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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

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OCCUPATIONAL EXPOSURE TO LEAD

Final Standard

[4510-26-M]

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 50$\mu g/m^3$ (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:

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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:

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, nontechnical 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 8(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 29 CFR Part 1911. 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 superceded 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 grippes" 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 consumed yearly by industries in the United States. Potential occupational exposure to lead and its compounds occur in at least 120 occupations, including lead smelting, the manufacture of lead storage batteries, the manufacture of lead pigments and products containing pigments, solder manufacture, shipbuilding and ship 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 coproporphyrin and delta-aminolevulinic acid (ALA), have been generally used to establish acceptable air lead levels and thereby to control occupational lead intoxication. At one time, an airborne exposure limit value of 500 $\mu g/m^3$ was generally accepted. Based on a recommendation of the U.S. Public Health Service in 1933, however, a value of 150 $\mu g/m^3$ was a common goal in industry in the 1940's.

150 $\mu g/m^3$ continued to be the most often accepted until 1957, when the American Conference of Governmental Industrial Hygenists (ACGIH) increased the value to 200 $\mu g/m^3$. In 1971, however, ACGIH recommended lowering this exposure limit back to 150 $\mu g/m^3$. (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 $\mu g/m^3$ as determined on the basis of an 8-hour time-

weighted average, was based on a national consensus standard of the American National Standards Institute (Z37.11-1969). When the consensus standard was originally adopted, no rationale was provided for the level selected.

In January 1973, pursuant to section 22(d) of the Act, the Director of the National Institute for Occupational Safety and Health (NIOSH) submitted to the Secretary of Labor a criteria document for inorganic lead, which recommended, among other things, lowering the existing permissible exposure limit for lead from 200 $\mu g/m^3$ to 150 $\mu g/m^3$. (Ex. 1.)

On August 4, 1975, the Director of NIOSH forwarded a letter to the Deputy Assistant Secretary of Labor for Occupational Safety and Health which revised the recommendations in the criteria document. In it, he recommended that the permissible exposure limit for airborne concentrations lead be reduced from 150 $\mu g/m^3$ to lower ranges. This letter followed a joint effort by the staffs of both OSHA and NIOSH to analyze and review scientific data not available or relied upon in the original criteria document and which resulted in a reevaluation of earlier recommendations.

On October 3, 1975, OSHA proposed a new occupational safety and health standard for occupational exposure to lead (40 FR 45934) (Ex. 2). The proposal included a permissible exposure limit of 100 $\mu g/m^3$ combined with provisions for environmental monitoring, medical surveillance, employee training and other protective measures. The notice requested submission of written comments, data, and opinions.

In a notice published on January 4, 1977 (42 FR 808) (Ex. 21), OSHA announced the availability of the preliminary technological feasibility and economic impact statements prepared by John Short Associates. It also gave notice that an informal hearing would begin in Washington, D.C. on March 15, 1977. On February 15, 1977 (42 FR 9190). (Ex. 25) notice was given that the final economic impact statement was available to the public and that the economic impact had been certified pursuant to Executive Order 11821.

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 50 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 1 through 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 to the hazard dealt with by such standard for the period of his working life.
>
> 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 attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws (Sec. 6(b)(5)).

Sections 2(b) (5) and (6), 20, 21, 22, and 24 of the Act show that Congress recognizes that conclusive medical or scientific evidence including 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 by 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 the courts which have reviewed standards promulgated under the Act. In sustaining the standard for occupational exposure to vinyl chloride (29 CFR 1910.1017), the U.S. Court of Appeals for the Second Circuit stated that "it remains the duty of the Secretary to act to protect the working man, and to act even in circumstances where existing methodology or research is deficient. *Society of the Plastics Industry Inc. v. Occupational Safety and Health Administration*, 509 F. 2d 1301, 1308 (2nd Cir. 1975), cert. den. sub nom., *Firestone Plastics Co. v. United States Department of Labor,"* 95 S. Ct. 1998, 4 L. Ed. 2d 482 (1975).

A similar rationale was applied by the U.S. Court of Appeals for the District of Columbia Circuit in reviewing the standard 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-

vices already developed and in use. As discussed more fully in the section on feasibility, standards may require improvements in existing technologies or require the development of new technology. *Society of the Plastics Industry, Inc.* v. *Occupational Safety and Health Administration,* supra at 1309; *American Iron & Steel Institute* v. *OSHA,* 577 F. 2d 825 (3rd Cir. 1978).

Where appropriate, the standards are to include provisions for labels or other forms of warning to apprise employees of hazards, suitable protective equipment, control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and appropriate medical examinations. Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illnesses (section 8(c)). The permanent standard for lead was developed on the basis of the above legal considerations.

III. Executive Summary

The following is a summary of the health effects, permissible exposure limit, medical removal protection, and feasibility sections of the final standard. A brief description of OSHA's decisions in the final standard and their rationale is set forth in this summary. A more detailed discussion of each of these sections appears as Attachments A-D.

A. Health Effects

The record demonstrates that lead has profoundly adverse effects on the health of workers in the lead industry. Inhalation, the most important source of lead intake, and ingestion result in damage to the nervous, urinary, and reproductive systems and inhibit synthesis of the molecule heme, which is responsible for oxygen transport in living systems. The adverse health effects associated with exposure to lead range from acute, relatively mild, perhaps reversible stages such as inhibition of enzyme activity, reduction in motor nerve conduction velocity, behavioral changes, and mild central nervous system (CNS) symptoms, to permanent damage to the body, chronic disease, and death.

The signs and symptoms of severe lead intoxication which occur at blood lead levels of 80 μg/100g and above are well documented. The symptoms of severe lead intoxication are known from studies carried out many years ago and include loss of appetite, metallic taste in the mouth, constipation, nausea, pallor, excessive tiredness, weakness, insomnia, headache, nervous irritability, muscle and joint pains, fine tremors, numbness, dizziness, hyperactivity, and colic. In lead colic, there may be severe abdominal pain, such that abdominal surgery mistakenly has occasionally been performed.

Damage to the central nervous system in general and the brain (encephalopathy) in particular is the most severe clinical form of lead intoxication. The most severe, often fatal, form of encephalopathy may be preceded by vomiting, apathy progressing to drowsiness and stupor, poor memory, restlessness, irritability, tremor, 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 (peripheral 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 lead exposure. There is evidence that prolonged exposure can increase the risk of nephritis, mental deficiency, premature 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. There 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 birth defects, mental retardation, behavioral disorders or die 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 heretofore 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 psychological disturbances. 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 early 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 imperfectly understood. OSHA believes that while incapacitating illness and death represent one extreme of a spectrum of responses, other biological effects such as metabolic or physiological changes are precursors or sentinels of disease which should be prevented. This disease process can be subdivided according to Bridbord (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 there is a continuum of effects. 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 pathophysiologic changes from exposure to lead. Pathophysiologic changes indicate the occurrence of important health effects. Rather than revealing the beginnings of illness the standard must be selected to prevent an earlier point of measurable change in the state of health which is the first significant indicator of possibly more severe ill health in the future. The basis for this decision is twofold—first, pathophysiologic 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 pathophysiologic 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 requires that blood (PbB) 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 physiological 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. The remainder of this summary will address the health effects evidence in each system: heme synthesis inhibition, and damage to the nervous, urinary, and reproductive systems. 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 if the lungs of an individual did not function well. The central nervous system is particularly sensitive to the lack of oxygen and neurological damage could conceivably occur prior to anemia 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 lead 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 leading to anemia begin to occur? (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 dehydrogenase (ALAD), an enzyme responsible for the synthesis of a precursor to heme, is observed at PbB levels below 20 μg/100 g. At a PbB level of 40 μg/100 g more than 20 percent of the population would have 70 percent inhibition 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), occurs at this PbB level; 11 percent of adult males are excreting more than 10 μg/l.

The build-up of another product of impairment indicating inhibition of another enzyme, ferrochelatase, also occurs at low PbB levels. At a PbB level of 50 μg/100 g a larger proportion of the population would suffer these effects and the effects would be more extreme. At a PbB level of 50 μg/100 g, 70 percent of the population would have 70 percent inhibition of ALA-D, 37 percent would have urinary ALA (ALA-U) values larger than 10 μg/l 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 all cells of the body is an effect 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 subcellular 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 higher PbB level a greater proportion 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 internal environment 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 μg/100 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 μg/100 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 during the hearings.

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 physiolgical 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 symtomatic 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 * * *." A much more 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 cells of the body. Enzyme (ALA-D) inhibition due to lead exposure has been found in the liver at PbB levels below 40 μg/100 g (Ex. 5(22)). Electron microscope studies have revealed mitochondrial changes associated with lead exposure such as lead 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 liver. Millar found parallel decreases in ALA-D activity in the blood and in the brain at PbB levels above 30. (Ex. 23(68)), ref. Millar. This evidence supports Piomelli's suggestions that changes in heme synthesis in the blood forming (hematopoietic) system reflect changes that occur in other tissues. The work of Fishbein 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 well below 80 μg/100 ml (mean PbB was approximately 60 μg/100 ml). (Ex. 105D). Fishbein also noted anemia in 37 percent of these same workers, 17 percent of whom had blood lead levels below 60 μg/100 ml.

While the evidence relating lead effects of heme synthesis to symtoms 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 measurable effects 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 it 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 through to the onset of clinical symptoms. 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 "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 individuals subjective lack of feeling adverse effects. 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 lead 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, Lilis et al. (Ex. 24, (10)) has demonstrated central nervous system symptoms (tiredness, fatigue, nervousness, sleepnessness or somnolency, or anxiety) in 56 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 behavioral 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 around 40 μg/100 ml. Lilis testified that about 60μg/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 levels of 40 or 45, that means that at those levels you already find something going wrong in the body" (Tr. 2702). Repko has carried out behavioral tests and demonstrated adverse effects in visual reaction time, as well as deficits in hearing among workers having a mean blood lead level of 46 μg/100 ml. Valciukas 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. These 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 non-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 to be a threshold level for behavioral changes and mild CNS symptoms in adults, and to protect against long-term neurological effects, blood levels should never exceed 60 μg/100g.

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 lead levels below 70 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 extremity. 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 a 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., Geraid et al., Guadriglic et al., Araki, W. R. Lee, Repko, Lilis, Fischbein et al., and Seppalainen 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 Second 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 Seppalainen et al. and the data reported in the literature that changes in nerve conduction velocity occur in some lead workers at blood levels exceeding 50 μg/100ml. It was thought that no conclusion could be drawn from the one case in the blood lead range 40-49 μg/100ml.
>
> 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 more than one nerve is an early stage in the development of clinically manifest neuropathy. There is no evidence that these changes progress. Reversibility should be studied. Although 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. 262, p.64.) (Critical effect is a defined point in the relationship between dose and effect in the individual, namely the point at which an 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 coworkers. 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 exposure levels previously thought to be of relatively

little consequence. Seppalainen has stated:

Of course, in terms of health, the importance of slight subclinical neuropathy can be questioned, too, and we did not find any evidence that the well-being of these workers was influenced by the neuropathy, apart from a few complaints of numbness of the arms. Thus, the term "poisoning," in its orthodox sense, cannot be applied to these disorders. But neuropathy, no matter how slight, must be regarded as a more serious effect than the quite reversible alterations in heme synthesis, because the nervous system has a poor regenerative capacity, and the acceptability of such a response must be judged from that point of view. Since the entire question belongs to the diffuse "gray area" between health and disease, it is more than probable that opinions will diverge. We think, however, that no damage to the nervous system should be accepted, and that, therefore, present concepts of safe and unsafe PbB levels must be reconsidered (Ex. 5(12), p..183).

Recovery from the effects of chronic lead poisoning may be feasible in some cases, if the worker is removed 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. 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 disease and peripheral neuropathy after treatment with chelation therapy, most studies have not been encouraging, 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 only partially reversible, if at all, with chelation therapy and/or removal from further exposure. This is not particularly surprising, however, since experience with other heavy metal intoxication has been similar. Nervous system damage from arsenic and mercury responds minimally to chelation therapy. Apparently, irreversible changes occur once the heavy metal is bound by nervous tissue. Although further study is 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. 27(7), p. 55).

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.

In order to prevent peripheral neuropathy as evidenced by slowing in NCV's Seppalainen testified that "to be safe, I would say 50 μg/100 g blood" is the necessary level (Tr. 147). Dr. Seppalainen further recommended that studies be performed to determine "the safety at the level of 50 μg/100 ml" (Tr. 153). OSHA agrees that the current evidence demonstrates that nerve conduction velocity reduction occurs at 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 blood lead levels are maintained below 50μg/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 workers may be afflicted with this 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 manifestation 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. 1732.) 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 Lilis, 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 mechanism, it is also necessary to protect the thousands of workers who are potentially in danger of developing renal disease. The record indicates that blood lead 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 thare 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 lead levels 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 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 the next 20 years, 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 precisely whether the blood lead was above or below 80 or above or below 60 for example, might be an important factor in determining the eventual development of renal disease in lead workers?

Dr. Wedeen: Yes; that is just what I meant, that the accumulative effects and the cumulative body burden may be very different from the blood lead level at any moment in time.

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 during the working lifetime, Would you have some reservations about a blood lead maximum standard, even at 60?

Dr. Wedeen: I certainly would. And I think I just expressed the basis for it, You will note that in my recording of these patients, very very few of them had blood lead levels over 60. I just feel that while the blood lead level is maybe 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. 1765-1766).

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 im-

portant because the worker has lost the functional reserve, the safety, provided by two normal kidneys. If one kidney becomes damaged, the normal person has another to rely upon. The lead worker with 50 percent loss of kidney function has no such security. Future loss of kidney function will normally occur with increasing age, and may be accelerated by hypertension or infection. The usual life processes will bring the lead worker to the point of uremia, while the normal individual still has 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. 1747-1750).

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 body burden 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. *Repoductive 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 (teratospermia) 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 (hypospermia) and decreased motility (athenospermia) were observed not only in the preceding roups 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 teratospermia. The other parameters measured, hypospermia and athenospermia, 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 miscarriage rate in women whose husbands were exposed to lead. Experimental investigations have also shown both a reduction in the number of offspring of laboratory animals and 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" Zielhuis and Wibowo criticized the study by Lancranjan et al., and there was considerable critical discussion of it during the hearings. OSHA has 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 teratospermia 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 uncontroverted 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 damage to the fetus from exposure to lead but there are extensive studies which demonstrate neurobehavioral effects at blood leads of about 30 μg/100 ml and above in children. OSHA believes that the fetus and newborn would be at least as susceptible to neurological damage as would older children and therefore data on children is relevant to the fetus, although acknowledging the duration of exposure may be more limited in the fetus. OSHA asserts 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. 45936; Ex. 95). OSHA agrees with Dr. Vilma Hunt 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, cardiorespiratory 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 were in evidence. 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 lead 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 leads 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 reasonably protective insofar as it 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(31)), the National Academy of Sciences (Ex. 86M), and the EPA (FEIS (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 in order to prevent 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 or developing child blood lead levels 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 the 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. More than a dozen witnesses testified on this issue; many others offered their views in response to questions; over 400 pages of the transcript of these proceedings were devoted to this issue. Ms. Hricko testified that women of childbearing age had been excluded from employment because "the response of industry has been to "protect women workers from lead's reproductive hazards by refusing to hire them or by forcing them to prove that they can no longer bear children." (Ex. 60 (a)(ii)). However, there was also testimony which demonstrates that women have and do work in production areas of battery manufacturing (Tr. 1245, 4057, 4506, 4855, 5529, 5898). In its proposal OSHA raised the issue of whether "certain groups of adult workers may have greater susceptibility to lead intoxication than the general worker population. One such group is female employees of childbearing age." (Ex. 2, p. 45936). The LIA argued in its post hearing brief that OSHA is not obligated to set a health standard which would insure equal employment for all persons. That is, a standard should not be promulgated which would be based on protection of the fetus and the pregnant female since that would require a lower PEL which would have correspondingly greater costs of compliance. Industry testimony further suggests that women of childbearing potential could be "protected" by excluding them from employment in many parts of the lead industry.

Other parties to the hearings argued that given the data on male reproductive abilities and potential genetic effects in males and females, fertile men were equally at risk as women of childbearing age; therefore, the standard should be designed to protect all exposed workers, male and female.

Dr. Stellman testified as follows:

> In summary, it can be stated that there is no scientific justification for placing all women of childbearing age into a category of a susceptible subgroup of the working population. There is sufficient data available to show that a significant proportion of the population is at risk from the effects of exposure to lead, and hence can also be deemed susceptible. Further, if the intent of the OSHA standard is to protect workers from reproductive effects, there is still justification for treating women separately from men. (Tr. 1161-62)

This view was supported by other witnesses (Ex. 92; Ex. 343; Ex. 59; 60A). Dr. Hunt, for example, stated:

> There is no evidence to allow a conclusion that women of childbearing age themselves are more susceptible to the adverse effects of lead. The susceptible population is made up firstly of the fetus in utero, actually present in the work environment and secondly the offspring of male and female workers with blood lead levels high enough to alter their genetic integrity. (Ex. 59, p. 26.)

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, decreased 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 the risk of reproductive effects would be minimized at this level.

