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Occupational Safety and Health Administration

Occupational Exposure to Inorganic Arsenic

Final Standard

[4510-26]

Title 29—Labor

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

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to Inorganic Arsenic

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

ACTION: Final Standard for Occupational Exposure to Inorganic Arsenic.

SUMMARY: This rule limits occupational exposure to inorganic arsenic to 10 $\mu g/m^3$ (micrograms per cubic meter of air) based on an 8 hour time-weighted average. The basis for this action is evidence that exposure to inorganic arsenic poses a cancer risk to workers. The purpose of this rule is to minimize the incidence of lung cancer among workers exposed to inorganic arsenic. Employees protected by this standard work principally in the nonferrous metal smelting, glass and arsenical chemical industries. Provisions for monitoring of exposures, recordkeeping, medical surveillance, hygiene facilities and other requirements are also included. The 10 $\mu g/m^3$ limit has been set because it will provide significant employee protection and is the lowest feasible level in many circumstances.

DATES: Effective date: August 1, 1978.

Startup dates:

August 1, 1978—Respirator use for employees exposed above 500 $\mu g/m^3$.

As soon as possible but no later than September 15, 1978—Completion of initial monitoring.

October 1, 1978—Complete establishment of regulated areas.

Respirator use for employees exposed above 50 $\mu g/m^3$.

Completion of Initial Training.

Notification of use.

December 1, 1978—Respirator use over 10 $\mu g/m^3$.

Completion of initial medical.

Completion of compliance plan.

July 1, 1979—Completion of lunch rooms and hygiene facilities.

December 31, 1979—Completion of engineering controls.

All other requirements of the standard have as their startup date August 1, 1978.

ADDRESS: For additional copies of this regulation contact: OSHA Office of Publications, U.S. Department of Labor, Room N-3423, Washington, D.C. 20210, telephone 202-523-8677.

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SUPPLEMENTAL INFORMATION:

INTRODUCTION

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. The new standard on occupational exposure to inorganic arsenic which appears at 29 CFR 1910.1018, applies to all employments in all industries covered by the Act with the following exceptions. For the reasons explained below, the standard does not apply to pesticide application, agriculture, and the treatment and use of arsenically preserved wood.

This document also amends Table Z-1 of 29 CFR 1910.1000. Entries for calcium arsenate and lead arsenate are deleted because they are replaced by the new standard. The existing entry, "Arsenic and its compounds (as As)—0.5 mg/m^3," is amended to read "Organic arsenic and its compounds (as As)—0.5 mg/m^3." The existing entry covers both organic and inorganic arsenicals. As the new standard covers inorganic arsenic, the entry in Table Z-1 is accordingly amended to clarify that it only covers organic arsenicals. The existing entry in Table 1 for arsine remains unchanged for the reasons discussed below.

Pursuant to section 4(b)(2) of the Act, The Occupational Safety and Health Administration (OSHA) has determined that this standard is more effective than the corresponding standards now applicable to the maritime and construction industries and currently contained in Subpart B of Part 1910, and Parts 1915, 1916, 1917, 1918, and 1926 of Title 29, Code of Federal Regulations. Therefore, those corresponding standards are superseded by the new inorganic arsenic standard in § 1910.1018. A new paragraph (e) is added to § 1910.19 to clarify the applicability of this new inorganic arsenic standard to the construction and maritime industries.

I. BACKGROUND

Arsenic (As) is commonly present in amounts ranging from less than 0.001 percent to 6 percent in sulfide ores mined for their copper, lead, zinc, gold, and silver content. Arsenic is also widely distributed naturally in small amounts (2-5 ppm) throughout the earth's crust. For example, it is found in iron ore and coal. Further, trace amounts of organic arsenic (less than 1 ppm) are naturally present in most living organisms including those man uses for food.

