his testimony Blejer expressed his opinion that routine administration of chelating agents constitutes “prophylactic” chelation: “Routine administration of chelating agents amounts to essentially prophylaxis, meaning you are just treating the blood leads or the symptomatology and you are sending the individual back to the exposure, *** to be re-exposed.” (Tr. 243)

These views were supported by Epstein (Tr. 1112) and Finklea. (Ex. 246A)

In view of the strong criticisms that have been made against prophylactic chelation, and in view of the fact that such warnings have a twenty year history, it is tragic that any major instances of prophylactic chelation should have occurred. Nevertheless, extensive testimony was presented which did demonstrate that prophylactic chelation has occurred and is occurring in workplaces throughout the country (Tr. 5631, 5634, 6125); hence the necessity for prohibiting any chelation which falls within the Blejer and Bridbord definition of “prophylactic”.

Various workers and their union officials testified concerning their direct experiences with prophylactic chelation.

George Becker of the United Steelworkers of America, (USWA) testified concerning his personal experience with prophylactic chelation. (Tr. 4991-4992) He also testified that one worker told a NIOSH investigator in 1973 that he took as many as 250 versenate pills a week “to make sure that he didn’t become leaded.” (Tr. 4992)

In addition, union testimony reinforced the experience of Becker. Givens, Teamsters (Tr. 2171), Mirer, UAW (Tr. 446), Belizkey, Rubber
Workers (Tr. 2357-39; Ex. 38c, p. 4), all discussed the indiscriminant use of prophylactic chelation.

One of the most thoroughly studied cases of prophylactic chelation presented were the combined cases of the N. L. and Quemetco smelter study conducted by Fishbein et al. Becker described his initial contacts with the problems at these plants through USWA Local 5554:

Employees from each smelter had complained to the company doctor of nausea, stomach cramps, headaches and fatigue. Chelation was still practiced, although under different circumstances. Oral chelation had been halted at the NL smelter. Instead, employees were receiving EDTA administered solution intravenously IV treatments at the local hospital on an outpatient basis. The situation at Quemetco smelter appeared to be even worse. Oral chelation, pills of the cuprimine variety were being distributed by the company doctor. In response to my expressed concern about this form of chelation I was told by Quemetco's doctor that, "They are absolutely safe and if I had my way they would be handed out to the lead workers like salt." (Tr. 4999)

The study of Fishbein et al. gives a more detailed description of what was occurring in these smelters:

The 47 workers in Plant 1 and 24 in Plant 2 had had at least one course of chelation therapy, but 45 (24 in Plant 1 and 21 in Plant 2) had had it repeatedly (up to 10 times) (Table 16). The fact that there were more workers with repeated courses of chelation therapy in Plant 2 is consistent with the longer duration of employment of these workers.

Over the years, histories given indicated that several patterns of chelation therapy had been followed. For example, the duration of courses of Intravenous Versenate varied from 3 days to 10 days. The prevailing practice in one plant had been to administer chelating agents in most cases without removing the worker from his usual lead exposure. Under such circumstances, it was not surprising that chelation therapy had to be used frequently, since the deleterious effect of the chelating agent would be counterbalanced by the continuous exposure and absorption of lead.

Most workers were given chelation therapy on an ambulatory basis. However, 14 had had hospital admissions for lead poisoning over the years, for what seemed to have been acute episodes (toxic) in the course of their chronic lead poisoning. Change in job assignment, to areas of lesser lead exposure, was reported by only 23 of the examined workers. The fact that chelation therapy had been used to much larger extent than had removal from exposure might have been due to the existence of rather homogeneous air lead levels in the plants, which had large open workspaces. (105 P, pp. 30, 31)
which only specified that the standard and its appendices be available. There was testimony which suggested OSHA "track employer compliance with the educational requirements very closely. (Ex. 334, p. 53006)" OSHA intends to develop, in the future, specific safety and health training and education materials on lead for distribution and presentation to employees by employers in addition to the training requirements in this regulation. These materials will inform employees of the hazards of exposure to lead and appropriate protective measures as discussed in this preamble and final regulation.

Although the emphasis of education and training is for the worker subject to exposure at or above the action level, training requirements exist which must be observed even if the initial monitoring or determination indicates that exposures are below the action level. Specifically, the final standard's accessibility of information requirements extend to all employees. The employer must also inform all employees, including those below the action level, of the contents of Appendices A and B of the regulation, when published.

The training program for employees subject to exposure to lead at or above the action level or for whom the possibility of skin/eye irritation exists, is generally in keeping with the proposal. During the hearings there was considerable testimony on the need to inform workers, both male and female, of the severe effects on the reproductive system from exposure to lead. (Tr. 557, 604, 4511, Ex. 343, p. 106.) For example, Andrea Hricko stated: "Employee and job applicants must be informed that excessive exposures to lead have resulted in reproductive difficulties, including fertility problems, menstrual disorders, stillbirths, miscarriages and other hazardous effects so that they understand the significance of blood, sperm and pregnancy testing (Tr. 694)."

OSHA is in complete agreement with this view and therefore will require the employer to develop an education program which addressed the danger of exposure to lead on the reproductive system, and on employee options for protection. OSHA believes employer compliance with this provision is essential, the agency considers it important to assist in this process by providing both written and audio visual materials to the employer for use in training. OSHA intends to develop, in the future, specific safety and health training and education materials on lead for distribution and presentation to employees by employers in addition to the training requirements in this regulation. These materials will inform employees of the hazards of exposure to lead and appropriate protective measures as discussed in this preamble and final regulation. Where the training program is provided in the workplace, the employer will be required to include them as part of his education and training program.