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 biosynthesis 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 this 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/m³ 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 airlead 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 level 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 unquestionably exists 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 blood lead levels over time 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 originally developed by S. R. Bernard by the Center for Policy Alternatives (CPA) combines experimentally observed properties of mammalian lead transport and metabolism, including considerations of the dynamics of blood lead response 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, known as a multicompartment mammillary model. Such models postulate that the substance in question first appears in the blood, and then is transported or diffused into a number of different compartments from the blood, corresponding to the different organ systems 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 are individually taking up and excreting lead after an initial dose. The more exponential terms required to fit the data, the more compartments. Second, the investigator can actually follow 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 subjects. After observing the rates of release of the substance in question from the whole body and/or tissues, the investigator is left with a series of exponential retention equations which relate amount of lead left in each compartment after a given time to the initial dose. Using rather complicated but well-developed mathematical techniques, this set of equations can be solved subject to the constraint that all of the ingested substance is accounted for, to yield the rate constants for transfer between compartments. The CPA study also included specific consideration of particle size and individual variability in response to air lead, which is necessary in predicting 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 leads 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 heretofore unseen in attempts to establish air level to blood 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 values 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:

$$\text{Current Blood-Lead} = a(\text{Current Air Lead}) + b + \text{Individual error}$$

(a=slope of the line; b=blood lead at zero air lead)

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 blood lead level and long term average air lead exposure. This has the practical effect of incorrectly predicting that the mean PbB level at 200 $\mu g/m^3$ will be close to that at 100 $\mu g/m^3$, which was a criticism made by LIA during the hearings. To the degree that the contribution of prior exposure to curent blood 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 additional 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 level 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 also 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 the 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*

LINEAR RELATIONSHIPS

Blood Lead=a(Air Lead)+b

Source of Relationship	b	a	Non-Linear
King: Smelting (3)	52	0.053	
Battery (1)	46	.032	
Pigments (2a)	30.	.07	
Pigments (Quadratic fit)			(1)
Globe-Union	39.7	.1229	
ASARCO (El Paso)	32	.185	
Williams	30.1	.201	
Delco-Remy (Buncher)	37.45	.0628	
Azar/Hammond			(2)
CPA: Bernard model and assumption C			
Job tenure (years)-			
0.95	25.80	.1521	
3.4	28.30	.2062	
9.0	29.80	.2404	
16.0	30.64	.2604	
28.5	31.46	.2778	

[1] Blood Lead=26+.12 (Air lead)+.000098 (Air Lead)^2

[2] Log(Blood Lead)=1.3771+.153 log 40(Air)+128÷168

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/m^3) 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 (25-200 μg/m^3), 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 lead 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 sample 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. 2(32)) 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 of the plastics workers' exposures may have been qualitatively (particle size, solubility) different from 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 lead-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 three basic components:

(1) Individual differences in the long term (years) average blood level response to a given air lead level;

(2) Individual differences resulting from true short term (days or weeks) fluctuations in blood lead level; and

(3) Apparent short term variability from measurement error.

Based on an analysis of data from the Delco-Remy battery plant, it is estimated that true long term blood lead variability corresponds to a standard deviation of approximately 5.5 μg/100g. This is likely to be an underestimate of true long term differences in blood lead resulting from a constant air lead exposure because a single plant over a limited time is unlikely to include as large a diversity in the many factors producing long term variability as would prevail in a random sample of all lead-using industries. The value of 9.5 μg/100g, used in the previous CPA work as an upper bound on true long term variability, appears to be the best mid-range estimate of total (short and long term) true variability. A high range estimate for total variability (including measurement error) suggested in the record is approximately 15 μg/100g. OSHA has used a standard deviation 9.5 μg/100g in calculating the distribution of blood lead levels at particular air lead levels. This distribution has then been utilized to calculate the incremental benefits of the permissible exposure limit over the other alternatives of 40 μg/m³, 100 μg/m³ and 200μg/m³. The results are found in the benefits subsection of the PEL section.

B. PERMISSIBLE EXPOSURE LIMIT

1. *General considerations.* The final standard establishes a permissible exposure limit (PEL) of 50 μg/m³ averaged over an eight hour period. The decision to establish this PEL was based on consideration of the health effects associated with exposure to lead, feasibility issues, and the correlation of airborne concentrations of lead with blood lead levels that are in turn associated with adverse effects and symptoms of lead exposure.

At the time the proposal was issued, OSHA stated that "in order to provide the appropriate margin of safety, as well as to provide significant protection against the effects, clinical or subclinical, and the mild symptoms which may occur at blood lead levels below 80 μg/100 g it is necessary to set an airborne level which will limit blood lead (PbB) levels to 60 μg/100 g. A maximum blood lead level of 60 μg/100 g corresponds to a mean blood lead level of about 40 μg/100 g" (Ex. 2, p. 45938). Based upon the extensive evidence of adverse health effects associated with exposure to lead, OSHA has determined that in order to provide necessary protection against the effects of lead exposure, the blood lead level of lead workers must be kept below 40 μg/100 g.

In establishing 40 μg/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 μg/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 lead level of workers, both men and women, who wish to plan pregnancies should be maintained at less than 30 μg/100 g during this period, and this knowledge forms the basis for the action level of 30 μg/m³ established in this final standard which the agency believes will maintain the majority of blood lead levels below 30 μg/100 g.

OSHA recognizes that a PEL of 50 μg/m³ will not achieve the goal of maintaining the blood lead levels in all occupationally exposed workers below 40 μg/100 g. Based on the calculations using the CPA adaptation of the Bernard model, OSHA predicts 0.5 percent of worker blood leads will exceed 60 μg/100 g; 5.5 percent of the workers will have a PbB between 50-60 μg/100 g; 23.3 percent will be between 40-50 μg/100 g; and overall, 29.3 percent of exposed lead workers will have PbB above 40 μg/100 g at any one time when uniform compliance with 50 μg/m³ PEL is achieved. However, this represents a substantial improvement over current industry conditions. The current blood lead level distribution assuming compliance with 200 μg/m³ is approximately (1) greater than 60 μg/100 g, 22.4 percent; (2) 50-60 μg/100 g, 32.6 percent; (3) 40-50 μg/100 g, 28.7 percent; (4) The total above 40 μg/100 g, 83.8 percent.

In establishing 40 μg/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 meets the test of feasibility. OSHA has determined that 50 μg/m³ represents the lowest level for which there is evidence of feasibility for primary and secondary smelting, SLI battery manufacturing, pigment manufacturing, and brass/bronze foundries. The 50 μg/m³ 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 μg/100 g, and will virtually eliminate all blood lead levels above 60 μg/100 g.

This level of 50 μg/m³ 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 industries, technology looming 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 μg/m³ represents the best intersection between maximization of health benefits and feasibility.

2. *Health effects.* In the proposal, OSHA questioned whether both clinial and subclinical effects of exposure 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 pathologial 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 characteized 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 a immediate 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 inhibits 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 substrate 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 symtoms of lead poisoning. Biological variability between individuals will necessarily cause differences in the PbB level at which a particular person will experience each stage in this disease continuum; therefore, 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 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, Tola'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 anemia, are not the most significant clinical effects of heme synthesis disruption nor the earliest. He stated that "a much more 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 following exposure to lead, and that this disruption results in alteration of the process of 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 very serious consideration with respect ot 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 hematopoietic 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 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 effects of the disruption of heme synthesis in the hematopoietic 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. 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 clincial 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 the 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 lead 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 tissue. 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.

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 provide an indication of 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 early 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 workers. A dose-response relationship for the slowing of MNCV has been determined, and it is apparent 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 as yet undetermined, 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 pathophysiologic 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 damage and disease (neuropathy).

In order to prevent peripheral neuropathy as evidenced by a slowing in NCV'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 if the worker is removed 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 studies have not been encouraging, 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 only partially reversible, if at all, with chelation therapy and/or removal from further exposure. This is not particularly surprising, however, since experience with other heavy metal intoxication has been similar. Nervous system damage from arsenic and mercury responds minimally to chelation therapy. Apparently, irreversible changes occur once the heavy metal is bound by nervous tissue. Although further study is 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. 27(7) p. 55.)

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.

c. *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 routine screening after serious damage has occurred. Elevated BUN and S-creatinine are measurable only after two-thirds of kidney function is lost, or upon manifestation of symptoms of renal failure. OSHA agrees with the conclusions of Wedeen: "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. 1750) since in this situation "progression to death or dialysis is likely." (Tr. 1732). The record indicates that blood lead is an inadequate indicator of kidney disease development, since rather than being a complete measure of body burden, it is merely a measure of absorption when sampled close to the time of exposure.

Given these conclusions, OSHA must approach the prevention of kidney disease by recognizing the limited usefulness of certain biological parameters. Therefore, OSHA believes any standard established for lead must provide some margin of safety and 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 burdens lead. (Tr. 1771)

d. *Reproductive system.* The record clearly demonstrates that lead has profoundly adverse effects on the course of reproduction. Prior to conception exposure to lead is responsible for menstrual and ovarian cycle abnormalities in women, decreased libido, impotence and altered sperm formation in men, and lowered fertility and genetic damage in both males and females. Genetic damage may result in spontaneous miscarriage, stillbirth, or in a disease or birth defects in a live born child. There is data which documents that miscarriage and stillbirth may be caused by maternal lead esposure during pregnancy. In fact, lead has been used as a abortifacient. In women exposed to lead, Fhim has reported that the mothers of premature babies had significantly higher mean blood leads than did mothers with normal pregnancies.

There is conclusive evidence that lead crosses the placenta of pregnant women and enters the fetal tissues; lead levels in the mother'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 increases from that point to birth. 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 a 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 affected—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 provisions 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 following birth. Compliance with 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 effected 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. Given the data in this record, OSHA believes there is no basis whatsoever for the claim that women of childbearing age should be excluded from the workplace in order to protect the fetus or the course of pregnancy. Effective compliance with all aspects of these standard will minimize risk to all persons and should therefore insure 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 80μg/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. 2700-01), Dr. Needleman (Tr. 1085-86; 1106-07); Dr. Epstein (Tr. 1051-52, 1058-65, 1067-68, 1072, 1073-74, 1104-05); Dr. Lancrajan (Tr. 1771), Dr. Wolfe (tr. 4140), Dr. Teitlebaum (Tr. 374-78), Dr. Bridbord (Tr. 1976-02), Dr. Fishbein (Tr. 2660-61, 2669) and Dr. Piomelli (Tr. 467).

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 1.5 μg/m³ designed 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 the 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 lead per deciliter of blood. Blood lead levels above 30 micrograms are associated with an impairment in cell function which EPA regards as adverse to the health of chronically exposed children. There are a number of other adverse health effects associated with blood lead levels above 30 micrograms in children as well as in the general population, including the possibility that nervous system damage may occur in children even without overt symptoms of lead poisoning." (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 (15)) 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 accumulating 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 body 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 Zielhuis at the Amsterdam meeting in 1972 recommeded an individual limit 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, in 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, 45 or 40, and I think that same argument, deriving out of sharp and clinical and experimental evidence, would apply to the worker that is, that if you look more carefully for evidence of impairment, you are going to find it.
>
> The fact that an adult worker will spill aminolevulinic acid in his urine, at a blood

lead of 40, to me says, that this is a clinical effect of significance. (Tr. 1078, 1106-07.)

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 lead 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 blood levels associated with adverse effects and symptoms of lead exposure, and to correlate these blood lead levels with airborne concentrations of lead. During the hearings, industry representatives steadfastly maintained that blood lead levels cannot be correlated with, nor predicted from, air-lead concentrations. Based on the record evidence, OSHA has concluded to the contrary. While many studies in the record have limitations, these limitations by no means imply that the data are useless or that no reliable relationship exists between long term air lead exposures and blood lead levels. Given the extent to which the likely systematic errors in the short term studies in the record are understood, the observed equations 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 could be explicity incorporated into a more comprehensive description of the general system.

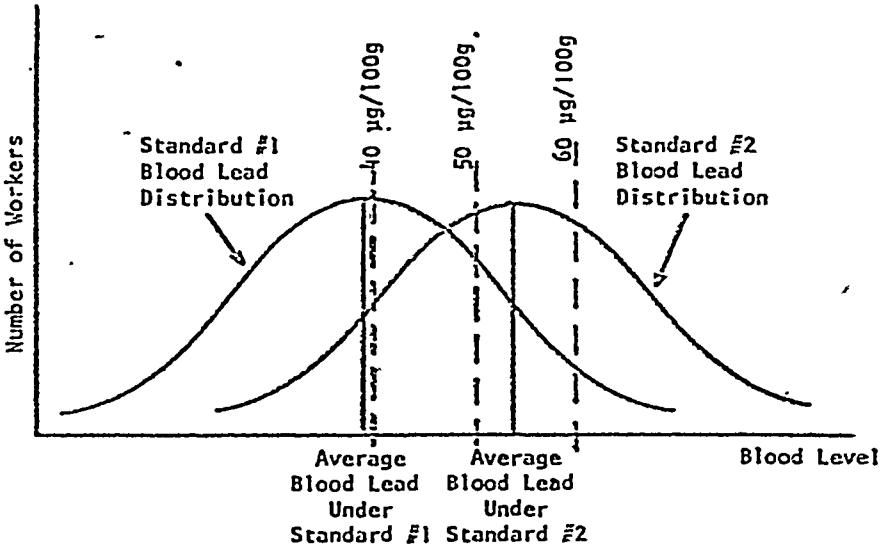
In order to accurately predict the effect on blood lead levels which would be caused by long term exposure to various levels of air lead, it was necessary to construct a model that takes into account the important factors which affect blood lead levels. The physiological model originally developed by S. R. Bernard and adapted by the Center for Policy Alternatives (CPA) combines experimentally observed properties of mammalian lead transport and metabolism, including consideration of the dynamics of blood lead response to long term exposure. The model also accounts for the 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. Furthermore, the CPA study includes a specific consideration of individual variability in response to air lead, which is necessary in predicting the responses of large populations 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 exposures and blood leads 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



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 drawn at 40, 50, and 60 μg/100g. 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.

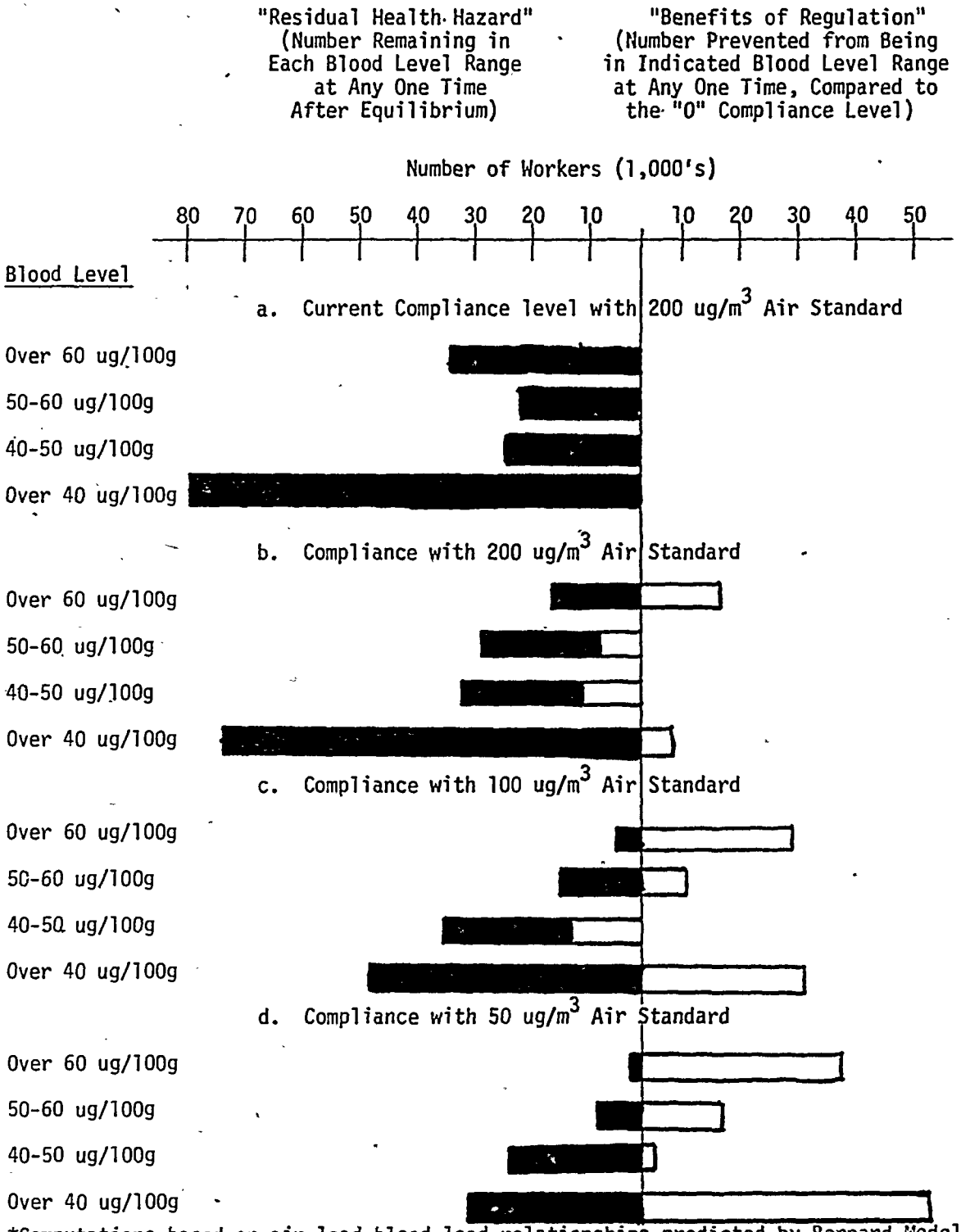
Second, it should be stressed that the measurement of benefits chosen represents a continuous "flow," not a "stock." As time passes and workers move into and out of employment in lead-related industries, the differences between compliance with various PEL's continuously generate differences in the population 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.)