Approximately 97 percent of arsenic enters end-product manufacture in the form of arsenic trioxide (As_2O_3 or "white arsenic"). This compound, which is used in the synthesis of many other arsenic compounds, is released by and obtained as a by-product of the smelting of sulfide ores of copper, lead, and zinc. Arsenic is generally regarded, however, as a troublesome impurity in these metals which is eliminated through the smelting process. The Tacoma, Wash., facility of ASARCO, Inc. (formerly the American Smelting & Refining Co.) is the sole U.S. producer of arsenic trioxide.

ASARCO's arsenic production capacity is estimated to be 11,000 tons per year. World arsenc trioxide production averages approximately 60,000 tons per year, while U.S. consumption averages 30,000 tons per year. Most of the 36 copper, lead, and zinc smelters produce some amount of arsenic-bearing flue dust as a by-product of their operations. In the past, some of this flue dust was reprocessed by ASARCO-Tacoma, in order to reclaim the amounts of precious metals and arsenic it contains. Recent information, however, indicates that ASARCO has been reducing the amount of flue dust it will accept for reprocessing, and that much of the dust is being stored by the originating smelters.

Arsenic and its compounds have a variety of applications. The major use (comprising approximately 69 percent of U.S. consumption) is for insecticides and herbicides. Before World War II inorganic arsenic compounds (primarily calcium arsenate and lead arsenate) were the most widely used pesticides. Substitutes have now replaced arsenicals in many uses. However, the record of this proceeding indicates that two arsenicals are used in the raising of cotton, especially dry field production in Texas. Arsenic acid, an inorganic pentavalent arsenical, is used as a desiccant. Methane arsonates, organic arsenicals (not covered by the standard), are used as pesticides. Approximately 40 percent of the U.S. consumption of arsenic trioxide (12,000 tons) is utilized in the synthesis of these two chemicals.

Approximately 11 percent of total U.S. arsenic trioxide consumption is used in glass production as a clarifying and reducing agent. Only small quantities (a few pounds per ton) are usually used in some forms of glass. This use has been reduced as substitutes have been developed.

Approximately 7 percent (2,100 tons) of the total U.S. consumption of arsenic trioxide is used in the synthesis of arsenical wood preservatives, principally chromated copper arsenate (CCA). Wood preservatives make wood more resistant to termites, fungi, and rot. In doing so, they extend the useful life of the wood (from 6 to 36 years) helping conserve a natural resource and lessening the need for persistent insecticides for termite control. There are several types of wood preservatives, but for some uses, the record indicates that arsenical preservatives are preferred. (See the Final Environmental Impact Statement (FEIS) and its references.)

Other uses of inorganic arsenicals are for lead alloys (5 percent), flotation reagents for concentrating copper ores (5 percent), and feed additives (2 percent). Small quantities are used in the production of drugs, semi-conductors, light omitting diodes, devices to turn solar energy into electricity and in other electronic applications. Lengthier discussions of role of arsenicals can be found in the FEIS and in the Technological Feasibility Analysis and Inflationary Impact Statement (IIS) by Arthur Young & Co. (AY).

The exact number of workers exposed to inorganic arsenicals is unknown at this time. AY estimated that approximately 660,000 employees were involved in the commercial cycle of arsenic, and that 7,400 employees were exposed to over 4 $\mu g/m^3$ of inorganic arsenic. This latter number is an underestimate because of employee turnover and limited data in some areas and for some facilities.

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. Occupational safety and health standards provide notice of the requisite conduct or exposure level and provide a basis for assuring 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. 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. (s. 6(b)(5))

Sections 2(b)(5) and 6, 20, 21, 22, and 24 of the Act reflect Congress' recognition 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, standards cannot be postponed because definitive medical or scientific evidence is not currently available. Indeed, standards need only be supported by the best available evidence. The legislative history makes it clear that: "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Committee on Education and Labor, Report No. 91-1291, 91st Cong., 2d Session, 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 (C.A. 2, 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 insufficent data is presently available to make a fully informed factual determination. Decision-making 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 (C.A.D.C. 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. Rep. No. 91-1282, 91st Cong., 2d Sess., p. 58 (1970). Nevertheless, considerations of technological feasibility are not limited to devices already developed and in use. 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 Inst.* v. *OSHA*, No. 76-2358 (3rd Cir., 3/28/78).