The proposal did not require the posting of signs, but raised the issue of whether signs or labels would be appropriate. However, it is important, and section 60(a)(7) of the Act requires, that appropriate forms of warning, as necessary, be used to apprise employees of the hazards to which they are exposed in the course of their employment. OSHA believes, as a matter of policy, that employees should be given the opportunity to make informed decisions on whether to work at a job under particular working conditions. For example, for the control of potential safety and health problems involves the cooperation of employees, the success of such a program is highly dependent upon the worker's understanding of the hazards attendant to that job.

In light of the serious nature of the hazard of exposure to lead, OSHA believes that sign posting is needed as well as periodic training to adequately inform employees of the poisoning hazard. The appearance of the phrase "Poison" on the warning sign will serve as a daily reminder of the hazard and as an objective check on whether employees are actually being informed of this hazard. The warning signs will inform all employees entering such areas of the need to utilize respirators and other protective equipment which the employer is to provide. Additionally, the phrase "No Smoking or Eating" relates directly to requirements in the standard which limit activities within lead contaminated areas. (See discussion in paragraph on Hygiene Facilities and Practices.)

The final standard requires records of exposure measurements. The records required include name and job classification of employees measured, details of the sampling and analytic techniques, results, and type of respiratory protection worn. The final standard also requires records of medical surveillance (biological monitoring & medical exam results). These include names of employees, the physician's written opinion, and a copy of the results of the examination. These records must be kept for 40 years or for at least 20 years after termination of employment, whichever is longer.

The final standard also contains a limited recordkeeping requirement concerning temporary medical removals effected pursuant to the medical removal protection program. The employer must establish and maintain an accurate record for each employee removed from current exposure to lead. The record is to contain four entries each time an employee is removed. First, the employee must be identified by name and social security number. Second, the date of removal and return must be stated. Third, the employer must briefly explain how each removal was or is being accomplished. This description need be no more detailed than such statements as "Employee X was transferred from position A to position B during the entire period of removal," or "Employee X was laid off for the entire period of removal," or "Employee X is currently working half shifts until a transfer opportunity becomes available." Fourth, the record must indicate whether or not the reason for the removal was an elevated blood lead level. If removal is due to a reason other than an elevated blood lead level, this precise reason should not be stated so as to prevent disclosure of confidential medical information.

The purpose of the foregoing recordkeeping requirement is to enable the Secretary, employers, and their authorized representatives to assess the operation of, and an employer's compliance with, the medical removal protection program. The limited but per-
tinent information contained in these records while in other cases enable these assessments to be made without interviewing large numbers of employees or placing undue burdens on employers by requiring further time consuming and burdensome examinations of payroll records, production, or completion of medical records and medical examinations which likely would be necessary in the absence of the standard's limited record-keeping requirements. Due to the limited purposes to be served by these records, the standard requires an employer to maintain each medical record only for so long as the duration of an employee's employment.

In the final standard, there have been deletions in the areas of record-keeping which OSHA has determined to be excessively costly and minimally effective: (1) mechanical ventilation measurements and (2) employee training. A third deletion has been made, specifically in the area of medical surveillance records. The proposal required that a signed copy of any employee's refusal to participate in the medical surveillance program be included among the other records. This provision has been deleted. OSHA believes that the problem of employee refusal will be mitigated by the standard's Medical Removal Protection program, which will minimize disincentives to worker participation. Therefore, this provision has been deleted in the final standard.

The participants at the hearing generally agreed with the necessity for keeping records but objected to the length of the record retention period. The extended retention period is needed for several purposes. Lead is known to have both acute and chronic effects, depending on the level and duration of exposure. The onset of clinical symptoms may occur many years after exposure. OSHA requires these records be maintained to document the medical and exposure history of the worker in order to assist the physician in determining the dose to the worker over his work tenure.

OSHA is also concerned that the physician be able to follow asymptomatic workers who have been exposed to low lead levels over long periods of time, in order to ascertain the long-term effects of low level exposure. In this regard, another important function the combined records serve is to provide a data base for much-needed scientific and epidemiological research into the effects of chronic low level lead exposure. Lastly, maintenance of records for 40 years will enable a future review of the adequacy of the standard.

The final standard requires that records be made available to the Director and Assistant Secretary, that environmental and biological monitoring records, and medical results of mental and biological monitoring records be provided to employees and their authorized representatives. The lead standard also requires that the Assistant Secretary and Director have access to the records for enforcement and research purposes. Employers and their representatives need access to both environmental and biological monitoring records to assess an employer's progress in (1) controlling worker exposure to lead, and (2) complying with the lead standard, particularly the medical removal and transfer provisions. These records are particularly useful in this regard. Consistent with the current widespread dissemination of individual blood lead level results, and the need for employers and employees to have this data, the standard makes blood lead level results available to all employees and their representatives. In so deciding, the agency has carefully balanced the pressing need for worker access to this limited form of medical data against the confidentiality that would normally be afforded to most forms of laboratory test results.

The transfer provisions in the proposal have been left unchanged except that NIOSH is to be notified at the expiration of the retention period so that it can determine if the records are still needed for research purposes.

O. Observation of Monitoring: Paragraph (o)

Section 8(c)(3) of the Act requires that employers provide employees or their representatives with the opportunity to observe monitoring of employees' exposure to toxic materials or harmful physical agents. In accordance with this section and consistent with the proposal and other OSHA standards, the standard contains provisions for such observation. To assure that it is right and meaningful, observers are entitled to an explanation of the measurement procedure, to observe all steps related to the measurement procedure, and to record the results. Since results will not normally be available at the time of monitoring, the standard has been clarified to indicate that the observers are entitled to receive the results of the monitoring when returned by the laboratory. To ensure that right and meaningful, observers must be provided with, and is required to use, any personal protective devices required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

P. Effective Date: Paragraph (p)

The effective date is February 1, 1979, which is approximately three months prior to the issuance of the standard and its effective date is intended to provide sufficient time for employers and employees to become familiar with the existence of the standard and its requirements.