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



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

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

Blood Level Standard Deviation = 9.5 ug/100g

Long Term Average Air Lead Exposure	Total Number of Workers	≥ 60 ug/100g	50-60 ug/100g	40-50 ug/100g	Total ≥40 ug/100g
		a. Current Compliance Level			
> 100 ug/m^3	41,622	27,652	8,508	4,166	40,326
50-100 ug/m^3	55,885	5,125	14,379	19,732	39,243
	97,507	32,777	22,887	23,898	79,569
		b. Compliance with 200 ug/m^3			
> 100 ug/m^3	41,622	9,340	13,569	11,958	34,867
50-100 ug/m^3	55,885	5,125	14,379	19,732	39,243
	97,507	14,465	27,948	31,690	74,110
		c. Compliance with 100 ug/m^3			
> 50 ug/m^3	97,507	2,562	14,041	32,870	49,475
		d. Compliance with 50 ug/m^3			
< 50 ug/m^3	97,507	498	5,373	22,729	28,599
		Incremental Benefits			
b over a		18,312	-(5,061)	-(7,792)	5,459
c over a		30,215	8,846	-(8,972)	30,094
d over a		32,279	17,514	1,169	50,970
c over b		11,903	13,907	-(1,180)	24,635
d over b		13,967	22,575	8,961	45,511
d over c		2,064	8,668	10,141	20,876

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 32,777 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 "b" 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 14,000. 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 lead 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 rather than relying on biological indices for the following reasons:

1. Evaluation of the industrial environment by proven industrial hygiene techniques is a direct measure 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 then is a direct measure of the control of lead exposure. Biological monitoring is designed to ascertain problems in 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 80, 70, or 60 μg/100 g would be excessive and 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 percent 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 excessive exposure or it 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 of workers. Excessive exposure to lead would not immediately effect excessive blood lead levels. In fact, some workers' blood leads 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 unsubtantiated. OSHA believes there is no doubt that an air to blood 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 air standard OSHA has concluded there is little or no basis for accepting the asserted success of an enforcement mechanism based on future biological monitoring.

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 μ100g/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/m³. The CPA application of the Bernard model predicts a mean blood lead level of 34.6 μg/100 g at 50 μg/m³ when compliance with the standard is achieved, compared to a mean PbB level of 40.2 μg/100 g at 100 μg/m³.

The number of workers whose PnB levels were initially greater than 60 μg/100 g will be substantially reduced from 32,777 to 498 with compliance at 50 μg/m³. For 100 μg/m³, the benefits are also substantial, 32,777 to 2,562 with the incremental benefit for 50 μg/m³ over 100 μg/m³ being 2,064. There are 22,887 workers whose PbB are between 50 and 60 μg/100 g. Compliance with 50 μg/m³ would reduce that number by 17,514, whereas at 100 μg/m³, the number would be 8,846 with incremental benefit of 8,668 for 50 versus 100 μg/m³. Between 40 and 50 μg/100 g there are 23,898 and compliance with 50 and 100 μg/m³ results in a decrease at 50 μg/m³ of 10,141 and increase at 100 μg/m³ of 8,972 with a benefit of 50 versus 100 μg/m³ of 10141. Lastly, there are 9,569 workers whose PbB levels are above 40 μg/100 g. Compliance with 50 μg/m³ and 100 μg/m³ respectively would reduce the numbers to 28,599 and 49,475 with an incremental benefit of 20,876 for 50 vs 100 μg/m³.

SUMMARY

Incremental Benefit (by number of workers) 50 μg/m³ vs 100μg/m³

Number of Workers removed:

>60 μg/100 g	2,064
50-60 μg/100 g	8,668
40-50 μg/100 g	10,141
>40 μg/100 g	20,876

In summary, OSHA finds that 50 μg/m³ will provide significantly increased protection to exposed employees over what would be achieved at 100 μg/m³, 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/m³.* 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/m³.

The evidence of adverse health effects cited in the proposed lead standard and in this final standard demonstrates that a PEL of 200 μg/m³ 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/m³ 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/m³ until compliance has been achieved at that level and medical evaluation has determined whether or not it is protective. OSHA believes the evidence already exists which demonstrates that 200 μg/m³ 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/m³ versus the current level of compliance with 200 μg/m³ 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/m³ vs. 200 μg/m³

Number of workers removed:

>60 μg/100 g	32,270
50-60 μg/100 g	17,514
40-50 μg/100 g	1,169
>40 μg/100 g	50,970

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/m³ standard and that the arguments set forth in favor of a 200 μg alternative are not compelling.

(d) 40 μg/m³.

The United Steel Workers of America proposed 40 μg/m³ as an alternative to 100 μg/m³ in the proposal.

OSHA has calculated the equilibrium distribution of blood lead levels assuming rigorous compliance with 40 μg/m³ and has compared these results to a similar calculation for 50 μg/m³. The results are as follows:

BLOOD LEAD DISTRIBUTION (IN PERCENT)

	>40 μg/100g	40-50 μg/100g	50-60 μg/100g	>60 μg/100g
40 μg/m³ (24.2%)		19.9%	4%	0.3%
50 μg/m³ (29.3%)		23.3%	5.5%	0.5%

OSHA has determined that the incremental benefit of 40 μg/m³ versus 50 μg/m³ 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/m³ 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, or at or above 50 μg/100 g of whole blood averaged over the previous 6 months. These two ultimate blood lead level removal triggers are gradually phased in over a period of 4 years. 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 years will be needed for some segments of the lead industry to completely engineer out excessive plant air lead emissions. During this time heavy reliance will have to be placed on respiratory protection—a frequently inadequate means of worker protection. Again, temporary medical removal is essential for those inadequately protected. Temporary medical removal is a crucial 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 is 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 cannot serve to identify 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 could fully participate in the medical surveillance program and risk losing his or her livelihood, or resist participating in a meaningful fashion and thereby lose the many benefits that medical surveillance and temporary medical removals can provide. Convincing evidence 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 participation in medical surveillance programs under several prior OSHA health standards which lack MRP benefits. Evidence concerning the issue of worker of fear impeding participation was not confined to testimony 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 of 1969. Experience under this progam reveals the extent to which economic disincentives adversely affect participation even in medical surveillance programs where job transfer and limited economic protection are guaranteed. 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 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 place these costs of worker 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 obligaton 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 cental 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 step could not possibly 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 would 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 satisfactory 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 conjuction 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 respiratory protection proves 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 employees having blood lead levels at or above 80 μg/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 will have a reasonable opportunity to reduce their current employees' blood lead levels before particular blood lead level removal triggers come into effect.

Employers who comply 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 smoothly 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 work force (much less than 6 percent should need temporary medical removals at any point in time. With experience, employers should acquire the ability 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 lead record rejects any suggestion that small companies by virtue of size are incapable of protecting worker health. And, the level of health protection an employer provides, not size, will be the prime determinant of an employer's MRP costs.

7. *Temporary medical removal and return criteria.* The ultimate blood lead level removal criteria derive from the conclusion that long-term blood lead levels in excess of 40 μg/100 g of whole blood must be avoided. Removal at a blood lead level of 60 μg is mandatory since this level will invariably represent numerous months of a blood lead level in excess of 40 μg during the overall period of absorption up to 60 μg and excretion down below 40 μg. Removal when an average blood level over the past 6 months is at or above 50 μg is required since this long-term average indicates a worker's blood lead level is either steadily increasing above 40 μg or has stabilized appreciably above 40 μg. Blood lead level measurements have a significant inherent measurement variability. To reduce the impact of this factor, both the temporary removal and return of workers due to elevated blood lead levels are based on the combined results of at least two independent measurements.

The standard provides that the return of a worker removed due to an elevated blood lead level to his or her former job status is also governed by the worker's blood level. During the years that the ultimate removal criteria are being phased in, the return criteria have been set to assure that a worker's blood lead level has substantially declined during the period of removal. A worker removed due to a blood lead level at or above 80 μg must be returned when his or her blood lead level is at or below 60 μg/100 g of whole blood; if removed due to a level at or above 70 μg, return shall follow when a level of 50 μg/100 g of whole blood is achieved. Once the ultimate removal criteria have been phased in, return depends on a worker's blood lead level declining to 40 μg/100 g of whole blood.

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 despite 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 non-work-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 increased 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 at 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 $\mu g/m^3$ action level. Work 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 so as to permit return of the worker 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 80 μg need only be removed from work having a daily eight hour TWA exposure to lead at or above 100 μ/m^3. During the second year following the effective date of the standard, workers removed due to blood lead levels at or above 70 μg need only be removed from work having a daily eight hour TWA exposure to lead at or above 50 μ/m^3. 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, all removed workers must be removed 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 to the extent 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 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 at his or her normal job such that the time weighted average exposure is below the action level. The worker might even be temporarily laid off or arrangements might be made for the removed worker to temporarily perform comparable work at 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 altered by some countervailing obligation. A removed worker is provided no automatic right to veto an employer 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 poses major conflicts with existing collective bargaining relationships. To the extent conflicts exist, they should be easily resolved during the lengthy phasein 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 bargaining 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 4-year 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 to exposure to lead due to a final medical determination which differed from the opinion of the examining physician chosen by the employer, then the return of the worker (or the removal of limitations placed upon the worker) must be delayed until after a final medical determination has been reached on these issues. The second exception applies to situations where an employee has been on removal status for the preceding 18 months due to an elevated blood lead level, and a medical determination is being obtained as to continued removal of the worker. In this very limited instance the standard requires that the employer maintain the status quo—i.e., removal—until the full physician review mechanism has had an opportunity to form a final medical determination concerning the employee.

12. *Definition of MRP benefits.* The standard requires an employer to provide MRP benefits to a worker on each occasion that a worker is removed from exposure to lead or otherwise limited. This requirement is defined as meaning that the employer must maintain the earnings, seniority and other employment rights and benefits of a worker as though the worker had 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 far 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 a worker's body burden of lead 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 continue to 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 are to 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 formed the basis for provisions 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 worker 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 question. 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 a 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) maxi-

mize meaningful participation in the standard's medical surveillance program, (2) facilitate the use of temporary medical removals, and (3) appropriately 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 lead standard.

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 3(8) 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 occupational health standards be based on "experience gained under this and other health and safety 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 set 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(g)(2)'s grant of general rulemaking authority provides additional support for MRP's adoption. The preceding statutory provisions demonstrate that Congress indended 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 not considered by Congress 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 established a broad 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 attention to one extremely hazardous industry—coal mining. The 1969 Coal Act was a comprehensive response to coal mine hazards, including thirty statutory pages of specific health and safety regulations as detailed as any existing OSHA standard. In the context of its comprehensive review of coal mining, Congress considered the appropriateness of an MRP-type program with regard to coal mine workers pneumoconiosis. Congress went beyond merely 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 the 1977 amendments 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 voiced approval of MRP. 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 workmen's compensation law or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of employment." Section 4(b)(4) was addressed in the legislative history, and has been applied in case law to date, only as a means of either preventing private causes of action under the OSH Act, preventing federalization of state workmen's compensation law, preventing duplication of federal regulations, or preserving state regulatory authority over safety and health matters. MRP is unrelated to all of these policies, including the policy against federalization of state workmen's compensation law. MRP neither intends nor operates to define or expand state law in this area. To the contrary, if MRP as a preventive health mechanism succeeds as intended, there hopefully will be no occupational lead disease left for state workmen's compensation law to address. To the extent such a result constitutes a conflict with state law, it is fully intended by the Act.

Various legal arguments were also presented in the lead proceeding to the effect that MRP somehow impermissibly conflicts with federal labor law, and with the Equal Pay provisions of the Fair Labor Standards Act. Having researched and considered these arguments, OSHA finds them to be without merit.

D. FEASIBILITY

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 most 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 the latest available scientific data in the field, 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 it can confidently state is feasible for all affected industries. The final standard has a PEL of 50 $\mu g/m^3$ as an 8-hour TWA, which, within 90 days, must be met by any combination of engineering controls, work practices (including administrative controls), and personal protective equipment. Compliance with the PEL exclusively by engineering controls and administrative controls including work practices is required to be phased-in over time according to an implementation schedule. The schedule varies by industry on the basis of technological and economic limitations on each industry's ability to comply, and for five industries whose compliance period in the schedule exceeds 1 year, includes an interim exposure limit of 100 $\mu g/m^3$.

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 $\mu g/m^3$ 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, and evaluating whether compliance is feasible, OSHA has identified affected industries and investigated potential compliance methods including the available technology in those industries. It has attempted to estimate the length of 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 required engineering and administrative controls including work practices are not sufficient. 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 can 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 1960'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 "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 softening process that removes antimony and other metals.

Because 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.

Thus, the corrosive property of the molten metal has prompted the use of open vessels and crude mechanical methods. The nature and scale of primary smelting have made the application of standard engineering techniques difficult. While the 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 some modification of existing processes. This conclusion is not in agreement with the conclusions of DBA and lead industry representatives. (Ex. 355, 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 infeasibility 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 at all work stations at all times. (Tr. 3971-72; 796, 797.) This interpretation was rejected in *SPI* v. *OSHA.* (Vinyl chloride) and *AISI* v. *OSHA* (coke ovens). DBA and industry representatives also limited their considerations to retrofit technology only and did not generally consider technological change unless it had been proved successful and could be implemented immediately. (Tr. 5793; Tr. 796-97; Tr. 872-73; Ex. 26, pp. 4-5, 4-8; Ex. 29(29A).) Long-run technological solutions were not considered, even those which may be more cost-effective. This creates an a priori limitation on the gamut of possible approaches to compliance.

OSHA has concluded that compliance with the PEL may require up to 10 years for this industry. Primary smelting is not generally regarded as innovative. Dr. First characterizes the history of technological change in this industry as conservative and having "a strong bent to make changes very slowly and in small steps." (Ex. 270, p. 17.) Other limitations on the rate of change are the size and complexity of the hot metal operations in these plants.

Further, the degree of technological change necessary to achieve 50 $\mu g/m^3$ may require development and implementation of innovative technology,

possibly including alternatives to pyrometallurgy. OSHA believes that the 10 years provided in the implementation schedule represent maximum 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 feasibility attachment on specific operations may prove to be sufficient. (Tr. 1463.)

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 $\mu g/m^3$ 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 chloride to produce 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 plants, for example, has ranged from 40 to 140 (Ex. 138D, 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 reuse.

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 reprocessed 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 drossing to remove copper and other impurities.

Following the drossing, the lead may be "softened" 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 industry are exposed to lead. (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 $\mu g/m^3$. Data after this date showed 102 of 129 air lead levels above 100 $\mu g/m^3$ and 87 of 129 above 200 $\mu g/m^3$. (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 $\mu g/m^3$ interim level. Based upon its study of seven representative smelters, Dr. Thomas Smith testified for DBA that compliance by secondary smelters with a standard of 100 was technologically feasible. (Tr. 798) One company, Keystone Resources, which operates four secondary smelters across the country commented that "our controls are such that we feel we could also meet the action level (50 $\mu g/m^3$) specifications" (Ex. 3(39)). Before the implementation of engineering controls, average air lead at Keystone Resources was 1,036 $\mu g/m^3$. The controls reduced the average to 126 $\mu g/m^3$. (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 $\mu g/m^3$ level. (Ex. 26, p. 5-38; Tr. 956.)

Attaining these levels, however, may in a few instances require extensive modifications of current processes. IHE, 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 $\mu g/m^3$ airborne lead. (Ex. 138D, 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 drossing, such as continuous vacuum drossing. (Tr. 2387-80; Tr. 6530-31.) Svend Bergsoe, president of Paul Bergsoe and Son of Glostrup, Denmark, described in detail his new technique for smelting scrap lead products. (Tr. 5142-5204.) 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. 5194.) In addition a flash furnace agglomerates the flue dust, and the process is entirely enclosed.

With the possible exceptions of installing afterburner and agglomeration 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. 5192). This cost 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. 138 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 ("burned") into groups that 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

of lead dust. Dust forms as well during reclamation of rejected grids, parts, and pasted plates, and during removal of plate groups from defective batteries.

The record indicates that in the battery industry available methods can control employee air levels of lead below 50 $\mu g/m^3$, 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 $\mu g/m^3$. (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 room) atmosphere of less than 50 micrograms per cubic meter of air. (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 in 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, when 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. 270, p. 19.)

IHE's specifications are designed primarily for larger operations. They assume that production is continous 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. 1007.)

Testimony from operators 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 $\mu g/m^3$, and its was just slightly over, 110 $\mu g/m^3$. (Tr. 1247-48.)

Some operations with high exposures are done only intermittenly 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, such plants may not need the same controls as a plant that pastes plates all day every day. In fact, alteration of production schedules or employee rotation may be effective. 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, APSEE, Inc., and Kermatrol, Inc., testified that they could provide the technology for compliance at sharply reduced costs.