Where appropriate, the standards are required 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. Moreover, where a standard prescribes medical examinations or other tests, they must be made available at no cost to the employees (section 6(b)(7)). 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)).

III. History of the Regulation

In 1943, the American Standards Association (now the American National Standards Institute or ANSI) proposed a standard for arsenic of not more than 15 micrograms of elemental arsenic per cubic meter of air (hereinafter $\mu g/m^3$). However, by 1945, this standard was increased by a factor of 10 to 150 $\mu g/m^3$.

In 1947, the American Conference of Governmental Industrial Hygienists (ACGIH) recommended a Maximum Airborne Concentration (MAC) of 100 $\mu g/m^3$. In 1948 this was changed to a Threshold Limit Value (TLV) of 500 $\mu g/m^3$. It appears that this level was set to protect against the hazard of dermatitis from arsenic trioxide, without consideration of carcinogenicity.

In 1976, based on its evaluation of evidence of carcinogenicity ACGIH adopted two new TLV's for arsenic trioxide. In the smelting environment, a level of 50 $\mu g/m^3$ (as arsenic) along with a ceiling of 5 ppm for sulfur dioxide and a level of 50 $\mu g/m^3$ for antimony trioxide (as antimony) was recommended. In non-smelting environments a level of 250 $\mu g/m^3$ (as arsenic) was recommended. The detailed basis for arriving at these levels is not clear on the record.

The ACGIH has separate standards for lead arsenate and calcium arsenate. A limit for lead arsenate of 150 μg lead arsenate/m^3 has remained in effect since 1957. (There are at least six distinct lead arsenate compounds. Depending on the molecular formula, this limit expressed as elemental arsenic (As) can range from approximately 20 to 55 $\mu g/m^3$). According to ACGIH documentation, lead arsenate was considered to present the double threat of chronic toxicity due to its lead content and acute toxicity due to its arsenic content. The limit for calcium arsenate of 100 $\mu g/m^3$, adopted by ACGIH in 1957, was later changed to the present 1,000 μg (1 mg) calcium arsenate/m^3 (equivalent to 380 μg As/m^3).

In 1969, the Secretary of Labor promulgated the 1968 Threshold Limit Values of the ACGIH including the limit for "arsenic and its compounds" (500 $\mu g/m^3$ as arsenic) lead arsenate (150 $\mu g/m^3$ as lead arsenate) and calcium arsenate (1,000 $\mu g/m^3$ as calcium arsenate), under the Walsh-Healy

Public Contracts Act (41 U.S.C. s35 et seq.) (34 FR 788-796) after an opportunity for a public hearing and written comments (33 FR 14258). These standards were subsequently adopted as established Federal Standards under section 6(a) of the Occupational Safety and Health Act of 1970 (36 FR 10466, 36 FR 15101) and included in what is now table Z-1 of § 1910.1000.

The Occupational Safety and Health Administration began the process of revising the current standard governing occupational exposure to inorganic arsenic after receipt of the National Institute for Occupational Safety and Health (NIOSH) document, "Criteria for a Recommended Standard * * * Occupational Exposure to Inorganic Arsenic," in January 1974. On September 20, 1974, after notice published in the FEDERAL REGISTER, OSHA conducted an informal fact-finding hearing[1] on the possible health hazards associated with occupational exposure to arsenic and its inorganic compounds. Findings presented at the hearing and through post-hearing comments implicated inorganic arsenic as a human carcinogen. Recent mortality studies conducted both in the United States and abroad furnished strong additional evidence to corroborate previous studies which showed excess respiratory and lymphatic cancer mortality among workers exposed to inorganic arsenic.

In view of this additional information, NIOSH submitted revised recommendations to OSHA on November 8, 1974, advocating that occupational exposure to arsenic and its inorganic compounds be limited to "no detectable level." NIOSH later published a new criteria document containing these modified recommendations and a discussion of the new information considered. The new NIOSH recommendations called for controlling occupational exposure to inorganic arsenic so that no worker is exposed to a concentration of arsenic in excess of 0.002 mg (2 μg) per cubic meter of air as determined by a 15-minute sampling period.