Any petitions for administrative reconsiderations of this standard or for an administrative stay pending judicial review must be filed with the Assistant Secretary of Labor for Occupational Safety and Health within 45 days of the publication of this standard in the Federal Register. Any petitions filed after this date will be considered to be filed untimely. This requirement is considered essential to permit the Agency to give full consideration to each petition and respond in advance of the effective date of the standard.

Q. Appendices: Paragraph (q)

The appendices included with the regulation are intended to provide information and are not intended to create any additional obligations not otherwise imposed.

R. Startup Dates: Paragraph (r)

Startup dates for specific provisions have been extended from the proposal. This is based on OSHA's experience with other standards as to the time required for employers to complete air monitoring, and medical surveillance, and to obtain necessary equipment, respirators, and protective clothing. If there is no specific start up date set forth in the standard, then the startup date is the effective date of the standard. If the time period for meeting any of these startup dates cannot be met because of technical difficulties, any employer is entitled to petition for a temporary variance under §6(b)(6)(A) of the Act.

V. Authority

This document was prepared under the direction of Elula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Ave., NW, Washington, D.C. 20210.

Accordingly, pursuant to sections 4(b), 6(b) and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1735, 1593, 1599; 29 U.S.C. 653, 655, 657), Secretary of Labor's Order No. 8-76 (41 FR 25059) and 29 CFR Part 1911, Part 1910 of Title 29, Code of Federal Regulations is hereby...
amended by adding a new permanent standard for occupational exposure to
inorganic lead at §1910.1025 and by making consequential amendments to
Table Z–2 of 29 CFR 1910.1000. 

In addition, pursuant to the above authority, section 4(b)(2) of the Act
(41 Stat. 1592; 29 U.S.C. 653) and the specific statutes referred to in section
4(b)(2), OSHA has determined that this new standard is more effective than
the corresponding standards now in Subpart B of Part 1910, in Parts
1915, 1916, 1917, and 1918 of Title 29, Code of Federal Regulations, and also
the safety and health standards promulgated under the Walsh-Healy Act
on Arts and Humanities Act (20 U.S.C. 951 et seq.). Therefore, to the
extent that these corresponding standards are inconsistent with this new
standard, they are superseded by the new §1910.1025.

The application of the new standard to the maritime industry is implement-
ed by adding a new paragraph (g) to §1910.19.

Signed at Washington, D.C., this 8th day of November, 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations (CFR) is amend-
ed as follows:

1. A new paragraph (g) is added to
§1910.19 to read as follows:

<table>
<thead>
<tr>
<th>Paragraph</th>
<th>Amended</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1910.1000</td>
<td>[Amended]</td>
</tr>
</tbody>
</table>
| Table Z–2 in §1910.1000 is amend-
ed by deleting the following entry:
| Lead and its inorganic compounds | (257.11–1899) 0.2 mg/m² |
| 3. A new §1910.1025 is added to Part
1910 to read as follows: |

§1910.1025 Lead.

(a) Scope and application. (1) This
section applies to all occupational ex-
posure to lead, except as provided in
paragraph (a)(2).

(2) This section does not apply to
construction work as defined in 29
CFR 1910.12(b) or to agricultural op-
erations covered by 29 CFR Part 1928.

(b) Definitions. "Action level" means
employee exposure, without regard to
the use of respirators, to an airborne
concentration of lead of 30 micro-
grams per cubic meter of air (30 µg/m³)
averaged over an 8-hour period.

"Director" means the Director, Na-
tional Institute for Occupational
Safety and Health (NIOSH), U.S. De-
partment of Health, Education, and
Welfare, or designee.

"Lead" means metallic lead, all inor-
ganic lead compounds, and organic
lead soaps. Excluded from this defini-
tion are all other organic lead com-
ounds.

(c) Permissible exposure limit (PEL).

(1) The employer shall assure that no
employee is exposed to lead at concen-
trations greater than fifty micrograms
per cubic meter of air (50 µg/m³) aver-
gaged over an 8-hour period.

(2) If an employee is exposed to lead
for more than 8 hours in any work
day, the employer shall calculate
a time weighted average (TWA) for
that day, the permissible exposure limit, as

Maximum permissible limit (in µg/
m³) = 400 + hours worked In the day.

(3) When respirators are used to sup-
plement engineering and work practice
controls to comply with the PEL and
all the requirements of paragraph (d)
have been met, employee exposure, for
the purpose of determining whether
the employer has complied with the
PEL, may be considered to be at the
level provided by the protection factor
of the respirator for those periods the
respirator is worn. Those periods may
be averaged with exposure levels
during periods when respirators are
not worn to determine the employee’s
daily TWA exposure.

(d) Exposure monitoring. (1) General.

(i) For the purposes of paragraph
(d), employee exposure is that expo-
sure which would occur if the employ-
ee were not using a respirator.

(ii) With the exception of monitor-
 ing under paragraph (d)(3), the em-
ployer shall collect full shift (for at
least 7 continuous hours) personal
samples including at least one sample
for each shift for each job classifica-
tion in each work area.

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

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

(3) Basis of initial determination. (i)
The employer shall monitor employee
exposures and shall base initial deter-
minations on the employee exposure
monitoring results and any of the fol-
lowing, relevant considerations:

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

(B) Measurements of airborne lead
made in the preceding year if the sam-
ping and analytical methods used
meet the accuracy and confidence
levels of paragraph (d)(9) of this sec-
tion; and

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

(ii) Monitoring for the initial deter-
mination shall be limited to a rep-
resentative sample of the exposed em-
ployees who the employer reasonably
believes are exposed to the greatest
airborne concentrations of lead in the
workplace.