The new approaches might aid large as well as small plants in meeting the 50 $\mu g/m^3$ standard. Some operations in either large or small operations will quickly be able to achieve the 50 $\mu g/m^3$ standard. The UAW asserted that aggressive implementation of such conventional control techniques as enclosure, ventilation, and process redesign can achieve the 50 $\mu g/m^3$ 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 $\mu g/m^3$ standard. (Tr. 5053.)

d. *Brass and bronze foundries.* The lead 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 lead content of copper based ingots averages 5 percent. (Ex. 26, p. 5-73.) Over 1620 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 56 percent of the particulate matter has been shown to be lead oxide when the alloy has a high lead content. Any workers in the vicinity of the melting or pouring operation as well as employees working to operate or maintain baghouse dust collectors may be subject to inhalation of these lead containing fumes. Sources of airborne lead 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 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 $\mu g/m^3$ within one year. DBA concluded that feasible engineering controls are available to met this level. (Ex. 26, p. 5-73, Tr. 800.) They found that most plants do not at present have enough control in effect. Significant improvements are necessary for compliance with the proposed standard. For example, half the plants currently do not use baghouses and the majority do not provide heated make-up air. Gary Mosher, representing the American Foundrymens Society, explained that "exhaust systems have been devised and designed that will close capture * * * fumes right at the ladle and the furnace." He further testified that such methods are effective in bringing exposure below 200 $\mu g/m^3$, but did not express an opinion as to whether such techniques are effective in bringing exposure below 100 $\mu g/m^3$. (Tr. 2801).

OSHA, however, has concluded that conventional technology in the industry has been shown effective for lowering exposures from melting and pouring to 100 $\mu g/m^3$. 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 melts; (4) use of the Hawley Trav-L-Vent; and (5) increased use of dilution ventilation 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.

e. *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 linoleum, 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. (Ex. 26, p. 5-92.) 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. 5-93.)

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 manufacture is a combination of chemical-physical processes involving both wet and dry reactions, including precipitation, filtering, washing, fusing, calcining, etc. The processes may be carried out as 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 old. 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-lead 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 barriers 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.

f. *Other industries.* For the 11 other industries that were discussed in the DBA report or its supplement (Ex. 65-B), technological considerations are detailed in the feasibility 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 various forms of "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 individual firms.

In attachment D to the preamble, OSHA has made a detailed examination of the cost estimates of its contractor (DBA) and those of the principal industry consultants (CRA). Differences in estimates are discussed and reconciled where 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 levels below 100 $\mu g/m^3$ might, in several industries, require extensive technological development for which long periods of implementation time would be required, thus precluding meaningful quantification of 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 sufficient for 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 perhaps 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-

plementation of substantial technological change, possibly including alternatives to pyrometallurgy which are now in the experimental stage. 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 $\mu g/m^3$ interim level is in a range between $32 million and $47 million (in 1976 dollars). The total annualized cost at the 100 $\mu g/m^3$ 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 $6.202 and $8.133 million. Based on total 1975 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 sufficient to cover the incremental costs of meeting the 100 $\mu g/m^3$ 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. 6-25). 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, as well as in the short-run, will most likely be price inelastic, and finally, the foreign supply of refined lead will probably be relatively inelastic in the short-run, the significant period in which domestic producers could recapture a substantial portion of compliance costs. As to the long-run, several factors can and may operate to make the foreign response to changes in U.S. price indeterminate.

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 Heineke's work (the basis of the DBA analysis), and OSHA's evaluation of Heineke's conclusions support 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.

At least one major producer, Amax, is confident that the industry will be able to pass costs forward. They stated 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.)

(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 sever as indicated in the CRA analysis. The increasing price of lead has improved the marginal conditions attributed to several mines by CRA. Further, the incentive to ship abroad depends on foreign costs maintaining their present relationship to U.S. costs excluding OSHA impacts, a questionable assumption. Finally, OSHA believes that the differential can rise somewhat above the cost of transporting the ore to foreign smelters because of the obvious advantages of adequate U.S. smelting and refining capacity to the domestic mines.

(3) The industry has the ability to pass costs forward or backward sufficient not only to recover the cost of the 100 $\mu g/m^3$ interim level, but to assure that any likely cost associated with the PEL will not jeopardize long-run profitability. In the assessment of market power, OSHA disagrees with the conclusion in the CRA report. The difference is most apparent in the analyses of the non-Missouri operations of ASARCO. (Ex. 127, pp. 2-79 through 2-84.) CRA calculates the annual compliance cost of the proposed standard to these operations at $3.7 million or approximately 1 cent per pound of refined lead. They are aware that ASARCO had announced its intention to spend $55.2 million at El Paso and $32.2 million at East Helena to control air quality problems associated with lead productions. These capital costs, when annualized, produce an additional 6.2-cents-per-pound expense to the company, almost one-third of the market price of lead used in the analysis. The CRA cost pass-back analysis limits ASARCO's recovery from the mines to a maximum of 2 cents per pound. Their elasticity analyses preclude any long-run price increase. They conclude that the incremental OSHA costs seriously jeopardize continuing operation of the ASARCO Western smelters and refinery since the air quality controls would seem to cost ASARCO 4 cents per pound out of profit. They attribute ASARCO's willingness to continue in business to the externalities of custom smelters which extract "metals such as silver, cadmium, bismuth, and selenium as well as the slag processing which improves the flexibility of the ASARCO system." (Ex. 127, p. 2-84) CRA makes no attempt to document this claim. It is obvious that ASARCO was willing to risk an enormous sum of money. Either they anticipated an ability to recover that long-run expense in terms of price increases or cost pass backs or some combination of both.

OSHA concludes that the segment of the primary industry claimed to be in the most financial trouble, the Western custom smelters, have sufficient market power to survive enormous increases in costs. The money scheduled to be spent on air quality problems may alleviate some occupational lead problems as well. More important, it is the most impressive possible statement of the perception of the long-run viability of the industry by the largest producer. Since ASARCO announced these commitments, the price of lead has nearly doubled.

(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.

DBA'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 show 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:

Company	Capital costs (percent)	Annual costs (percent)
ASARCO	45.6	11.3
Amax	5.4	1.7
St. Joe	15.4	4.5
Gulf Resource	54.3	15.9

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 uneconomical for Gulf 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 $0.579 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 1975 profit was $6.2 million. Its average profit between 1970 and 1975 was $10.664 million overall and about $5.332 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 decision 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.

(5) If compliance costs reduced the profitability of Bunker Hill to a point where Gulf Resources decided to close its lead operations, the competitive structure of the primary sector would be largely unaffected. DBA stated it this way (Ex. 26, p. 6-26):

> If one or more producers of primary refined lead should be forced to shut down lead refining operations, concentration in primary refined lead production could increase substantially. Such an event would no doubt facilitate cooperative behavior among the surviving primary lead producers. However, this probably would not affect significantly the nature of competition in refined lead.
>
> The degree of concentration in primary refined lead production is already potentially high enough to achieve a joint 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. Thus the competitive situation probably would not be significantly affected even if the imposition of the proposed occupational lead exposure standard leads to a reduction of the number of firms engaged in primary lead production.

(6) The compliance schedule for meeting the 50 $\mu g/m^3$ 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 any firm to completely rebuild an existing smelter (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 greater than now envisioned for existing equipment and thus lower long-run costs of compliance. DBA stated that "we can expect to see new, innovative and cost-effective compliance methods being introduced as a result of enforcement of the standard." (Ex. 26, p. 2-16.)

The 10-year compliance time constitutes a planning horizon sufficient to allow all firms maximum flexibility in capital planning. OSHA believes the long-run outlook for the industry is favorable and there exists some combination of engineering controls and work practices, including administrative controls, which will permit all four firms to remain in the market. Because the economic and environmental conditions of the western smelters vary widely from those in Missouri and among themselves, OSHA has established a time frame designed to maximize the technological and economic options for the industry. This compliance period is sufficient to allow each firm the opportunity to assess the likely state of the market and to raise the capital necessary for conversions required by air and water quality standards, other OSHA standards, and the 50 $\mu g/m^3$ lead standard. OSHA has concluded that this flexibility is necessary for achieving the most cost-effective solution for the industry consistent with necessary worker protection.

(b) *Secondary smelting and refining.* Compliance with the interim level in 3 years and PEL in 5 years appears feasible since extensive process modification as well as refinement of recent technological developments may be necessary for some firms. In addition, the Bergsoe smelting 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 adaptation if new 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 $18.9 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 $\mu g/m^3$ 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 technology) is determinable. To completely rebuild with the Bergsoe process would cost

approximately $90.6 million excluding land costs.

OSHA has concluded that compliance with neither the 100 $\mu g/m^3$ nor the final PEL of 50 $\mu g/m^3$ is likely to have severe impacts in this industry. This is in general accordance with the views of CRA and DBA. Both predicted some closures from high-cost marginal operations but expected no drastic impact on the structure of this industry. DBA seemed to be somewhat more pessimistic about closure than the industry study. DBA noted that although concentration has been increasing (Ex. 26, pp. 6-6, 6-7), production within the industry is still not highly concentrated, primarily as a result of low entry barriers. Sources of scrap can be easily acquired and initial capital requirements are low. (Ex. 127, p. 1-29.) As a result, secondary producers have little control over prices, even in the short run, essentially following the market. (Ex. 26, p. 6-10.) They will be able to shift compliance costs forward onto product prices only if primary producers raise prices. OSHA has determined that the DBA impact assessment is faulty in two respects. First, DBA did not consider the possibility that primary smelters might be able to pass through some of the compliance costs and secondary smelters would benefit accordingly. More importantly, DBA did not analyze the ability of secondary firms to pass cost back to scrap dealers. CRA anticipates that the average compliance cost will be passed back and thus only firms whose costs exceed the average would have to absorb any compliance cost even absent a price rise.

These estimates make no allowance for the use of administrative controls which should bring further reduction from these estimates. Firms will be able to increase prices to the extent that the primary producers do so. However, at least the average compliance costs can be passed back to the scrap dealers. Thus only the highest cost marginal firms are likely to face a decision on whether or not to cease operations.

(c) *Battery manufacturing.* Control of lead exposure for the more than 12,000 exposed employees in accordance with 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 process. Less complex, and less expensive compliance solutions appear to be possible for small producers, including the use of employee rotation.

OSHA estimates the capital cost of meeting the 100 $\mu g/m^3$ interim level to be in the range of $205.1 to $230 million with annualized costs of $25 to $28.1 million.

The battery industry is essentially an oligopolistic industry with a fringe of small independent producers who compete in regional or specialty markets (Ex. 26, p. 6-37). It is comprised of 138 companies who operate a total of 200 plants, but the 5 largest companies, who operate 55 plants having 78 percent of the total industry capacity, dominate the market. (Ex. 26, pp. 6-33, 6-37.) The seven largest companies operate 70 plants and sell 90 percent of all the batteries sold (Ex. 26, p. 5-42). It is also an industry that has been in the process of consolidation for many years. In the past 20 years the number of firms in the industry has steadily decreased from over 300 in 1954 (Ex. 127, p. 3-4) to just 138 in 1972 (Ex. 26, p. 6-33).

The questionable assumptions underlying the IHE report (the engineering which provided the basis for the cost estimates) lead to the conclusions drawn by DBA and CRA that approximately 100 small battery manufacturers would exit the industry as a result of the proposed standard. (Ex. 127, p. 3-53; Ex. 26, p. 6-24.) OSHA does not believe that the approximately 100 small plants will have to assume the magnitude of cost used by DBA and CRA because of the overestimation of costs by IHE, because the lead quantity in small plants is lower (Ex. 349, pp. 16-18), and because of several available low-cost compliance alternatives, discussed earlier, which are uniquely suited to small plants. In addition, some small manufacturers might take advantage of economies of scale by 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 in recent years of very small firms (95 firms have less than 20 employees and a total of 2 percent of the market) leaving the industry because of unprofitability. These firms have discovered shrinking markets for their products, and 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. (Ex. 127, pp. 3-6.) These factors are expected to continue to put severe stress on the small battery manufacturer without respect to additional costs due to OSHA regulations, and the consolidation trend is expected to continue.

OSHA has concluded that even if the questionable DBA and CRA prediction that approximately 100 small manufacturers would exit the market were true, the standard is nonetheless feasible for the battery industry.

Closure of 100 small businesses would have a minimal impact on the competitive structure of the industry. Thirty firms operating 100 plants will remain, and the capacity of the 7 largest firms, now 90 percent of industry capacity, will 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 which the major producers do not choose to capture." (Ex. 349, p. 19; Ex. 26, p. 6-42; Ex. 127, pp. 3-7 through 3-9.) The small producers may set prices in small local markets where they supply retailers directly and take, in price, the equivalent of distributor markups or where special services (picking up old batteries, fast delivery, etc.) to the retailer allow price increases. (Ex. 127, p. 3-8.)

Battery prices will increase as a result of the passthrough of compliance cost. The industry price setters, the five major producers, will have compliance costs of about $0.74 per battery, with an industry average of $1.11. (Ex. 127, p. 3-35.) CRA has 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. (Ex. 127, Exec. Summ., p. 37.) This will allow small producers who enter the distribution chain at advanced stages to pass through costs of about $1.04 per battery (Ex. 127, Exec. Summ, p. 37.) except where they are not in competition with the major firms.

Closing of 100 plants employing 10 persons each would mean the loss of approximately 1,000 jobs. Compliance activities require additional manhours, however, and it is estimated that the net gain in employment, if production remains at the prestandard level, would be approximately 2,000 employees. Productivity, therefore, would decrease by just over 9 percent. The impact on wages would be small. (Ex. 26, p. 6-43 and 6-44.)

OSHA's evaluation of the technology available to the battery industry indicates that compliance with the PEL may be achieved by the same types of technological changes required to achieve the interim level of 100 $\mu g/m^3$, although further refinement, additions, and modifications may also be necessary. The compliance schedule requiring engineering controls and work practices to be used to reach 100 $\mu g/m^3$ 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. Large manufacturers should 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. For smaller manufacturers, OSHA has concluded that simple and inexpensive approaches can be effective in many situations, thereby drastically decreas-

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.

(d) *Brass and Bronze Foundries.* Compliance with the interim level of 100 $\mu g/m^3$ in 1 year is feasible in this industry with presently available technology, while compliance 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 cost. Costs of compliance will be passed on to the purchasers of castings, and DBA estimates that price increase would be equivalent to about $0.16 per pound 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 since substitutes for brass and bronze castings exist for some uses total industry output may fall. The industry association which testified at the hearings did not plead 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 retrofit technology which 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 $\mu g/m^3$ interim level would require a price increase of 1.7-3.7 percent instead of the DBA prediction of 16.6-21.6 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 includes an analysis of the record evidence and the policy considerations underlying the decisions adopted pertaining 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 minimize absorption 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 preexisted the final 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 employment 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 to which this standard applies is defined to include metallic lead, all inorganic lead compounds, and organic lead soaps. 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 soaps, have varying degrees of toxicity or have toxicological properties different than the inorganic group,[1] and thus are excluded from the scope of this standard. Some of these excluded compounds are covered by existing OSHA standards,[2] 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

[1] E.g., tetraethyl and tetramethyl lead are absorbed through the skin, unlike the inorganic compounds. See *Documentation of the Threshold Limit Values for Substances in Workroom Air*, American Conference of Governmental Industrial Hygienists, 3rd ed., 1971, 3rd printing, 1976, pp. 251-54.

[2] Tetraethyl lead has a permissible exposure limit of 0.075 mg (as Pb)/m^3 and tetramethyl lead a permissible exposure limit of 0.07 mg (as Pb)/m^3, both as an 8-hour TWA. 29 CFR 1910.1000, Table Z-1.

under the permissible exposure limit for chromic acid and chromates in Table Z-2 of S1910.1000, 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 $\mu g/m^3$); 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 impose obligations commensurate to the degree of hazard present. For a more complete discussion of each particular requirement, see following paragraphs (C) through (R).

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 and construction industries in Parts 1915-1918 and 1926 and in Subpart b of Part 1910, 29 CFR, would be superceded if they were determined to be not as effective as the final standard.

Several parties to the rulemaking contended that the construction industry should be exempt from coverage of the standard or that the standard should have special provisions for the construction industry because of the inherently different nature of construction employment as compared to industrial employment. (Ex. 3(30); 3(64); 3(98); 3(130); and 381A; Tr. 7290-7341.)

The primary reasons cited to support exemption of the construction industry 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 employee and his tools to move from place to place, resulting in varying exposure conditions; and (3) has a high number of temporary employees.[3] 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; 7309-10; Ex. 3(64), p. 3).[4] 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 contaminant source and exposure levels are often unique in any given task at any given time, and the air monitoring data derived can not serve its primary 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 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 to be unworkable. Because initial medical surveillance and periodic follow-up is predicated upon air monitoring results, the shortcomings of air monitoring for the construction industry, as discussed above, undermines the medical programs' effectiveness. The temporary worker may thus not get a medical exam or blood test until after the lab results of air sampling return, and follow-ups may be due long after he leaves the job. The need to protect the worker who begins employment with elevated blood lead levels may then only be ascertained after employment has been terminated. Also, high turnover rates and minimum medical personnel in remote and nonurban areas tend to aggravate the time problem.