On January 21, 1975, a proposed standard to control occupational exposure to inorganic arsenic was published in the FEDERAL REGISTER (40 FR 3392). The proposal included a detailed preamble describing the necessity for the proposed standard, the information relied upon in its development and the terms of the proposal in its entirety. The notice requested the submission of written comments, data, views and arguments on the issues raised by the proposal and scheduled an informal hearing pursuant to section 6(b)(3) of the Act (29 U.S.C. 655(b)(3)) for April 8, 1975. The hearings lasted 6 days.[1]

On November 8, 1974, a notice of OSHA's intent to prepare an environmental impact statement was published in the FEDERAL REGISTER (39 FR 39617) pursuant to 29 CFR 1999.3(d). Subsequent to the publication of that notice, a draft environmental impact statement (DEIS) was prepared and on March 21, 1975, the Council on Environmental Quality published a notice of availability of the inorganic arsenic DEIS (40 FR 12841). In addition to the 45 day comment period specified in 29 CFR 1999.4(g), the environmental impact, if any, of the proposed standard was also an issue for the informal hearing as provided by 29 CFR 1999.4(h) and the notice of proposed rulemaking (40 FR 3392).

In addition to the DEIS, OSHA also prepared the "Technological Feasibility Analysis and Inflationary Impact Statement" (IIS). On June 24, 1976 a notice was published in the FEDERAL REGISTER (41 FR 26029) announcing the availability of the document. This notice also announced that the second phase of the rulemaking hearing on the economic impact and technological feasibility of the proposed standard, as well as certain new scientific evidence which had been developed or obtained since the April 1975 hearing, would be held.

On July 16, 1976, a second FEDERAL REGISTER notice announced the intention to include, as an issue in the forthcoming hearing, testimony and information on the advisability of including sputum cytology as part of required medical surveillance provisions in the final standard for inorganic arsenic (41 FR 29425). Following this second hearing (September 8-14, 1976)[1] post-hearing comments were received until November 2, 1976.

On November 5, 1976, a notice announcing the availability of certain new analyses of the potential carcinogenicity of pentavalent arsenic, as well as other information, was published (41 FR 48746). This notice provided for the submission of comments on the new materials by December 9, 1976.

The entire record, including 193 exhibits and approximately 2,500 transcript pages was certified by the Presiding Administrative Law Judges on January 27, 1977, and February 3, 1977, respectively, in accordance with 29 CFR 1911.17.

Prior to promulgation of the final standard, OSHA prepared a final environmental impact statement (FEIS) in accordance with 29 CFR 1999.5. Notice of the availability of the FEIS was published by the Council on Environmental Quality on February 11, 1977 (42 FR 8690).

This standard on occupational exposure to inorganic arsenic is based on a full consideration of the entire record of this proceeding including materials discussed or relied on in the proposal, the record of the informal hearing, all written comments and exhibits.

IV. OCCUPATIONAL HEALTH IMPLICATIONS

The impetus for this new inorganic arsenic standard is evidence of its carcinogenicity. This section analyzes that evidence in depth and is divided into seven parts as follows:

A. *Summary and General Considerations.* A discussion of some of the general considerations appropriate to the evaluation of epidemiologic studies.

B. *Respiratory Cancer.* A discussion of the study designs and the authors' conclusions; and OSHA's conclusion based on its analysis of the studies as well as some of the criticisms and comments contained in the record of the arsenic proceeding.

C. *Lymphatic Cancer.* Presentation of available data on the causal agents implicated in the lymphatic cancer deaths observed in two of the studies.

D. *Dose-Response.* A presentation of dose-response data derived from some of the studies, criticisms and adjustments where appropriate, as well as OSHA's analysis.

E. *Animal Studies.* A presentation of, and evaluation of animal studies pertinent to the evaluation of occupational carcinogenesis.