(4) Positive initial determination.
Where a determination conducted
under paragraphs (d)(2) and (d)(3) of
this section shows the possibility of
any employee exposure at or above
the action level, the employer shall
conduct monitoring which is repre-
sentative of the exposure for each em-
ployee in the workplace which is ex-
posed to lead.

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

(6) Frequency. (i) If the initial moni-
toring reveals employee exposure to be
below the action level the measure-
ments need not be repeated except as
otherwise provided in paragraph (d)(7)
of this section.

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

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

(7) Additional monitoring. Whenever there has been a production, process, control or personnel change which may result in new or additional exposure to lead, or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to lead, additional monitoring in accordance with this paragraph shall be conducted.

(8) Employee notification. (1) 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.

(ii) Whenever the results indicate that the representative employee exposure, without regard to respirators, exceeds the permissible exposure limit, the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the corrective action taken or to be taken to reduce exposure to or below the permissible exposure limit.

(9) Accuracy of measurement. The employer shall use a method of monitoring and analysis which has an accuracy (to a confidence level of 95%) of not less than plus or minus 20 percent for airborne concentrations of lead equal to or greater than 30 μg/m³.

Methods of compliance. (1) Engineering and work practice controls. The employer shall implement engineering and work practice controls (including administrative controls) to reduce and maintain employee exposure to lead in accordance with the implementation schedule in Table I below. Failure to achieve exposure levels without regard to respirators is sufficient to establish a violation of this provision.

<table>
<thead>
<tr>
<th>Industry</th>
<th>Compliance dates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200 * 100 * 50 μg/m³</td>
</tr>
<tr>
<td>Primary lead production</td>
<td>(1) 2 10</td>
</tr>
<tr>
<td>Secondary lead production</td>
<td>(1) 3 5</td>
</tr>
<tr>
<td>Lead-acid battery manufacturing</td>
<td>(1) 2 5</td>
</tr>
<tr>
<td>Nonsferous foundries</td>
<td>(1) 1</td>
</tr>
<tr>
<td>Lead pigment manufacturing</td>
<td>(1) 3 5</td>
</tr>
<tr>
<td>All other industries</td>
<td>(1) 0 1</td>
</tr>
</tbody>
</table>

Includes auxiliary activities listed on the same worksite.

*Expressed as the number of years from the effective date by which compliance with the airborne exposure level, as an 8-hour TWA, must be achieved.

On effective date.

(2) Respiratory protection. Where engineering and work practice controls do not reduce employee exposure to or below the 50 μg/m³ permissible exposure limit, the employer shall supplement these controls with respirators in accordance with paragraph (d).

(3) Compliance program. (i) Each employer shall establish and implement a written compliance program to reduce exposures to or below the permissible exposure limit and intermediate levels if appropriate, solely by means of engineering and work practice controls in accordance with the implementation schedule in paragraph (e)(1).

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

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

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

(C) A report of the technology considered in meeting the permissible exposure limit;

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

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

(F) A work practice program which includes items required under paragraphs (g) and (i) of this regulation;

(G) An administrative control schedule required by paragraph (e)(6), if applicable;

(H) Other relevant information.

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

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

(4) Basis of interim level. Where an employer's compliance plan provides for a reduction of employee exposures to or below the PEL solely by means of engineering and work practice controls in accordance with the implementation schedule in table I, and the employer has determined that compliance with the 100 μg/m³ interim level would divert resources to the extent that it clearly precludes compliance, otherwise attainable, with the PEL by the required time, the employer may proceed with the plan to comply with the PEL in lieu of compliance with the interim level if:

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

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

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

(5) Mechanical ventilation. (1) When a ventilation system 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 found in 5 days of any change in production, process, or control which might result in a change in employee exposure to lead.

(ii) Recirculation of air. If air from exhaust ventilation is recirculated into the workplace, the employer shall assure that the system has a high efficiency filter with reliable backup filters and controls to monitor the concentration of lead in the return air and bypass the recirculation system automatically if it fails are installed, operating, and maintained.

Administrative controls. If administrative controls are used as a means of reducing employee’s TWA exposure to lead, the employer shall establish and implement a job rotation schedule which includes the following:

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

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

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

Respiratory protection. (1) General. Where the use of respirators is required under this section, the employer shall provide, at no cost to the employee, and assure the use of respirators which comply with the requirements of this paragraph. Respirators shall be used in the following circumstances:

(i) During the time period necessary to install or implement engineering or work practice controls, except that
after the dates for compliance with the interim levels in Table I, no employer shall require an employee to wear a respirator longer than 4.4 hours per day;
(ii) In work situations in which engineering and work practice controls are not sufficient to reduce exposures to or below the permissible exposure limit; and
(iii) Whenever an employee requests a respirator.
(2) Respirator selection.
(i) Where respirators are required under this section the employer shall select the appropriate respirator or combination of respirators from Table II below.

<table>
<thead>
<tr>
<th>Airborne concentration of lead or condition of use</th>
<th>Required respirator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not in excess of 0.5 mg/m³ (10X PEL)</td>
<td>Half-mask, air-purifying respirator equipped with high efficiency filters. *</td>
</tr>
<tr>
<td>Not in excess of 2.5 mg/m³ (50X PEL)</td>
<td>Full facepiece, air-purifying respirator with high efficiency filters.</td>
</tr>
<tr>
<td>Not in excess of 50 mg/m³ (1000X PEL)</td>
<td>(i) Any powered, air-purifying respirator with high efficiency filters; or (ii) Half-mask supplied-air respirator operated in positive-pressure mode. *</td>
</tr>
<tr>
<td>Not in excess of 100 mg/m³ (2000X PEL)</td>
<td>Supplied-air respirators with full facepiece, hood, helmet, or suit, operated in positive pressure mode.</td>
</tr>
<tr>
<td>Greater than 100 mg/m³, unknown concentration</td>
<td>Full facepiece, self-contained breathing apparatus operated in positive-pressure mode.</td>
</tr>
</tbody>
</table>

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

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

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

(ii) The employer shall provide a powered, air-purifying respirator in lieu of the respirator specified in Table II whenever:
(A) An employee chooses to use this type of respirator; and
(B) This respirator will provide adequate protection to the employee.