OSHA has considered all the evidence in the rulemaking record on this issue and has concluded that there is insufficient evidence to satisfactorily resolve all the issues raised with respect to applicability of this standard to the construction industry. Construction is a diverse activity about which no valid generalizations can be drawn concerning the nature of lead exposure, the duration of a project, or the the duration of an employer-employee relationship, and the record does not support drawing rational distinctions between groups that can feasibly be covered by the standard and groups that cannot. OSHA's own contractor on the EIS suggested that "the feasibility of applying the various provisions of the standard should be examined before including the construction industry in the scope of the standard." (Ex. 65B, p. 31.) Accordingly, OSHA intends to utilize the expertise of the Construction Advisory Committee and will request that it review the rulemaking record and make recommendations on the most appropriate way the lead standard can be applied to the construction industry. These recommendations will then become the basis for a proposed modification to part 1926.

OSHA has determined that the final lead standard would be more effective than corresponding standards for the maritime industries because, as a comprehensive health standard integrating air monitoring, medical surveillance, training and other requirements, it would provide greater protection to employees exposed to lead than that provided by the current maritime standards. Unlike the construction industry, representatives from the maritime industries who participated in the rulemaking did not claim that the standard should not be applicable to maritime activities. In fact, the Shipbuilders Council of America, and industry trade association, stated that compliance with the proposed standard was feasible even though it objected to specific provisions. (Ex. 230.)

Specifically, the new standard would supercede references to the 1970 TLV's in sections 1915.11, 1915.21, and

[3] Construction work has a high turnover rate (300-600 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.)

[4] The Council of Construction Employers states that "large construction companies use air monitoring techniques to determine toxic concentrations of airborne contaminants. There is no doubt that such techniques are available and can readily provide useful information . . ." (Ex. 3(64), p. 2)

1917.11. The TLV for lead in 1970 was 200 $\mu g/m^3$ and to not supercede the current maritime standard would clearly allow a less protective, and hence less effective, standard to apply to the maritime industry. In addition, there are general standards for the maritime industries which, while not specifically applicable to lead exposure, would apply when lead exposure occurs in those industries. Where provisions in those standards clearly conflict with the new standard, the provisions of the new standard are intended to apply (e.g., s1915.23(a)(4)); however, where the present maritime standards are more specific or require additional protective action, they shall not be superceded. Examples of the latter case are in 1915.31(c), which deals with welding, cutting, or heating of toxic metals and sets forth specific work practices when these activities are performed. These sections would still apply, along with the new lead standard, but only to the extent they do not conflict with the new standard.

Finally, this standard does not apply to agricultural operations, standards for which are found in Part 1928, since OSHA had not proposed to cover agricultural operations and no comments were received on the issue.

B. DEFINITIONS: PARAGRAPH (b)

The final standard has deleted, as unnecessary, two definitions contained in the proposal. The definition of action level has been added to the final standard.

C. PERMISSIBLE EXPOSURE LIMIT (PEL); PARAGRAPH (c)

The final standard has a permissible exposure limit of 50 $\mu g/m^3$ as an 8-hour, time-weighted average.[5] This is the highest level of lead in air to which an employee may permissibly be exposed, exposure being defined as the actual concentration of airborne lead in an employee's breathing zone. Thus, the methods by which the employer chooses to reduce an employee's exposure to lead are not relevant to a determination of whether the PEL has been exceeded. The standard requires that the PEL be complied with immediately and at all times whether by engineering controls, work practices (including administrative controls), or respirators. A second obligation exists in the "Methods of Compliance" provision, paragraph (e) of the regulation, which requires engineering and work practices controls to be implemented according to a schedule to attain compliance with the PEL, and a violation of this paragraph may exist if the required means are not used to achieve permissible limits.

[5]The rationale for choosing this level as the PEL is discussed in part III and Attachment B of this preamble.

The PEL is an eigth-hour average of exposure for any work day. If respiratory protection is permissibly being used to comply with 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 not 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 the respirator, divided by the protection factor of the respirator. For example, if an employee is exposed to 100 $\mu g/m^3$ for 8 hours without a 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 the 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 in arriving at a 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 ($C \times T$) 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 $\mu g/m^3$.

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 a conversion 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), (67), (103), (107); Ex. 80; Ex. 234(16); Ex. 234(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. Koremus, Deputy Assistant Secretary of the Interior, advocated the tolerance of some lead compounds at higher airborne concentrations. Koremus pointed out that some 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 limits for lead compounds which "would not result in excess blood lead" (Ex. 3(57), p. 2) 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, citing the availability of the lead ion for absorption, the physical characteristics of the compound, and the route of absorption as distinguishing characteristics. (Ex. 3 (59).)

Bissonnette pointed specifically to the paint industry where the lead compounds used in paint pigments are "relatively insoluble." When paint is sprayed, the lead is "suspended and encapsulated in the paint mist" rendering it 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. (Ex. 3(59), p. 1.)

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. H. Berlsterm claimed that lead sulfide "does not pose a significant adverse health problem and should be specifically exempted" from the lead standard. (Ex. 3 (107), p. 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(59), p. 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, almost all lead to which employees covered by this standard will be exposed (e.g., lead fume, lead oxides) is relatively soluble. Most employees exposed to lead sulfide are mine and mill workers who fall under the jurisdiction of the Mine Safety and Health

Administration and are not covered by OSHA standards. Only the few employees involved in the handling of ore and concentrates at lead smelters will be exposed to lead sulfide and many of them may also be exposed to other, more soluble forms of lead such as recycled 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 exposure to lead-based paints are less toxic. Bissonnette's suggestion that painters' blood lead levels are normal despite high air lead levels because of lower toxicity is perhaps better explained by the fact that painters always wear respirators as protection from toxic vapors of solvents in the paint. (Tr. 1200.)

Another factor suggested by participants is the particle size of the lead aerosol. Particle size affects the respirability and hence absorption of lead into the blood. However, nonrespirable particles may also be absorbed into the blood through direct ingestion or from swallowing nonrespired particles trapped on the mucous membranes in the respiratory tract. (Ex. 439A, p. 3-12.) The rate of absorption in the gut is clearly different than in the lung. OSHA agrees that particle size is relevant to the determination of a PEL and accounted for particle size in developing its air-lead to blood-lead relationship.

D. EXPOSURE MONITORING: PARAGRAPH (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 appropriate, "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 primary purpose of monitoring is to identify the sources of lead emission and to determine the extent of employee lead exposure. This will enable the employer to select proper control methods and to evaluate the effectiveness of the selected methods. Additionally, monitoring enables employers to notify employees when their exposure levels exceed permissible limits, as required by section 8(c)(3) of the Act, and provides information necessary to the examining physician.

Paragraph (d) of the regulation contains provisions for monitoring employee exposure to airborne lead without regard to the use of respirators. The final standard is essentially unchanged from the proposal except for three differences: (1) the initial determination of employee exposure must be based, at least in part, on air sampling and analysis, (2) periodic monitoring must include full-shift personal samples, and (3) the monitoring frequency is reduced.

The proposed standard would have required all employers to make an initial determination of whether any employee 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 in certain industries 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 existed.

OSHA has reassessed this provision and decided that employers in all industries where lead is present in an occupational context should perform a minimal amount of exposure monitoring because it is the only precise method of determining lead-in-air concentrations and because it cannot be confidently predicted that lead exposures 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 anaylsis identified and collected information on 46 industries, representing at least 57 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 prevalence of lead poisoning and no precise measure of the extent of lead exposure. (Ex. 1, p. III-1.) For these reasons, it is important for each employer in whose workplace lead is present or used in an occupational context to make an initial determination of potential employee exposure based on a reliable and accurate method. To exclude all employers except those in traditionally high exposure industries from initial monitoring (as the proposed 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 reguirement is minimal in that it only requires monitoring of a repesentative sample of the employees believed to have the highest exposure levels. If these measurements indicate exposure below the action level, no further monitoring is required except where subsequent process or control changes would trigger a redetermination pursuant to paragraph (d)(7). If any employee is determined to be at or above the action level, then full-scale representative monitoring for all exposed employees is required.

In conducting the monitoring of employee exposures, the standard does not require that each individual employee's exposure level be measured. Although individual measurement is the ultimate indicator of an employee's exposure, OSHA believes that a requirement for individual measurement may be too burdensome, and that representative monitoring will adequately insure that the worker's exposure is maintained within the requirements of this standard. In establishments having more than one work operation involving the use of lead, in order for monitoring to be representative, 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 employer from taking individual exposure measurements of each of his employees; individual measurements are certainly considered to be representative; however, representative monitoring merely establishes the minimum that the employer must meet.

OSHA disagrees with testimony which suggests that little or no confidence can be placed in determinations of employee exposure which are not based on an actual measurement of the exposure of each individual employee. (Tr. 6073.) If the representative employee chosen is, in fact, representative and a sampling protocol utilizing full-shift samples is used, OSHA believes this will be adequate in ascertaining 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 calibration. (Ex. 3 (12), p. 4; Tr. 3626)

The objective of environmental monitoring is twofold: first, full shift personal sampling will enable the employer to determine an individual employee's exposure to airborne concentrations of lead.[6] Individual monitoring information combined with biological monitoring data and clinical evalua-

[6] OSHA recognizes that there will be day-to-day variability in airborne lead exposure experienced by a single employee. The permissible exposure limit is a maximum allowable value which is not to be exceeded; hence exposure must be controlled to an average value well below the permissible exposure limit in order to remain in compliance. This consideration forms the basis for OSHA's 95 percent confidence level requirements. (Ex. 314; Ex. 235; Ex. 150 A, pp. 30-32.)

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 (ingestion, 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 also 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 reflects 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 in order 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. 3 (125)) and labor (Ex. 343, pp. 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. 26, pp. 5-9, 5-35, 5-67), 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 implementation schedule to reduce employee exposure to lead below the PEL. For some industries, interim levels are established which the employer must achieve solely by means of engineering and work practice controls. During 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 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(31), p. 1.) These terms admittedly do not have precise meaning and often overlap, and the following is an attempt to set forth the meanings of these terms as they are commonly understood in the industrial hygiene community and used in this regulation.

"Engineering controls" employ mechanical means or process redesign to eliminate, contain, divert, dilute, or collect lead emissions at their source. Examples of this type of control include process isolation or enclosure; employee isolation (excluding respirators) or enclosure; closed material handling systems; product substitution or process redesign to eliminate the contaminant; and dilution or exhaust ventilation. "Work practice controls" or "work practices" accomplish the same results as engineering controls, but rely upon employees to repeatedly perform certain activities in a specified manner so that airborne lead concentrations are eliminated or reduced. This may be accomplished as simply as instructing employees to keep lids on containers, to clean up spills immediately, or to observe required hygiene practices. Good work practices are often required in conjunction with engineering controls; for example, where employees perform an operation under an exhaust hood, they must perform their work in such a way as to maximize the efficiency of the ventilation equipment.

Work practices also incorporate administrative controls within their scope. Administrative controls simply involve moving the employee to a place of lower exposure or reducing his work hours so that his daily, time-weighted average exposure is reduced. This type of control method does not act in any way on the source of the emissions.

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, is 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 LIA and BCI, concurred with this approach provided engineering and work practice controls were feasible. (Ex. 342, p. 6; Ex. 355; 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, process or equipment enclosure, 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 primarily a 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 the term "work practices" has been commonly thought to include employee rotation or other administrative types of control. However, OSHA's policy has generally been to denigrate 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 unknown, e.g., carcinogens. (See preamble to standard for occupational exposure to 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 ineffective, unreliable, and unsafe method of reducing employee exposure. The Council on Wage and Price Stability (Ex. 224) and some industry representatives (e.g., Ex. 3(107)) 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. 14.) 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 female employees or 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, and 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 properly selected for the environment in which the employee will be working, properly fitted to the employee, maintained and cleaned periodically, and worn by the employee when required.

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 ones 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. First also agreed that "stringent limits for lead exposure should be treated as goals to be reached over reasonable time periods." (Ex. 270, p. 19.) 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 plan, design, 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 inter-industry 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 feasiblity 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 raising and proving 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 appropraite, it should be sought. Similarly, the mandatory nature of these requirements is not 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 (e)(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 task 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 the production processes 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 plan should be a 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 and implemented 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 enabling compliance personnel to monitor employers' compliance activities.

The standard requires the employer to have the written plan completed and made available at the worksite according to a schedule determined by the compliance implementation schedule in table I of paragraph (e)(1). OSHA considers 6 months to be a sufficient planning period when the total compliance time is 1 year and the compliance effort is not complex. For those industries where compliance will require between 2 and 5 years, 1 year for planning and preparation of the plan is deemed adequate; for the primary lead production industry which has 10 years to comply with the PEL, as much as 5 years may be needed so as to incorporate the latest developments in emerging technology.

Upon examining the employer's compliance plan, the Secretary will determine whether the plan's schedule for implementation of engineering and work practice controls is designed to and will achieve compliance with the PEL by the required date. OSHA will take enforcement action 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 is extended such as to render completion by the required date unlikely. In addition the employer who has developed an adequate plan for reducing employee exposure below the PEL but does not meet the scheduled implementation dates in the plan will be subject to citation.

These written plans must be furnished upon request for examination and copying to representatives of the Assistant Secretary and the Director and to affected employees and their designated representatives. They must be reviewed and updated periodically at least every 6 months to reflect the current status of exposure control. OSHA views the requirement for written plans as an essential part of the compliance program since it will form the basis for determining the employer's ability to achieve the controls and provide the necessary documentation to OSHA of the compliance methods chosen, the extent to which controls have been instituted, and of the plans to institute further controls.

The inclusion of the 200 $\mu g/m^3$ level in the schedule is simply intended to continue the present standard, which has been in effect since 1971. This level will continue to be enforced until compliance with a lower level is required. For the five named industries, compliance with 100 $\mu g/m^3$ by engineering and work practice controls will be enforced at the times indicated as an interim milestone until ultimate compliance with the PEL is achieved. The time allowed for each industry to comply is based on record evidence of the nature of 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 $\mu g/m^3$ 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 require action that is inconsistent with action that would be required to reduce levels to the 100 $\mu g/m^3$ interim level. This is meant to cover the situation where the allocation of technical or economic resources to compliance with the interim level would divert resources from the final goal and clearly preclude compliance with the PEL, which would otherwise be attainable, by the required time. An example of where this situation may arise is where compliance with the interim level could 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, and the employer can demonstrate why compliance with the interim level is incompatible with compliance with the PEL, the employer must conform the compliance plan accordingly and notify the OSHA Area Director nearest the workplace. This notification requirement is intended to alert OSHA that an employer intends to bypass the interim level and to initiate an in-

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 air 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 weight of the evidence from the hearing 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 back up equipment." (Ex. 343, p. 126) The Battery Council International agreed. (Ex. 342, p. 7) The LIA suggested that "since the outdoor ambient air in the vicinity of a lead plant often contains a relatively high air-lead concentration, properly designed recirculation systems may furnish the workplace with air that is in fact lower in lead concentration than the air which would otherwise be drawn in through conventional air systems." (Ex. 335) Similarly, Caplan of IHE stated that "a well-designed recirculation system could provide a healthier working environment than would a conventional exhaust and make-up air system . . . If you would permit recirculation, again and always with adequate safeguards, then the designer and the owner and operator can afford to be more generous with the amount of air handled in the exhaust hoods and dust control hoods, and therefore achieve better results." (Tr. 3719)

In its report for the BCI, IHE described a safe design for recirculation. (Ex. 29(29A), pp. 6-7) The system would consist of a self-cleaning fabric filter as the first air cleaning devices followed by a second or high-efficiency backup filter of the HEPA type. This second filter can be tested in place to assure its proper functioning, and there are no moving parts to reduce the efficiency of such a filter bank. Other controls can easily be installed to monitor the concentration of lead oxide dust in the air, and to bypass the recirculation systems automatically if it fails. Schneider also described a safeguard system used in the beryllium industry. (Tr. 2075-76) Based on the availability of these designs, OSHA believes that safe recirculation of air is technologically feasible and can be sufficiently protective. Recirculation is also fuel efficient and economically desirable because tempering of additional make-up air would not be required and additional air quality systems may not be necessary. (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. 29(29A).) Caplan testified that the capital cost of installing a safe recirculation system can be recovered in one year 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 employee health.

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 proposal except certain provisions 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 whenever 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 by the standard. For example, male and female workers whose blood lead levels are in the 30-50 μg/100g range may desire increased protection, especially if they intend to parent in the near future.

While respirators are the least 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 considered 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 NIOSH's Testing and Certification Branch, noted that respirators have traditionally been designed to fit men and only recently has NIOSH proposed regulations to amend Subpart K of Part 11, 30 CFR, for dust, fume and mist respirators, to include a test panel composed of women test subjects. (Tr. 1360)

Edward Baier, Deputy Director of NIOSH, further emphasized that while respirators are not suited to women's faces, they are also not suitable for persons wearing a beard or mustache or even persons with a scar. (Tr. 1459). Many other participants elaborated on other problems associated with respirator fit. (Ex. 91, Tr. 1240-1; Tr. 6433; Tr. 6476; Ex. 155A).

There are more problems associated with respirator use 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; Tr. 6476) Safety problems 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, 6616) 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 practice 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. 5812; Tr. 5821; Tr. 5508), and OSHA emphatically agrees that respirators are not to be used as a primary method of control. However, because of the lengthy compliance periods required by some industries to implement engineering controls and work practices, respirators will be necessary in the interim as the only available protective method.