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

(3) Respirator usage.
(i) The employer shall assure that the respirator issued to the employee exhibits minimum facepiece leakage and that the respirator is fitted properly.
(ii) Employers shall perform quantitative face fit tests at the time of initial fitting and at least semiannually thereafter for each employee wearing negative pressure respirators. The test shall be used to select facepieces that provide the required protection as prescribed in Table II.
(iii) If an employee exhibits difficulty in breathing during the fitting test or during use, the employer shall make available to the employee an examination in accordance with paragraph (i)(3)(ii) of this section to determine whether the employee can wear a respirator while performing the required duty.
(iv) Respirator program.
(A) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (c), and (f).
(B) This respirator will provide adequate protection for the employee.
(v) The employer shall assure that contaminated protective clothing which is to be cleaned, laundered, or disposed of, is placed in a closed container in the change-room which prevents dispersion of lead outside the container.
(vi) The employer shall inform in writing any person who cleans or launderers protective clothing or equipment of the potential as harmful effects of exposure to lead.
(vii) The employer shall assure that the containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) are labelled as follows: CAUTION: CLOTHING CONTAMINATED WITH LEAD. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH THE APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

TABLE II.—Respiratory Protection for Lead Aerosols

(ii) The employer shall provide clean change rooms for employees who work 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 used, and cosmetics are not applied, except in change rooms, lunchrooms, and showers required under paragraphs (1)(2)-(1)(4) of this section.

(2) Change rooms. (i) The employer shall provide clean change rooms for employees who work in areas where their skin or clothing comes in contact with fume, dust, mist, or liquids containing lead or where employees are exposed to lead above the PEL, without regard to the use of respirators.
(ii) The employer shall assure that change rooms are equipped with separate storage facilities for protective work clothing and equipment and for street clothes which prevent cross-contamination.

(3) Showers. (i) The employer shall assure that employees who work in areas where their skin or clothing comes into contact with dust, mist, or liquids containing lead or where their airborne exposure to lead is above the PEL, without regard to the use of respirators, shall be provided with showers, including enclosed and heated change rooms. The employer shall provide showers in accordance with §1910.141(a)(3) of this Part.

(iii) The employer shall assure that employees, who are required to shower pursuant to paragraph (j)(3)(i) do not leave the workplace wearing any clothing or equipment worn during the work shift.

(4) Lunchrooms. (i) The employer shall provide lunchroom facilities for employees who work in areas where their skin or clothing comes into contact with dust, mist, or liquids containing lead or where their airborne exposure to lead is above the PEL, without regard to the use of respirators.

(ii) The employer shall assure that lunchroom facilities have a temperature controlled, positive pressure, filtered air supply, and are readily accessible to employees.

(iii) The employer shall assure that employees who work in areas where their skin or clothing comes into contact with dust, mist, or liquids containing lead or where their airborne exposure to lead is above the PEL, without regard to a respirator wash their hands and face prior to eating, drinking, smoking, or applying cosmetics.

(iv) The employer shall assure that employees do not enter lunchroom facilities with protective work clothing or equipment unless surface lead dust has been removed by vacuuming, down-draft booth, or other cleaning method.

(5) Lavatories. The employer shall provide an adequate number of lavatory facilities which comply with §1910.141(d) (1) and (2) of this Part.

(5) Effective date for construction plans. Construction plans for changerooms, showers, lavatories and lunchroom facilities shall be completed no later than 6 months from the effective date and these facilities shall be constructed and in use no later than 1 year from the effective date.

(i) Medical surveillance. (1) General. (i) The employer shall institute a medical surveillance program for all employees who are or may be exposed above the action level for more than 90 days per year.

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

(iii) The employer shall provide the required medical surveillance without cost to employees and at a reasonable time and place.

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

(A) At least every 6 months to each employee covered under paragraph (j)(1)(i) of this section;

(B) At least every 2 months for each employee whose last blood sampling and analysis indicated a blood lead level at or above 40 µg/100 g of whole blood. This frequency shall continue until two consecutive blood samples and analyses indicate a blood lead level below 40 µg/100 g of whole blood; and

(C) At least monthly during the removal period of each employee removed from exposure to lead due to an elevated blood lead level.

(ii) Follow-up blood sampling tests. Whenever the results of a blood lead level test indicate that an employee's blood lead level exceeds the numerical criterion for medical removal under paragraph (k)(1)(i), the employer shall provide a second (follow-up) blood sampling test within two weeks after the employer receives the results of the first blood sampling test.

(iii) Accuracy of blood lead level sampling and analysis. Blood lead level sampling and analysis provided pursuant to this section shall have an accuracy to a confidence level of 95 percent, within plus or minus 15 percent or 6 µg/100ml, whichever is greater, and shall be conducted by a laboratory licensed by the Center for Disease Control (CDC) or which has received a satisfactory grade in blood lead proficiency testing from CDC in the prior twelve months.

(iv) Employee notification. Within five working days after the receipt of biological monitoring results, the employer shall notify in writing each employee whose blood lead level exceeds 40 µg/100 g. (A) of that employee's blood lead level result, and (B) that the standard requires temporary medical removal with Medical Removal Protection benefits; when an employee's blood lead level exceeds the numerical criterion for medical removal under paragraph (k)(1)(i) of this section.

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

(A) At least annually for each employee for whom a blood sampling test conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 µg/100 g;

(B) Prior to assignment for each employee being assigned for the first time to an area in which airborne concentrations of lead are at or above the action level;

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

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

(ii) Contents. Medical examinations made available pursuant to paragraph (j)(3)(i)(A)–(B) of this section shall include the following elements:

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

(B) A thorough physical examination, with particular attention to teeth, gum, hematologic, gastrointestinal, renal, cardiovascular, and neurological systems. Pulmonary status should be evaluated if respiratory protection will be used;

(C) A blood pressure measurement;

(D) A blood sample and analysis which determines:

(1) Blood lead level;

(2) Hemoglobin and hematocrit determinations, red cell indices, and examination of peripheral smear morphologic features;

(3) Zinc protoporphyrin;

(4) Blood urea nitrogen, and;

(5) Serum creatinine.

(E) A routine urinalysis with microscopic examination; and

(F) Any laboratory or other test which the examining physician deems necessary by sound medical practice.

The content of medical examinations made available pursuant to paragraph (j)(3)(i)(C)–(D) of this section shall be determined by an examining physician, and if requested by an employee, shall include pregnancy testing or laboratory evaluation of male fertility.
RULES AND REGULATIONS

(III) Multiple physician review mechanism. (A) If the employer selects the initial physician who conducts any medical examination or consultation provided to an employee under this section, the employee may designate a second physician.

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

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

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

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

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

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

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

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

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

(E) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(iv) Information provided to examining and consulting physicians. (A) The employer shall provide an initial physician conducting a medical examination or consultation under this section with the following information:

(1) A copy of this regulation for inorganic lead including all Appendices;

(2) A description of the affected employee's duties as they relate to the employee's exposure;

(3) The employee's exposure level or anticipated exposure level to lead and to any other toxic substance (if applicable);

(4) A description of any personal protective equipment used or to be used;

(5) Prior blood lead determinations; and

(6) All prior written medical opinions concerning the employee in the employer's possession or control.

(B) The employer shall provide the foregoing information to a second or third physician conducting a medical examination or consultation under this section upon request either by the second or third physician, or by the employee.

(v) Written medical opinions. (A) The employer shall obtain and furnish an employee with a copy of a written medical opinion from each examining or consulting physician which contains the following information:

(1) The physician's opinion as to whether the employee has any detectable medical condition which would place the employee at increased risk of material impairment of the employee's health from exposure to lead;

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

(3) Any recommended limitation upon the employee's use of respirators, including a determination of whether the employee can wear a powered air purifying respirator if a physician determines that the employee cannot wear a negative pressure respirator; and

(4) The results of the blood lead determinations.

(B) The employer shall instruct each examining and consulting physician to:

(1) Not reveal either in the written opinion, or in any other means of communication with the employer, findings, including laboratory results, or diagnosis unrelated to an employee's occupational exposure to lead; and

(2) Advise the employee of any medical condition, occupational or nonoccupational, which dictates further medical examination or treatment.

(vi) Alternate physician determination mechanisms. The employer and an employee or authorized employee representative may agree upon the use of any expeditious alternate physician determination mechanism in lieu of the multiple physician review mechanism provided by this paragraph so long as the alternate mechanism otherwise satisfies the requirements contained in this paragraph.

(4) Chelation. (i) The employer shall assure that any person whom he retains, employs, supervises or controls does not engage in prophylactic chelation of any employee at any time.

(i) If therapeutic or diagnostic chelation is to be performed by any person in paragraph (i)(4)(ii), the employer shall assure that it be done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring and that the employee is notified in writing prior to its occurrence.

(k) Medical Removal Protection.

(1) Temporary medical removal and return of an employee.

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

(A) First year of the standard. During the first year following the effective date of the standard, the employer shall remove an employee from work having a daily eight hour TWA exposure to lead at or above 100 pg/m^3 on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 80 micrograms/g of whole blood;

(B) Second year of the standard. During the second year following the effective date of the standard, the employer shall remove an employee from work having a daily eight hour TWA exposure to lead at or above 50 pg/m^3 on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 40 micrograms/g of whole blood;

(C) Third year of the standard, and thereafter. Beginning with the third year following the effective date of the standard, the employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 20 micrograms/g of whole blood; and

(D) Fifth year of the standard, and thereafter. Beginning with the fifth year following the effective date of the standard, the employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 10 micrograms/g of whole blood; and

(ii) If therapeutic or diagnostic chelation forms part of the medical removal process, the employer shall provide the employee with follow-up medical removal and return services as required by paragraphs (k)(2) and (k)(3).

(iii) If chelation is not part of the medical removal process, the employer shall provide the follow-up medical removal and return services as required by paragraphs (k)(2) and (k)(3).

(iv) If the employee is not fully returned to work, the employer shall provide the employee with such follow-up medical removal and return services as required by paragraphs (k)(2) and (k)(3).

(F) Compliance assurance program. (i) Each employer shall ensure the compliance with the requirements of this section, the final regulations associated with this section, and any interpretation or opinion of a federal agency or representative which is finally adopted under the order of the Secretary.

(ii) Each employer shall include in its program of monitoring actions to ensure compliance with the requirements of this section and any regulations, interpretations, or opinions associated with this section.

(iii) Each employer shall provide copies of this section and any regulations, interpretations, or opinions associated with this section to the employees involved in the program of monitoring or ensuring compliance with the requirements of this section.
The employer shall remove any limitations placed on an employee or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

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

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

(B) Return. The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions. If—III(1) the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician; (2) the employee has been on removal status for the proceeding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(ii) Provision of medical removal protection benefits. The employer shall provide to an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

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

(iv) Removal of other employee special protective measures or limitations. The employer shall return an employee to his or her former job status, or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

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

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

(B) Return. The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions. If—III(1) the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician; (2) the employee has been on removal status for the proceeding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(ii) Provision of medical removal protection benefits. The employer shall provide to an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

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

(iv) Removal of other employee special protective measures or limitations. The employer shall return an employee to his or her former job status, or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

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

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

(B) Return. The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions. If—III(1) the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician; (2) the employee has been on removal status for the proceeding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(ii) Provision of medical removal protection benefits. The employer shall provide to an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

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

(iv) Removal of other employee special protective measures or limitations. The employer shall return an employee to his or her former job status, or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

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

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

(B) Return. The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions. If—III(1) the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician; (2) the employee has been on removal status for the proceeding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(ii) Provision of medical removal protection benefits. The employer shall provide to an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

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

(iv) Removal of other employee special protective measures or limitations. The employer shall return an employee to his or her former job status, 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.