A daily limit on duration of respirator usage (e.g., Tr. 1459; Tr. 5801-11; Ex. 343, p. 118) has been considered by OSHA, especially for those industry segments 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 respirator will only be required to be worn for a period of time which, when averaged with the period the respirator is not worn, does not exceed the PEL. For example, if environmental monitoring shows that an employee's exposure level without regard to a respirator is 100 $\mu g/m^3$, the respirator need be worn only a little more than 4 hours. (See paragraph (c)(3) of the regulation and discussion in paragraph C of the Summary and Explanation.)

The evidence in the record on the inadequacy, discomfort, and hazards associated with respirator usage support some limitation of full-shift wearing of respirators for long periods of time. (Ex. 155, p. 9) Four industries (secondary lead production, battery manufacturing, pigment manufacturing, and nonferrous foundries) are not required to meet the PEL for five years; one industry (primary lead production) is not required to meet it for 10 years. OSHA has concluded that for these industries 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 to 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 foundries. The time limit is based on the maximum amount of time an employee would have to wear a respirator (assuming a protection factor of 10) if the employer has complied with the interim level, and as such, imposes no additional 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 use other 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 develop a compliance plan which by-passes the interim level. OSHA believes this is an acceptable method of compliance, but the agency does not believe the employee 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 compliance in order to reduce the burden to the employer without compromising the health of the employee. The employees cannot be expected to accept these more flexible compliance provisions if they are to bear the brunt of the effects of that flexibility by being required to wear respirators continuously. Worker antipathy toward respirators is well documented in the rulemaking records of this and other OSHA standards and in addition the agency is concerned that respirator use for 8 hours over an extended period of time may constitute a health risk to individual employees, especially those with cardio-respiratory disorders.

Because of the discomfort and hazards associated with negative pressure respirators, coupled with the possibility of long-term use in some industries, OSHA has required employers to provide powered, air purifying (positive pressure) respirators (PAPR) to employees who request one, so long as it will provide adequate protection against the hazard for which a respirator is worn. Powered positive-pressure respirators provide greater protection to individuals (Tr. 1556), especially those who cannot obtain a good face fit on a negative pressure respirator (Ex. 155, p. 8), and will provide greater comfort when a respirator needs to be worn for long periods of time. OSHA believes employees will have a greater incentive to wear respirators if discomfort is minimized.

The standard requires the employer to select respirators in accordance with Table II from those approved by MSHA or NIOSH. The respirator selection table will enable the employer to provide the type of respirator which affords the proper degree of protection based on the airborne concentration of lead. While the employer must select the appropriate respirator from the table on the basis of the airborne concentration of lead, he may always select a respirator providing greater protection, that is, one prescribed for higher concentration of lead than present in his workplace. The respirator table is based on the NIOSH recommendation presented during the March 1977 hearing. (Ex. 86I, 86J, 87, 88, 89, 90, 91)

Similar to the proposal, single use respirators are not permitted to be used by the final standard. The 3M Company criticized the exclusion of the single use respirator from the respiratory selection table. (Ex. 3(36)) The original exclusion of single use respirators was based primarily on the inadequate protection factor, the fact that lead is a systemic poison, and the current provisions of 30 CFR Part 11 for approving single use respirators.

OSHA is particularly concerned about the penetrability of the single use respirator in a lead environment, which raises doubts about the protection factor of 5. OSHA will request that NIOSH study the efficacy of single use respirators in the future and make their findings known to the Agency. OSHA has reviewed the basis of its original decision concerning the protection afforded by a single use respirator and accepts the respirator decision logic in eliminating single use respirators for use with systemic poisons.

The standard further requires that the employer institute a respiratory protection program in accordance with 29 CFR 1910.134. This section contains basic requirements for proper selection, use, cleaning and maintenance of respirators.

The standard also requires that respirators be properly cleaned and filters replaced when necessary. (Tr. 5565, Ex. 91, Chapters 8 and 9)

The employer is also required to assure that the respirator facepieces fit. Proper fit of the respirator is critical. (Ex. 91; Tr. 1828, 4724) As a negative pressure is created within the facepiece when the wearer breathes, unfiltered air may enter the facepiece if gaps exist. (Ex. 91) Obtaining a proper fit on each employee may require the employer to provide two or three different mask styles.

In order to insure that the employee's respirator fits properly and that facepiece leakage is minimized, there was agreement by industry, government 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 negative pressure respirators is required by the standard because it is more accurate 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 qualitative fit test is subjective, relying upon the employee's sense of smell, the quantitative fit test uses instrumentation inside the facepiece to determine the integrity of the seal.

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 employees will be wearing respirators for extended periods of time, OSHA 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. 1556), 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 needed and to understand 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 respiratory 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 azide) 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, most employers presently provide clothing and equipment at no cost to employees. (Ex. 26, pp. 5-11, 5-35, 5-68; Tr. 2215, 3788, 4078, 4147, 5055, 5263, 5554, 5656, 6156, 6256, 6257, 6287, 6300, 6310, 6393).

The proposal did not specify 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 200 $\mu g/m^3$, 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 thus do not impose significantly new obligations on employers. (Tr. 1253, 1656)

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 plant (e.g., Dr. Teitlebaum, 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 he attributed 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. 2922) 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. 2196-99; 2379)

I. 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 from the effective date of the 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 presently 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; 2905; 2943; 3655; 3785; 4395; 4397; 4844; 4875; 5651; 5655; 6154; 6209; 6270) Employee usage of these facilities has been limited in some cases because, absent mandatory obligations, employers have not been successful in encouraging such usage. (Tr. 2567, 4875, 6318, 6453-54) The standard does not impose mandatory obligations on employees, as some employers have suggested, because employers are in a better position to impose and enforce work rules or practices. OSHA does however believe that employees 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 make compliance with them a condition of employment. (Tr. 2070; 2943) Labor union officials have offered to assist industry in enforcing equitable hygiene practices. (Tr. 1038, 2943, 2969) OSHA's experience has been that if employees understand the need for these provisions and if the hygiene rules are imposed in a fair and equitable manner, employers will experience a minimal lack of cooperation from employees.

The final standard requires employers 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 underwear, 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 challenged the provision as unnecessary. In fact, many industries maintain shower facilities and advise their employees to shower at the end of their shift. Some companies require that workers shower. (Tr. 5658, 6259) OSHA believes showering is a necessary practice providing protection to employees and their families which far outweighs the limited burden placed on employers.

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 wash their hands and face prior to eating or smoking and do not enter the lunchroom wearing protective clothing, unless cleaned beforehand. OSHA feels it is imperative that employees have a clean place to eat, free from the toxic substance with which they work all day. Filtered air lunchrooms will shield employees from the dangers of food which would otherwise become contaminated by lead dust, mist or fume. (Tr. 2074) Employees are required to wash before eating to further minimize the possibility of food contamination and reduce the likelihood of additional lead absorption from contaminated food, beverages or tobacco. To further insure minimal food contamination, protective clothing must either be removed or cleaned before entering the lunchroom (Tr. 2074). Instead of requiring any particular method, employers are given discretion to choose any method for removing surface lead dust which does not disperse the dust into the air.

The hygiene provisions in the final standard are necessary and appropriate to protect employees within affected industries from unwarranted and dangerous exposure to lead not necessary to job performance. Few, if any, participants in the rulemaking denied the benefits afforded by these provisions.

J. MEDICAL SURVEILLANCE: PARAGRAPH (J)

The medical surveillance program is part of this standard's comprehensive approach to prevention of lead-related disease. Its purpose is to supplement the standard's primary mechanisms of disease prevention, the elimination or 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 limit 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. In general, the proposal met with approval from all interested parties although there was disagreement on specific issues such as the content of the medical exam and the frequency of biological monitoring. 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 MRP 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 (PbU) or urine ALA levels (ALAU); 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. 4358), the consensus in the record was in favor of deleting urine measurements and adding ZPP monitoring. (Tr. 1309, 1311-12, 2656, 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 lead 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. G1.) 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 of lead; 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 effect on the body. (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-amino-levulinic 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 iron is not inserted into the molecule, then zinc, having a great affinity for protoporphyrin, takes the place of the iron, thus forming ZZP. (Tr. 435.) Whereas the heme molecule serves in a very necessary body funciton, 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 internal 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 individual exposure. (Ex. 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.)

Once 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 elevations in these two 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(39); Tr. 439.) It is possible that the ZPP test is one of the earliest and most reliable means of monitoring chronic lead absorption in workers. (Ex. 105E; Ex. 309; Tr. 465; Ex. 99B; Ex. 343.)

An elevation in ZPP 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 measureable 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 bimonthly 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, 662.)

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 present calibration problems, and careful attention must also be given to quality control procedures. Under these circumstances, it would seem wise to develop a biologic screening approach which incorporates ZPP or an equivalent screening test with blood lead determinations. (Ex. 84)

OSHA agrees with these concerns but believes the utility of the ZPP method outweighs its drawbacks. In order to eliminate any uncertainties associated with the method OSHA will request NIOSH to carry out a careful evaluation of the ZPP technique especially with respect to quality control requirements and report their findings to OSHA at a later date.

If the employee's airborne lead exposure is above the action level at least 30 days a year, then, routine monitoring of an employee's blood lead and ZPP levels is to be made available at least every 6 months after the initial tests. If the PbB exceeds 40 μg/100 g the monitoring frequency must be increased to at least every 2 months and not reduced until two consecutive PbB's are below 40 μg/100 g. If PbB levels exceed the removal criteria under paragraph (k)(1)(i), a second PbB must be provided within 2 weeks to confirm the accuracy of the results. This followup is intended to assure that no unnecessary removals occur.

Since the goal of this standard is to maintain PbB's below 40 μg/100 g, individuals with higher levels should be monitored periodically to detect further unacceptable elevations. OSHA believes that every 2 months is a reasonable and adequately protective monitoring frequency for employees above 40 μg/100 g. For those below 40 μg/100 g but above the action level, semiannual monitoring is sufficient to detect elevated levels if they occur.

During the hearings there was considerable testimony which questioned the accuracy of blood lead determinations and suggested there were significant discrepancies in blood lead results depending on the source of testing. (Ex. 343; Tr. 1647, 1675, 1311-12.) A graphic illustration of the difficulties in measuring blood levels was provided by NIOSH in their submission of a report on the blood lead proficiency testing program of the Center for Disease Control which demonstrated that only 33 percent of the laboratories achieved an acceptable score (Ex. 86F). An acceptable score was based on the following criteria:

1. The accuracy required is 15 percent or 6 μg/100 ml, whichever is greater

2. Grade=Number of responses within acceptable range/number of challenges × 100.

An annual grade of 75 is considered satisfactory.

Blood lead level determinations have a crucial role in this standard with respect to their use to protect the health of the individual worker. The impact of blood lead levels is especially important in terms of medical removal protection. Inaccurate PbB could increase costs to the employer and fail to protect the employee. Testimony in the record reflects the participants' concern that OSHA 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. 8005-07) and Teitlebaum (Tr. 390-92) 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 μg/100 ml, whichever is greater.

The standard requires medical examinations to be provided to an employee initially (for new workers, prior to assignment to a job where lead exposure would exceed the action level, and for current employees, within 180 days of the completion of air monitoring) and annually thereafter if the employee's blood lead level exceeded 40 μg/100 g at any time during the preceding year. Initial examinations are necessary to provide information to establish a baseline to which subsequent data can be compared. (Tr. 1405-06; 1501; 4358.) They will also be helpful in identifying individuals who would be at increased risk from lead exposure. (Tr. 1405-06; 1501.) Followup exams will document the continuing effect of lead exposure on individual workers and will facilitate a medical evaluation of whether continuing exposure is advisable.

The required examination includes a work history and medical history; a physical examination; determinations of blood lead level (PbB), hematocrit, hemoglobin, peripheral smear morphology and red cell indices; (Tr. 6562); levels of zinc protoporphyrin (ZPP), routine urinalysis (specific gravity, sugar, protein determinations, and microscopic examination), blood urea nitrogen (BUN), and serum creatinine (S-Creat). (Ex. 284A, p. E1.) This is similar to the requirement in the proposed standard except that mandatory pregnancy testing has been deleted and ZPP, BUN, and serum creatinine tests have been added. BUN and serum creatinine, although late indicators of kidney disease, are the best available routine diagnostic tests for kidney function and have been included for that reason. (Tr. 6562-63.) They can also be performed from the single blood sample taken for the other tests. Measurement of glomerula filtration rates or creatinine clearance would provide earlier indications of decreased renal function, but those tests are more in the nature of research techniques, are expensive, and would be clearly impractical for almost all employers to provide.

Medical consultations, with examinations as appropriate, are required to be provided upon request by an employer (1) whenever an employee has developed symptoms commonly associated with lead-related disease, (2) when an employee desires advice concerning the effects of lead on reproductive capacity, and (3) when an employee has demonstrated difficulty in 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 analyzing sperm number, 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 twofold: 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. 7361-7362, 7386-7387, 7392-7393; Ex. 379A(2), p. 31) In light of the major shortage 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 mandate 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 supervision 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 Hale 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. 416C, 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. 368, pp. 15-16; Ex. 369, p. 15; Ex. 379A, Att. 1; Ex. 404B (D-1), p. 4; Ex. 404B (D-2), pp. 16-17; 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-2; Ex. 430C-3; Ex. 430D(4b), Sections 78-79; Ex. 430 D(15), 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, they choose 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 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 and confidence in the employer-retained physician where merited. If workers distrust a company doctor and the diagnoses of a second physician on several occasions proves there is no basis for distrust, 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.

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, 4261-4262, 4284, 4852, 5088-5090, 6026-6029, 6049, 7262, 7623, 7691-7692, 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 is often viewed as simply a paid agent of the employer, not as a neutral physician maintaining a close doctor-patient relationship with the employee. (Tr. 4284, 4780-4782, 4851, 5088-5090, 6032-6033, 7276-7279, 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, therefore at odds with devotion to worker health. (Tr. 4284, 4809-4811, 7276-7279, 8096; Ex. 379A, p. 12; Ex. 411B(4), pp. 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, 4757, 4773-4774, 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 elevations, or one 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 a company official, not from the 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 employer-retained physician. (Tr. 222, 226-240, 530-532, 1111-1112, 1272-1273, 2169-2172, 2200-2201, 2537-2539, 2542, 2676-2681, 2983(13)-2983(17), 4998-5002, 5022, 5102, 6026, 6043-6045, 6878-6879, 6881; Ex. 20; Ex. 84, p. 9; Ex. 86H; Ex. 117A; Ex. 118D; Ex. 166; Ex. 167, pp.; 5-7; Ex. 246A.) The practice has been condemned for several decades by the LIA itself (Tr. 3242-3245; Ex. 335, p. 88), though they note that the practice continues. (Tr. 3242-3245.) This practice vividly demonstrates that there are some physicians examining lead-exposed workers who fail to accord protection of worker health the priority it deserves. The multiple physician review mechanism is designed to check the influence of these physicians, and assure employees that no matter what the practices of the initial physician, the standard contains a mechanism whereby competent and impartial medical determinations can be achieved.

A final source of evidence indicating the need for a physician review opportunity comes from the ongoing debate within the occupational medical community. (Tr. 8241, 8247.) For example, the Journal of Occupational Medicine has in recent years carried numerous articles concerning worker confidence in employer-retained physicians. (Ex. 413A-413H.) Widely divergent opinions have been expressed in these articles, but a substantial portion of this professional commentary verifies the existence of a crisis of confidence. As one employer representative in the lead proceeding remarked:

> I would like to assure you that the competent occupational health physicians that I know are as concerned and frustrated as you about the existence of poor practitioners of occupational medicine in the profession. (Tr. 5137.)

There is general recognition that a significant problem exists, and OSHA has adopted the multiple physician review mechanism in part to assure that the problem does not obstruct successful operation of the standard's medical surveillance program.

The preceding paragraphs explain in some detail OSHA's reasons for the inclusion of a multiple physician review mechanism since this is a relatively 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 (5th Cir., filed Sept. 16, 1977.)) The discussion concerning and 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 there are many competent 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. OSHA is convinced that there are situations where employer-retained physicians have a close doctor-patient relationship with lead exposed employees, and the employees have confidence in the physician's abilities and devotion. In those circumstances, there will seldom be any use of the multiple physician review mechanism. Where this close relationship of trust and confidence does not exist, however, an opportunity for a second medical opinion is appropriate.

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 or consultation being provided, 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 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, an employer may condition its participation in, and payment for, the

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 must inform the employer (orally or otherwise) that the employee intends to seek a second medical opinion. The employee must also initiate steps within this time to make an appointment with a second physician. These steps would include actually making an appointment, or contacting a physician with the request that a referral to a specialist be arranged.

The standard contains no more limitation upon an employee's choice of a second physician than the standard places on an employer's choice of the initial physician. The second physician, like the initial physician, need only be licensed to practice medicine. There is no subspecialty of medicine solely concerned with lead-related diseases, and since lead-related diseases affect numerous systems of the body, it would not be appropriate to limit the choice of doctors to any one specialty. It is certainly to an employee's advantage to choose a competent physician, thus OSHA relies on this self-interest to assure the value of the second opinion. For example, where am employee's difference with the initial physician revolves around a particular body system—e.g., nervous system—it is likely that the employee will choose a specialist in that body system—e.g., a neurologist. Where, however, the dispute revolves around several body systems, or the employee cannot identify one specific system, the employee will likely choose the general practitioner or internist most familiar with the employee's medical history or current health status.

The standard provides that the second physician shall review any findings, determinations or recommendations of the initial physician, and may conduct such examinations, consultations and laboratory tests as the second physician deems necessary to facilitate this review. An additional provision in the standard requires the employer to supply the same information to the second physician upon request that must be supplied to an initial physician. The second physician, therefore, is provided an opportunity to fully assess the employee's health status with access to the same background information supplied to the initial physician.

If the second physician's findings, determinations, and recommendations are the same as those of the initial physician, then the multiple physician review process comes to an end. If, however, the opinions of the two physicians are in conflict, then the standard provides that the employer and the employee shall assure that efforts are made for the two physicians to resolve any disagreement. OSHA expects that the two physicians would as a general professional matter communicate with each other to resolve their differences, but the standard makes 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 the third physician a full opportunity to review the findings, determinations, and recommendations of the 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 required to provide a written medical opinion to the employer, which will operate to resolve the disagreement between the earlier physicians. The standard finally requires the employer to act in a manner 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. This requirement, however, is not intended to preclude an employer from establishing and implementing legitimate general medical criteria for its employees which may in special cases result in medical determinations even more conservative than the outcome of the multiple physician review process. The possibility of such a case arising, though, is extremely remote since there is no evidence that any employer using lead currently employs general protective medical criteria for its employees which are more restrictive than the final standard's requirements.

As with many of the provisions of the final lead standard, the success of the multiple physician review mechanism will largely depend upon employers and employees acting in a reasonable manner and with good faith. There are means by which an employer could attempt to frustrate the operation of this physician review process—for example, by instructing the initial physician to refuse to agree on the selection of a third physician. Such actions, however, would constitute a deliberate violation of the standard since the regulation necessarily implies that the employer will act in a manner calculated to effectuate the multiple physician review mechanism. Operation of the multiple physician review mechanism also depends on the cooperation and good faith of the employee. In most cases, good faith on the part of the employee will be assured, since it is the employee who is seeking to reverse the initial medical determination. The employee will be eager for the review mechanism to proceed as quickly and efficiently as possible. This will especially be so since the medical removal protection provisions of the standard provide that in most situations, the employer may act consistent with the opinion of the initial physician pending the final medical determination of the multiple physician review mechanism. In some cases, however, an employee might act in a manner clearly calculated to delay or otherwise prevent the review process from operating in an orderly manner. In this regard it is important to note that this physician review process is voluntary on the part of the employee, and the employee can terminate or abandon the review process at any time. Where an employee clearly acts to frustrate the operation 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 raises 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(H), 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. 13-15; Ex. 354(FF), p. 3; Ex. 354(GG), p. 2; Ex. 354(HH), p. 7; Ex. 385, pp. 13-14; Ex. 396A, 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 endorsed adoption of the

mechanism. (Tr. 7202-7205, 7246-7247, 7264, 7609-7610, 7691-7692, 7976-7980, 8072-8074, 8224-8226; Ex. 354(D), p. 5; Ex. 372, pp. 8-9; Ex. 374, pp. 139-140; Ex. 378, pp. 4-5; Ex. 450B, pp. 3-10; 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 in a variety of contexts. No evidence was offered suggesting that any of these existing mechanisms have proven unworkable or overly burdensome. In view of this, OHSA 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 expeditious alternate physician determination mechanism in lieu of the multiple physician review mechanism. The only condition is that the alternate mechanism otherwise satisfy the standard's requirements. OSHA's inclusion of this alternate mechanism provision follows the recommendation of the United Steelworkers of America. (Ex. 452, pp. 63, 68) The lead record indicates that some employers and unions are negotiating on special medical determination procedures which are not founded upon an employer's unilateral choice of the examining physician. (Tr. 8243-8244, 8271-8272; Ex. 430C-2; Ex. 452, p. 68) For example, the parties might decide in cases of dispute for an employee to go directly from an initial physician chosen by the employer to an agreed upon final physician—thus dispensing with the need for a second physician. Alternately, a final physician might be used in the first instance without recourse to other physicians. Or, an employee might be given the opportunity to choose this final physician. OSHA desires to encourage employers and employees to adopt medical determination procedures in which all parties have trust and confidence. The standard includes an explicit provision embodying this intention.

A major issue addressed in the proposed standard and throughout the rulemaking was chelation. The final standard prohibits prophylactic chelation of any employee by any person the employer employs, retains, supervises, or controls, and requires the employer to assure that any therapeutic or diagnostic chelation, if administered, is done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring.

Moreover, in cases where the examining physician determines that chelation is appropriate, the employee must be notified of this fact before such treatment. This should serve the purposes of informing the employee of a potentially harmful treatment, and affording the employee the opportunity to seek the review of this determination by another physician (see multiple physician review, above) thereby possibly acting as a check on an overly broad definition of "therapeutic" chelation by the examining physician.

A considerable body of testimony was presented concerning the use and abuse of chelation therapy in the treatment of lead poisoning. Experience accumulated by the medical and scientific communities over 20 years has largely confirmed the effectiveness of this type of therapy for the treatment of lead poisoning. It has also been established that there can be important adverse side effects associated with the use of chelating agents. The medical community has balanced the advantages and disadvantages resulting from the use of chelating agents in various circumstances establishing when the use of these agents is or is not acceptable. The general consensus of these professionals is that therapeutic chelation is acceptable but prophylactic chelation is not. Unfortunately, testimony given by lead workers has indicated that prophylatic chelation is occurring. Given that there is a glaring contradiction between theory and practice with regards to this issue, it is useful and necessary to review the health effects of chelation.

Blejer has described the development and functioning of the various chelating agents, stating:

A chelating agent is a chemical substance which will bind lead and certain other metals into a metal-chelate complex so as to make them biochemically and toxicologically inactive or unavailable. Chelation therapy in modern medicine had its inception during the First World War when dimercaprol, a heavy metal antagonist, was developed as an antidote for a lethal, arsenic-containing war agent called Lewisite. Thus, another name for dimercaprol is British antilewisite, or BAL for short. In the early 1950's a chelating agent began to be used: Ethylene-diamine-tetraacetate, or just EDTA. However, an adverse, very serious side of EDTA was that it chelated calcium in the blood and body tissues and that, when severe enough, this removal or chelation of calcium—an essential metal in human muscular biochemistry and function—could produce potentially fatal tetany. Consequently, other EDTA compounds which contain calcium in the molecule were developed. One of these and currently the most widely used, is calcium disodium edetate—also called Calcium EDTA, CaEDTA, Calcium Disodium Versenate, or Versenate. The calcium in CaEDTA is readily displaced by heavy metals, such as lead, to form stable complexes with the metallic ion locked or sequestered in the EDTA molecule. Following intravenous or intramuscular injections of Versenate, the chelate form is excreted in the urine with about 50% appearing in the first hour after administration.

In recent years another chelating agent called d-penicillamine, also known as penicillamine or Cuprimine, was developed for the treatment of excess copper in patients with a rare condition called Wilson's disease and also for the reduction of excess of cystine excretion in cystinuria, another rare condition. Judging from the California State reporting experience (Ex. 6(26)) in the last five or six years many physicians have begun to use pencillamine extensively and instead of Versanate or CaEDTA, either in the treatment of lead poisoning, or to reduce increased levels of lead absorption—as measured by elevated blood lead concentration—among occupationally lead-exposed workers.

The route and mode of administration of these three chelating agents vary: BAL is administered by intramuscular injection only and, to my knowledge, it is very seldom used to treat occupationally lead-exposed workers. CaEDTA, on the other hand, is commonly used by physicians among these workers: It can be administered by mouth, intramuscular injection or intravenous infusion. The third therapeutic compound, penicillamine or Cuprimine, is given orally only. (Ex. 53, p. 7, 8, 9)

The possible adverse side effects of the various possible chelating agents were reviewed by several experts. Blejer stated:

The main adverse effect of dimercaprol or BAL are nervousness, nausea, a feeling of pressure in the chest, and a transient rise in blood pressure. Currently, the use of BAL is recommended in conjunction with CaEDTA for severe lead poisoning with acute encephalopathy in children only. According to Hamilton and Hardy (Ex. 23(30)), BAL is contra-indicated in adult lead poisoning because, although it increases lead excretion, it may increase lead toxicity by forming a BAL-lead complex which is more toxic than the lead per se. Further, in lead workers concurrently occupationally exposed to cadmium, iron or selenium, such as occurs in some primary nonferrous smelters, BAL is contraindicated because the BAL-metal complexes are more toxic especially to the kidneys, than any of the metals by itself.

. . . . . .

Penicillamine or Cuprimine also has some very serious adverse effects which include the nephrotic syndrome and aplastic anemia. * * * (T)he drugs should not be given to patients allergic to penicillin because of cross-sensitivity between penicillin and penicillamine. Penicillamine has a plethora of other adverse effects which are 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 blood 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, throbocytopenia, thrombotic thrombocytopenic purpura, bone marrow hypoplasia, leukopenia and granulocytopenia ranging in severity from asymptomatic and reversible to agranulocytosis with fatalities. Thrombophlebitis, pancreatitis, cheilosis, glossitis, gingivostomatitis, sometimes with ulceration of the mucous membrane; polymyositis; mammary hyperplasia; peptic ulcer; myasthenia; elastosis perforans serpiginosa have been reported but are unusual. A syndrome closely resembling disseminated lupus erythematosus and pemphigus have occurred, as well as severe and ultimately fatal glomerulonephritis and intraalveolor hemorrhage (Goodpasture's syndrome). Iron deficiency may develop, especially in menstruating women and in children. Reversible optic neuritis and cheilosis, possibly connected with pyridoxine (vitamin B6) deficiency, have been reported.

In fact, some of the above warnings, precautions and adverse reactions pertain to long-term uses of penicillamine and many of the adverse effects occur rarely. Nevertheless, one still wonders why many physicians are using this drug in the so-called prophylaxis of increased lead absorption, or even in the treatment of lead poisoning among lead workers.

One is even more puzzled about such uses, especially because penicillamine has not been approved by the U.S. Food and Drug Administration for the treatment of lead poisoning either in children or adults. As stated by the Commissioner of FDA in a related memorandum dated May 28, 1976, to the Director of NIOSH, "Penicillamine is a certified antibiotic drug which was approved in 1974 for Wilson's disease and cystinuria. At the present time it is also being studied under investigational new drug exemptions for its use in rheumatoid arthritis and chronic lead poisoning in children. There are currently nine active individual investigators (approved) for the study of the use of penicillamine in chronic lead poisoning in children." (Ex. 53, pp. 9-13)

Bridbord and Blejer, in a review article extensively discussed effects of CaEDTA, stated:

A number of studies suggest that oral EDTA increases the absorption of lead from the gastrointestinal tract in instances where exposure to lead continues to occur.

Other studies have observed T-wave changes in the electrocardiograms of patients given chelation therapy. Studies also suggest that the metabolism of trace metals other than lead may be affected by long-term chelation therapy.

The effects of lead and of EDTA on the kidneys were evaluated in two recent papers. Lead-poisoned rats were given injections of EDTA IP. Inclusion bodies (lead-protein complexes believed to possibly protect against lead effects) in renal cell nuclei were found in various stages of dissolution and migration out of the nucleus. Cytoplasmic vacuoles were observed which contained material that resembled portions of intact nuclear inclusions. Inclusion bodies have not been observed in renal biopsies of male workers occupationally exposed to lead who have been repeatedly treated with chelating agents. Excretion of lead through the kidneys appears to be less in older men compared to younger men who have nuclear inclusion bodies in their renal tuble 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 tubula dysfunction may follow EDTA administration in lead poisoned children". (Ex. 86H, p. 7, 8)

Lilis 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 metal mobilizes as a nonionizable complex, 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 no adverse side effects are 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 given intravenously 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 Lilis' 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 separate circumstances 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. 86H, p. 20)

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 gastroenteric, neurologic and other symptoms and signs." (Ex. 86H p. 1)

Those who testified were generally in agreement with this statement though there was some variation in 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 lead-exposed adults is warranted only when there is frank and, in my opinion, severe symptomatology of lead poisoning, such as the now-rare 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 deleading," 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 Dr. Richard P. Wedeen, Professor of Medicine and a specialist in nephrology at the New Jersey Medical School in Newark, N J, there is a state where golmerular filtration dysfunction due to lead may be reversible by intravenous administration of CaEDTA. In my opinion, for such purposes, in expert hands and in appropriate clinical facilities, chelation therapy could therefore be used in the absence of overt symptomatology. In all of these instances, however, the affected worker must be monitored clinically by physicians expert or competent in the treatment of lead poisoning, with the treatment administered in appropriate clinical 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 work place. As stated previously—and it bears repetition often—such treatment still constitutes 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 chelation 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. Condemnation of prophylactic chelation was virtually universal. (Ex. 343, p. 91; Ex. 335, p. 88; Tr. 3242, 3683; Ex. 86H, pp. 8, 10, 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 of long term versenate therapy particularly on the kidneys combined with continued excess exposure to lead, a known renal toxin. (Ex. 246A)

Blejer testified that:

Prophylactic administration of $CaNa_2$ EDTA 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 $CaNa_2$ EDTA 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 Gaffey, (Ex. 5(28)), 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 condoned. (Ex. 6(19), p. 20)

Lilis 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 levulinic 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 probable 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, eosinophilia, 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 by individuals occupationally exposed occurs 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 ethics 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. 251)

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), Beliczky, Rubber

Workers (Tr. 2537-39; 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 NL and Quemetco smelters studied 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 intravenous 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 occuring 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 deleading effect of the chelating agent would be counterbalanced by 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 (colic) 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 a 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 F, pp. 30, 31)

Frequency of Chelation Therapy in Secondary Lead Smelter Workers

	Total number examined	Chelation therapy		Repeated courses of chelation therapy	
		No.	Pct.	No.	Pct.
Plant 1	113	47	42	24	20
Plant 2	45	24	53	21	44
Total	158	71	45	45	27

(Ex. 105F, Table 16)

The California State Occupational Disease report data . . . as well as the results of the Indianapolis, Indiana, and Vernon, California, clinical field surveys—conducted by the Environmental Sciences Laboratory, Mt. Sinai School of Medicine, City University of New York, as reported in May 1976 and January 1977, respectively—all indicate that not only is such chelation therapy with CaEDTA and/or penicillamine quite prevalent, but also that so has been the practice of administering CaEDTA intravenously on ambulatory, nonhospitalized basis, such as in a physician's office or even in a plant's dispensary or first-aid room. Moreover, in practically all of these cases there were not available data to indicate that the occupationally lead-exposed workers being thus medicated were being monitored for any of the untoward or adverse effects or oral penicillamine and/or CaEDTA or of intravenous CaEDTA administration. Although it is true that in many cases such lead-exposed workers were being medicated by physicians other than those retained full or part-time by the plant, it is also true that some of these workers were thus medicated by company-designated and/or employed physicians sometimes, as already stated, right in the physician's office or even at the work place itself. (Ex. 53, p. 18)

In summary, the use of chelating agents is known to involve certain health risks. These risks are minimized when the drug is administered under a strictly controlled setting with appropriate medical monitoring, over a short period of time, and in appropriate dosages. The use of such agents prophylactically is considered inappropriate. The repeated use of such compounds is not at all appropriate when an alternative such as controlling employee exposure is possible.

OSHA believes that chelating agents, such as calcium disodium edetate (EDTA), and penicillamine, are useful in the therapy of acute overexposure to lead. Such therapy should be done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring of the patient. Medical experts were not uniformly in agreement concerning the circumstances under which therapeutic chelation should be used, and OSHA can not define appropriate medical practice for the individual patient. Such decisions must be made by the physician, exercising sound medical judgment after an evaluation of all the relevant factors.

The testimony given by workers and health professionals which clearly indicated that prophylactic chelation has occurred and continues to occur in spite of the well established body of medical knowledge opposing it is of grave concern to OSHA. OSHA believes that the record indicates a need for extensive education both of health professionals and of workers concerning the circumstances of use and abuse of chelating agents and a mandatory prohibition in the standard of improper use of chelating agents.

The final standard requires, under the authority of section 6(b)(7), that the employer pay the costs of medical surveillance and make all the tests or procedures available to employees at a reasonable time and manner. The proposed standard required medical surveillance to be provided during the employee's normal working hours, but as was pointed out by several parties (e.g., Ex. 3(31)), medical personnel would probably not be available outside the regular daytime hours. Thus, employees who worked night shifts could not have examinations during their regular working hours. OSHA's concern is that medical surveillance is provided at a time and in a manner so as not to discourage employees from participating in the program. A standard of reasonableness should accomplish this goal.

K. MEDICAL REMOVAL PROTECTION: PARAGRAPH (K)

See summary in Part III and full exposition in Attachment C.

L. EMPLOYEE INFORMATION AND TRAINING: PARAGRAPH (L)

The final standard requires the employer to provide an information and training program for all employees exposed to lead above the action level. Information and training are an essential aspect of the overall protection of employees who can do much to protect themselves if they are informed of the nature of the hazards in the workplace. To be effective an employee education system must apprise the employee of the specific hazards associated with his work environment, protective measures which can be taken, and his rights under the standard. The need to train employees was agreed upon by virtually all of the participants in the rulemaking proceeding, and a training requirement was included in both the NIOSH Criteria Document (Ex. 1) and the proposed standard.

In addition, OSHA will require that materials provided to the employer by OSHA be made readily available to all affected employees. This requirement was not included in the proposal

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. 343, p. 106.) While 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 these materials are designated by the Assistant Secretary, the employer will be required to include them as part of his education and training program.