The employer shall remove any limitations placed on an employee or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

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

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

(B) Return. The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions. If—III(1) the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician; (2) the employee has been on removal status for the proceeding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(ii) Provision of medical removal protection benefits. The employer shall provide to an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

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

(iv) Removal of other employee special protective measures or limitations. The employer shall return an employee to his or her former job status, or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

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

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

(B) Return. The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions. If—III(1) the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician; (2) the employee has been on removal status for the proceeding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(ii) Provision of medical removal protection benefits. The employer shall provide to an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

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

(iv) Removal of other employee special protective measures or limitations. The employer shall return an employee to his or her former job status, 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.
which permits the return of the employee to his or her former job status
(P) The contents of any compliance
and job status; despite
plan in effect; and
(C) Instruction to employees that
what would otherwise be an
chelating agents should not routinely
unacceptable blood lead level, later
be used to remove lead from their
questions concerning removing the
bodies and should not be used at all
employee again shall be decided by a
except under the direction of a licen-
final medical determination. The em-
censed physician;
ployer need not automatically remove
(G) Access to information and train-
such an employee pursuant to the
ing materials.
medical removal protection
(i) The employer shall make readily
benefits to the employee
equal to that required by paragraph
available to all affected employers a
(k)(2)(I) of this section.
copy of this standard and its appen-
(i) Employee information and train-
(d) The employer shall provide
nings.
ning.
upon request, all materials relating to
(ii) The employer shall provide
the employee information and training
upon request, all materials relating to
program to the Assistant Secretary
the employee's medical condition, the
and the Director.
employer shall provide medical removal
(iii) In addition to the information
protection benefits to the employee
required by paragraph (1)(D)(v), the
equal to that required by paragraph
employer shall include as part of the
(k)(2)(I) of this section.
(iv) The training program shall be
(i) Training program.
repeated at least annually for each
(A) Each employer who has a work-
employee.
place in which there is a potential ex-
(b) The employer shall institute a
posure to airborne lead at any level
training program for and assure the
shall inform employees of the content
participation of all employees who are
of Appendices A and B of this regula-
subject to exposure to lead at or above
(i) Each record shall include:
the action level or for whom the possi-
(A) The date(s), number, duration,
bility of skin or eye irritation exists.
(B) A copy of the physician's written
(ii) the employer shall institute a
records.
training program for and assure the
(C) The name, social security
participation of all employees who are
number, and description of the duties
subject to exposure to lead at or above
of the employee.
the action level or for whom the possi-
(D) Any employee medical com-
bility of skin or eye irritation exists.
ments related to exposure to lead.
(iii) the employer shall provide
(E) A copy of the physician's written
initial training by 180 days from the
test results or reference to that
standard's effective date and prior to
information;
the time of initial job assignment for
(F) Results of any airborne exposure
those employees subsequently covered
monitoring done for that employee
by this paragraph.
and the representative exposure levels
by this paragraph.
supplied to the physician; and
by this paragraph.
(iv) Any employee medical com-
(F) The employer shall provide
ments related to exposure to lead.
monitoring and that is in excess of
(G) The employer shall maintain
the action level.
accurate record for each employee
(H) Medical removal.
monitored and of all other employees
required to remove employees
whose exposure the measurement is
who are subject to removal indica-
insufficient to represent; and
tions that this employee was
(i) The employer shall establish and
subject to medical surveillance as re-
maintain an accurate record for each
quired by paragraph (f) of this section.
employee removed from current exposure
to lead pursuant to paragraph (e) of
required to remove employees
this section.
whose exposure the measurement is
(ii) Each record shall include:
insufficient to represent; and
(A) The name, social security
(i) Exposure monitoring. (I) The
number and description of the duties
employer shall establish and maintain
of the employee;
ean accurate record of all monitoring re-
(B) A brief explanation of how each
quired in paragraph (d) of this section.
removal was or is being accomplished;
(ii) This record shall include:
(C) A statement with respect to each
(A) The date(s), number, duration,
removal indicating whether or not the
location and results of each of the
employee was removed from cur-
samples taken, including a description
rent exposure to lead as well as the
of the sampling procedure used to
corresponding date on which the em-
determine representative employee ex-
ployee was removed from the
posure where applicable;
former job status;
(B) A description of the sampling
(D) Name, social security number,
and analytical methods used and evi-
and job classification of the employee
dence of their accuracy;
monitored and of all other employees
(C) A type of respiratory protective
during the period for which the
devices worn, if
employee was removed from the
D) The purpose, proper selection,
current exposure to lead.
fitting, use, and limitations of respira-
(E) Voluntary removal or Restric-
tory devices worn, if
tive devices worn, if
in exposure to lead or otherwise
(F) The employer shall provide
places limitations on an employee due
to the effects of lead exposure on
medical removal protection benefits to
the employee's medical condition, the
employer shall provide medical removal
protection benefits to the employee
equal to that required by paragraph
(k)(2)(I) of this section.
(v) Voluntary Removal or Restric-
tive devices worn, if
tion of An Employee. Where an em-
ployer, although not required by this
section to do so, removes an employee
from exposure to lead or otherwise
places limitations on an employee due
to the effects of lead exposure on
the employee's medical condition, the
employer shall provide medical removal
protection benefits to the employee
equal to that required by paragraph
(k)(2)(I) of this section.
(vi) Access to information and train-
ing.
(i) Employee information and train-
ing.
(ii) The employer shall provide,
upon request, all materials relating to
the employee information and training
program to the Assistant Secretary
and the Director.
(vii) In addition to the information
required by paragraph (1)(D)(v), the
employer shall include as part of the
training program, and shall distribute
to employees, any materials pertaining
to the Occupational Safety and Health
Act, the regulations issued pursuant to
that Act, and this lead standard,
which are made available to the em-
ployer by the Assistant Secretary.
(m) Signs.
(v) The employer shall inform those
employees subsequently covered
by this paragraph.
(i) General. (I) The employer may
use signs required by other state
regulations or ordinances in addition
to, or in combination with, signs re-
quired by this paragraph.
(ii) The employer shall assure that
no statement appears on or near any
sign required by this paragraph which
contradicts or detracts from the mean-
ing of the required sign.
(2) Signs. (i) The employer shall post
the following warning signs in each
work area where the PEL is exceeded:
WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING
(ii) The employer shall assure that
signs required by this paragraph are il-
luminated and cleaned as necessary so
that the legend is readily visible.
(n) Recordkeeping.
(1) Exposure monitoring. (L) The em-
ployer shall establish and maintain an
accurate record of all monitoring re-
quired in paragraph (d) of this section.
(ii) This record shall include:
(A) The date(s), number, duration,
location and results of each of the
samples taken, including a description
of the sampling procedure used to
determine representative employee ex-
posure where applicable;
(B) A description of the sampling
and analytical methods used and evi-
dence of their accuracy;
(C) The type of respiratory protective
devices worn,
(D) Name, social security number,
and job classification of the employee
monitored and of all other employees
whose exposure the measurement is
insufficient to represent; and
(E) The environmental variables
that could affect the measurement of
employee exposure.
(iii) The employer shall maintain
these monitoring records for at least
40 years or for the duration of employ-
ment, plus 20 years, whichever is
longer.
(2) Medical surveillance. (I) The em-
ployer shall establish and maintain an
accurate record for each employee
subject to medical surveillance as re-
quired by paragraph (f) of this section.
(ii) This record shall include:
(A) The name, social security
number, and description of the duties
of the employee;
(B) A copy of the employee's written
medical records.
(C) Results of any airborne exposure
monitoring done for that employee
and the representative exposure levels
supplied to the physician; and
(D) Any employee medical com-
ments related to exposure to lead.
(iii) The employer shall keep, or
assure that the examining physician
keeps, the following medical records:
(A) A copy of the medical exama-
tion results including medical and
work history required under para-
graph (d) of this section;
(B) A description of the laboratory
procedures and a copy of any stand-
ards or guidelines used to interpret
the test results or references to that
information;
(C) A copy of the results of biologi-
cal monitoring.
(iv) The employer shall maintain or
assure that the physician maintains
those medical records for at least 40
years, or for the duration of employ-
ment, plus 20 years, whichever is
longer.
(3) Medical removals. (I) The em-
ployer shall establish and maintain an
accurate record for each employee re-
moved from current exposure to lead
pursuant to paragraph (e) of this sec-
tion.
(ii) Each record shall include:
(A) The name and social security
number of the employee;
(B) The date on each occasion that
the employee was removed from cur-
rent exposure to lead as well as the
corresponding date on which the em-
ployee was returned to his or her
former job status;
(C) A brief explanation of how each
removal was or is being accomplished;
and
(D) A statement with respect to each
removal indicating whether or not the
reason for the removal was an elevat-
ed lead level.
(iii) The employer shall maintain
each medical removal record for at

FEDERAL REGISTER, VOL 43, NO. 220—TUESDAY, NOVEMBER 14, 1978
least the duration of an employee's employment.

(4) Availability. (i) The employer shall make available a record of employee exposure to lead in a form and manner prescribed by the Administrator and shall maintain such record for at least 30 years after the last exposure for which such record is required.

(ii) When the employer ceases to do business and there is no successor employer, the employer shall give notice of such closing to the Director and shall turn over to the Director all records required by this section to the successor employer.

(iii) The employer shall provide affected employees or their authorized employee representatives an opportunity to observe any monitoring of employee exposure to lead conducted pursuant to paragraph (d) of this section.

(5) Observation procedures. (i) Whenever observation of the monitoring of employee exposure to lead requires entry into an area where the monitoring is being conducted, the employer shall provide the observer with and assure the use of such respirators, protective clothing, and such equipment, and shall require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the monitoring of lead performed at the place of exposure; and

(C) Record the results obtained or receive copies of the results when returned by the laboratory.

(6) Effective date. This standard shall become effective February 1, 1979.

(a) Appendices. The information contained in the appendices to this section is not intended by itself, to create any additional obligations not otherwise imposed by this standard nor detract from any existing obligations.

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

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

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

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

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

(5) Hygiene and lunchroom facilities under paragraph (f) shall be available as soon as possible but no later than the following schedule:

(A) Employees whose 8-hour TWA exposure exceeds 200 µg/m³ on the effective date.

(B) Employees whose 8-hour TWA exposure is less than 200 µg/m³ and not exceeding 100 µg/m³ on the effective date.

(C) Employees whose 8-hour TWA exposure is less than 100 µg/m³ on the effective date.

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

(A) Employees whose 8-hour TWA exposure exceeds 200 µg/m³ on the effective date.

(B) Employees whose 8-hour TWA exposure is less than 200 µg/m³ and not exceeding 100 µg/m³ on the effective date.

(C) Employees whose 8-hour TWA exposure is less than 100 µg/m³ on the effective date.

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

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

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

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