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. 657, 694, 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 as part of the medical surveillance program, e.g., fertility and pregnancy testing. OSHA believes this is a crucial provision of the standard. A worker, whether male or female, who is fully informed of the hazards of lead will be better able to avoid the adverse reproductive effects documented in the preamble. The knowledge of the hazard in this instance is crucial since there is concern that workers whose blood leads do not exceed the 30 μg/100 g level may still be at risk especially if they have extended tenure in a lead industry.

The training program is required to be completed for employees initially covered by the standard within 180 days of the effective date, thus allowing 90 days after the completion of initial monitoring, and for all new employees at the time of initial assignment to areas where there is a possibility of exposure over the action level. OSHA believes that it is important to train employees as soon as possible in order to maximize the benefits of the training program, and has acted accordingly.

The standard requires that the training program be provided at least annually. OSHA believes that an annual training program is both necessary and sufficient to re-inform the employees of the hazards and their rights and duties under the standard.

M. SIGNS: PARAGRAPH (M)

The final standard requires a sign to be posted in areas where lead exposure exceeds the PEL. The standard specifies the legend for these signs.

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 6(b)(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. Furthermore, when 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 hazards 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.)

N. RECORDKEEPING: PARAGRAPH (N)

Section 8(c)(3) of the Act (29 U.S.C. 657) mandates the inclusion of provisions requiring employers to maintain accurate biological and environmental monitoring records of employee exposures to potentially toxic materials. It also provides that employees or their representatives have access to such records.

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 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, employees, 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 will, in most 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, production, or confidential medical records—examinations which likely would be necessary in the absence of the standard's limited recordkeeping requirement. Due to the limited purposes to be served by these records, the standard requires an employer to maintain each medical removal record only for so long as the duration of an employee's employment.

In the final standard, there have been deletions in two areas of recordkeeping 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 removed. 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 whether lead was an etiologic agent in a disease progression. For example, renal and neurological disease do not necessarily have early warning indicators which physicians might use for evaluation. The records will serve to aid 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 be available to employees and their authorized representatives, and medical records to an employee or to a physician or other person designated by an employee or former employee. These provisions carry out statutory requirements. In addition, it is necessary for the Assistant Secretary and Director to have access for enforcement and research purposes. Employees and their representatives need access to both environmental and blood lead level 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 protection provisions. Blood lead level 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 employee exposures 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 insure that this right is 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 obtained. 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. The observer, whether an employee or designated representative, 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. The approximate three month period between the issuance of the standard and its effective date is intended to provide sufficient time for employers and employees to become informed of 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 Eula 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. 1592, 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-1 of 29 CFR 1910.1000.

In addition, pursuant to the above authority, section 4(b)(2) of the Act (84 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 (41 U.S.C. 35 et seq.), the Service Contract Act of 1965 (41 U.S.C. 351 et seq.), the Act of August 23, 1958 (33 U.S.C. 941), and the National Foundation 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 implemented 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 amended as follows:

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

§ 1910.19 Special provisions for air contaminants.

* * * * *

(g) Section 1910.1025 shall apply to the exposure of every employee to lead in every employment and place of employment covered by §§ 1910.13, 1910.14, 1910.15, 1910.16, in lieu of any different standard on exposure to lead which would otherwise be applicable by virtue of those sections.

§ 1910.1000 [Amended]

2. Table Z-2 in § 1910.1000 is amended by deleting the following entry:

Lead and its inorganic compounds (Z37.11-1969)	0.2 mg/m³

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 exposure 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 operations covered by 29 CFR Part 1928.

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

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

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

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

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

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

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

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

(d) *Exposure monitoring* (1) *General.* (i) For the purposes of paragraph (d), employee exposure is that exposure which would occur if the employee were not using a respirator.

(ii) With the exception of monitoring under paragraph (d)(3), the employer shall collect full shift (for at least 7 continuous hours) personal samples including at least one sample for each shift for each job classification in each work area.

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

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

(3) *Basis of initial determination.* (i) The employer shall monitor employee exposures and shall base initial determinations on the employee exposure monitoring results and any of the following, relevant considerations:

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

(B) Measurements of airborne lead made in the preceding year if the sampling and analytical methods used meet the accuracy and confidence levels of paragraph (d)(9) of this section; and

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

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

(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 representative of the exposure for each employee in the workplace which is exposed 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 information specified in paragraph (d)(3) of this section and shall also include the date of determination, location within the worksite, and the name and social security number of each employee monitored.

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

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

(iii) If the initial monitoring reveals that employee exposure is above the permissible exposure limit the 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.* (i) 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 $\mu g/m^3$.

(e) *Methods of compliance.* (1) *Engineering and work practice controls.* The employer shall implement engineering and work practice controls (including administrative controls) to reduce and maintain employee exposure to lead 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 I.—*Implementation schedule*

Industry[1]	Compliance dates[2]		
	200 $\mu g/m^3$	100 $\mu g/m^3$	50 $\mu g/m^3$
Primary lead production	(3)	3	10
Secondary lead production	(3)	3	5
Lead-acid battery manufacturing	(3)	2	5
Nonferrous foundries	(3)	1	5
Lead pigment manufacturing	(3)	3	5
All other industries	(3)	0	1

[1] Includes ancillary activities located on the same worksite.

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

[3] On effective date.

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

(3) *Compliance program.*

(i) Each employer shall establish and implement a written compliance program to reduce exposures to or below the permissible exposure limit and interim levels if 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 used, material processed, controls in place, crew size, employee job responsibilities, operating procedures and maintenance practices;

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

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

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

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

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

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

(H) Other relevant information.

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

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

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

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

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

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

(5) *Mechanical ventilation.* (i) When ventilation is used to control exposure, measurements which demonstrate the effectiveness of the system in controlling exposure, such as capture velocity, duct velocity, or static pressure shall be made at least every 3 months. Measurements of the system's effectiveness in controlling exposure shall be made within 5 days of any change in production, process, or control which might result in a change in employee exposure to lead.

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

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

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

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

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

(f) *Respiratory protection.*

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

(i) During the time period necessary to install or implement engineering or work practice controls, except that

after the dates for compliance with the interim levels in table I, no employer shall require an employee to wear a respirator longer than 4.4 hours per day;

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

(iii) Whenever an employee requests a respirator.

(2) *Respirator selection.*

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

TABLE II.—*Respiratory Protection for Lead Aerosols*

Airborne concentration of lead or condition of use	Required respirator[1]
Not in excess of 0.5 mg/m³(10X PEL).	Half-mask, air-purifying respirator equipped with high efficiency filters.[2 3]
Not in excess of 2.5 mg/m³(50X PEL).	Full facepiece, air-purifying respirator with high efficiency filters.
Not in excess of 50 mg/m³(1000X PEL).	(1) Any powered, air-purifying respirator with high efficiency filters; or (2) Half-mask supplied-air respirator operated in positive-pressure mode.[2]
Not in excess of 100 mg/m³(2000X).	Supplied-air respirators with full facepiece, hood, helmet, or suit, operated in positive pressure mode.
Greater than 100 mg/m³, unknown concentration or fire fighting.	Full facepiece, self-contained breathing apparatus operated in positive-pressure mode.

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

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

[3]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 (j)(3)(i)(C) of this section to determine whether the employee can wear a respirator while performing the required duty.

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

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

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

(g) *Protective work clothing and equipment.*

(1) *Provision and use.* If an employee is exposed to lead above the PEL, without regard to the use of respirators or where the possibility of skin or eye irritation exists, the employer shall provide at no cost to the employee and assure that the employee uses appropriate protective work clothing and equipment such as, but not limited to:

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

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

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

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

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

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

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

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

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

(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 APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

(viii) The employer shall prohibit the removal of lead from protective clothing or equipment by blowing, shaking, or any other means which disperses lead into the air, except as provided for in paragraph (i)(6) of this section.

(h) *Housekeeping.*

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

(2) *Cleaning floors.* (i) Floors and other surfaces where lead accumulates may not be cleaned by the use of compressed air.

(ii) Shoveling, dry or wet sweeping and brushing may be used only where vacuuming has been tried and found not to be effective.

(3) *Vacuuming.* Where vacuuming methods are selected, the vacuums shall be used and emptied in a manner which minimizes the reentry of lead into the workplace.

(i) *Hygiene facilities and practices.* (1) The employer shall assure that in areas where skin or clothing may come 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, food or beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied, except in change rooms, lunchrooms, and showers required under paragraphs (i)(2)–(i)(4) of this section.

(2) *Change rooms.* (i) The employer shall provide clean change rooms for employees who work in areas where their skin or clothing comes into contact with fume, 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 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 fume, dust, mist, or liquids containing lead or where their airborne exposure to lead is above the PEL, without regard to the use of respirators, shower at the end of the work shift.

(ii) The employer shall provide shower facilities in accordance with § 1910.141 (a)(3) of this Part.

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

(4) *Lunchrooms.* (i) The employer shall provide lunchroom facilities for employees who work in areas where their skin or clothing comes into contact with fume, 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 fume, 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, downdraft booth, or other cleaning method.

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

(6) *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.

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

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

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

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

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

(B) At least every two months for each employee whose last blood sampling and analysis indicated a blood lead level at or above 40 μg/100 g of whole blood. This frequency shall 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 and (B) that the standard requires temporary medical removal with Medical Removal Protection benefits; when an employee's blood lead level exceeds the numerical criterion for medical removal under paragraph (k)(1)(i) of this section.

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

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

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

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

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

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

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

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

(C) A blood pressure measurement;

(D) A blood sample and analysis which determines:

(*1*) Blood lead level;

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

(*3*) Zinc protoporphyrin;

(*4*) Blood urea nitrogen; and,

(*5*) Serum creatinine;

(E) A routine urinalysis with microscopic examination; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(*1*) A copy of this regulation for 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 detected medical condition which would place the employee at increased risk of material impairment of the employee's health from exposure to lead;

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

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

(*4*) The results of the blood lead determinations.

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

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

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

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

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

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

(k) *Medical Removal Protection.*

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

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

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

(B) *Second year of the standard.* During the second year following the effective date of the standard, the employer shall remove an employee from work having a daily 8-hour TWA exposure to lead at or above 50 $\mu g/m^3$ on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 70 $\mu g/100$ g of whole blood;

(C) *Third year of the standard, and thereafter.* Beginning with the third year following the effective date of the standard, the employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 60 $\mu g/100$ g of whole blood; and,

(D) *Fifth year of the standard, and thereafter.* Beginning with the fifth year following the effective date of the standard, the employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that the average of the last three blood sampling tests conducted pursuant to this section (or the average of all blood sampling tests conducted over the previous six (6) months, whichever is longer) indicates that the employee's blood lead level is at or above 50 $\mu g/100$ g of whole blood; provided, however, that an employee need not be removed if the last blood sampling test indicates a blood lead level at or below 40 $\mu g/100$ g of whole blood.

(ii) *Temporary removal due to a final medical determination.* (A) The employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a final medical determination results in a medical finding, determination, or opinion that the employee has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead;

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

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

(iii) *Return of the employee to former job status.* (A) The employer shall return an employee to his or her former job status:

(*1*) For an employee removed due to a blood lead level at or above 80 μg/100 g, when two consecutive blood sampling tests indicate that the employee's blood lead level is at or below 60 μg/100 g of whole blood;

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

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

(*4*) For an employee removed due to a final medical determination, when a subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead; and

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

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

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

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

(B) *Return.* The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions. If—I11(*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.

(2) *Medical removal protection benefits.*

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

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

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

(iv) *Workers' compensation claims.* If a removed employee files a claim for workers' compensation payments for a lead-related disability, then the employer shall continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation shall be reduced by such amount. The employer shall receive no credit for workers' compensation payments received by the employee for treatment related expenses.

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

(vi) *Employees whose blood lead levels do no adequately decline within 18 months of removal.* The employer shall take the following measures with respect to any employee removed from exposure to lead due to an elevated blood lead level whose blood lead level has not declined within the past eighteen (18) months of removal so that the employee has been returned to his or her former job status:

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

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

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

(D) Where the employer acts pursuant to a final medical determination

which permits the return of the employee to his or her former job status despite what would otherwise be an unacceptable blood lead level, later questions concerning removing the employee again shall be decided by a final medical determination. The employer need not automatically remove such an employee pursuant to the blood lead level removal criteria provided by this section.

(vii) *Voluntary Removal or Restriction of An Employee.* Where an employer, although not required by this section to do so, removes an employee from exposure to lead or otherwise places limitations on an employee due to the effects of lead exposure on the employee's medical condition, the employer shall provide medical removal protection benefits to the employee equal to that required by paragraph (k)(2)(i) of this section.

(l) *Employee information and training.*

(1) *Training program.*

(i) Each employer who has a workplace in which there is a potential exposure to airborne lead at any level shall inform employees of the content of Appendices A and B of this regulation.

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

(iii) The employer shall provide initial training by 180 days from the effective date for those employees covered by paragraph (1)(l) (ii) on the standard's effective date and prior to the time of initial job assignment for those employees subsequently covered by this paragraph.

(iv) The training program shall be repeated at least annually for each employee.

(v) The employer shall assure that each employee is informed of the following:

(A) The content of this standard and its appendices;

(B) The specific nature of the operations which could result in exposure to lead above the action level;

(C) The purpose, proper selection, fitting, use, and limitations of respirators;

(D) The purpose and a description of the medical surveillance program, and the medical removal protection program including information concerning the adverse health effects associated with excessive exposure to lead (with particular attention to the adverse reproductive effects on both males and females);

(E) The engineering controls and work practices associated with the employee's job assignment;

(F) The contents of any compliance plan in effect; and

(G) Instructions to employees that chelating agents should not routinely be used to remove lead from their bodies and should not be used at all except under the direction of a licensed physician;

(2) *Access to information and training materials.*

(i) The employer shall make readily available to all affected employees a copy of this standard and its appendices.

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

(iii) In addition to the information required by paragraph (1)(l)(v), the employer shall include as part of the training program, and shall distribute to employees, any materials pertaining to the Occupational Safety and Health Act, the regulations issued pursuant to that Act, and this lead standard, which are made available to the employer by the Assistant Secretary.

(m) *Signs.*

(1) *General.* (i) The employer may use signs required by other statutes, regulations or ordinances in addition to, or in combination with, signs required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign required by this paragraph which contradicts or detracts from the meaning of the required sign.

(2) *Signs.* (i) The employer shall post the following warning signs in each work area where the PEL is exceeded:

WARNING

LEAD WORK AREA

POISON

NO SMOKING OR EATING

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(n) *Recordkeeping.*

(1) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required in paragraph (d) of this section.

(ii) This record shall include:

(A) The date(s), number, duration, location and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure where applicable;

(B) A description of the sampling and analytical methods used and evidence of their accuracy;

(C) The type of respiratory protective devices worn, if any;

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent; and

(E) The environmental variables that could affect the measurement of employee exposure.

(iii) The employer shall maintain these monitoring records for at least 40 years or for the duration of employment plus 20 years, whichever is longer.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (j) of this section.

(ii) This record shall include:

(A) The name, social security number, and description of the duties of the employee;

(B) A copy of the physician's written opinions;

(C) Results of any airborne exposure monitoring done for that employee and the representative exposure levels supplied to the physician; and

(D) Any employee medical complaints related to exposure to lead.

(iii) The employer shall keep, or assure that the examining physician keeps, the following medical records:

(A) A copy of the medical examination results including medical and work history required under paragraph (j) of this section;

(B) A description of the laboratory procedures and a copy of any standards or guidelines used to interpret the test results or references to that information;

(C) A copy of the results of biological monitoring.

(iv) The employer shall maintain or assure that the physician maintains those medical records for at least 40 years, or for the duration of employment plus 20 years, whichever is longer.

(3) *Medical removals.* (i) The employer shall establish and maintain an accurate record for each employee removed from current exposure to lead pursuant to paragraph (k) of this section.

(ii) Each record shall include:

(A) The name and social security number of the employee;

(B) The date on each occasion that the employee was removed from current exposure to lead as well as the corresponding date on which the employee was returned to his or her former job status;

(C) A brief explanation of how each removal was or is being accomplished; and

(D) A statement with respect to each removal indicating whether or not the reason for the removal was an elevated blood lead level.

(iii) The employer shall maintain each medical removal record for at

least the duration of an employee's employment.

(4) *Availability.* (i) The employer shall make available upon request all records required to be maintained by paragraph (n) of this section to the Assistant Secretary and the Director for examination and copying.

(ii) Upon request, the employer shall make environmental monitoring, biological monitoring, and medical removal records available to affected employees, former employees or their authorized employee representatives for inspection and copying.

(iii) Upon request, the employer shall make an employee's medical records required to be maintained by this section available to the affected employee or former employee or to a physician or other individual designated by such affected employee or former employees for examination and copying.

(5) *Transfer of records.* (i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (n) of this section.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records required to be maintained by this section for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained by this section, the employer shall notify the Director at least 3 months prior to the disposal of such records and shall transmit those records to the Director if requested within the period.

(o) *Observation of monitoring.* (1) *Employee observation.* The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to lead conducted pursuant to paragraph (d) of this section.

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

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

(A) Receive an explanation of the measurement procedures;

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) Powered, air-purifying respirators provided under (f)(2)(ii)—210 days from 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) Employers for whom compliance with the PEL or interim level is required within 1 year from the effective date—6 months from the effective date.

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

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

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

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

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