F. *Valence Considerations.* A discussion and comparison of acute toxicity, mechanistic interactions and interconversion between trivalent and pentavalent arsenic, and an evaluation of the present relevance of this information on the assessment of carcinogenic risk.

G. *Conclusion.* Separate summaries, analyses and conclusions on the carcinogenic risk of exposure to trivalent and pentavalent arsenic.

A. SUMMARY AND GENERAL CONSIDERATIONS

OSHA has carefully reviewed the substantial body of evidence relating to the carcinogenicity of inorganic arsenic and has concluded that it is clearly a human carcinogen. There is virtually no dispute as to the carcinogenicity of trivalent arsenic. There is a substantial body of epidemiologic studies of arsenic-exposed workers in varying environments showing excess risk of lung cancer where the one common factor is exposure to inorganic arsenic. Moreover, excess risk increases consistently with increasing degree and exposure to inorganic arsenic. In addition as discussed in detail below, both the available evidence and policy considerations have led OSHA to conclude that pentavalent arsenic should be regulated as a human carcinogen.

The following sections analyze in depth the most important epidemiolo-

[1]Throughout this document references will be made to hearing transcript pages as follows: Fact-finding hearing (September 20, 1974)—FTR; Hearing, April 8-15, 1975—ATR; Hearing, September 8-14, 1976—STR.

gic studies which are part of the record. A brief review of the nature of epidemiology may clarify that analysis.

Epidemiology is the study of the distribution and determinants of disease in humans. It focuses not on any single individual but on groups of individuals. Evidence of carcinogenicity in humans can be derived from two types of epidemiological studies (1) descriptive epidemiological studies in which the morbidity or mortality of cancer in human populations is found to vary (spatially or temporally) with exposure to the agent and (2) analytical epidemiological studies (e.g., case-control or cohort studies) in which individuals' exposure to the agent are found to be associated with an increased risk of cancer. Epidemiological studies, when done properly, are the most direct measure of the carcinogenicity of an agent since man himself is the subject of these studies.

In contrast to the controlled experimental study of animal species, epidemiological studies of necessity rely upon the untoward effects of unplanned events in the past. For that reason, it may be difficult, in any one epidemiological study, to account for all potential confounding. variables. Thus while a single epidemiological study may in some cases demonstrate a cause-effect relationship, the most convincing evidence of causality from epidemiological studies comes when several independent studies done under diverse circumstances result in positive findings.

Any epidemiological study showing or not showing a positive association between an agent and an increased risk of cancer may be weighted to a greater or lesser extent insofar as the following criteria are met:

(1) *Definition of Study Population.* A clear description is made of the population from which the study group was selected, the method of selecting the subjects of the study group, the criteria and rationale for inclusion or exclusion of study subjects and the procedure and rationale by which the study subjects were classified according to presence or absence and degree of exposure.

(2) *Reference Population.* A clear description is made of the reference or standard population against which the study group is contrasted and the procedure and rationale for selecting that reference or standard population.

(3) *Disease Ascertainment and Classification.* A clear statement is made of the specific procedures and sources for disease ascertainment including the degree of completeness of that ascertainment track for the study and the reference population. The criteria are specified for classification of morbidity and mortality (e.g., nosology) and a statement is made addressing the comparability of study and reference population regarding this classification scheme.

(4) *Positive or Negative Bias or Confounders.* As the operation of factors in the study design or execution may lead erroneously to an observed excess or deficit of cancer risk among exposed individuals, a clear statement is made of the magnitude of over or underestimating disease risk in the study group. Such factors to be considered are selection of healthy individuals for work and ethnicity and life-style differentials.

(5) *Dose-Response Relationship.* A dose-response relationship is demonstrated, that is an increase in cancer morbidity or mortality with an increase in degree of exposure. Demonstration of such a relationship provides strong evidence for incriminating the agent under study as a causal factor in the etiology of cancer causation. However, because of difficulty in the quantification of actual degree of exposure (dose-rate, deposition, retention, excretion) such relationships may not always be apparent. For that reason the lack of a demonstrated dose-response relationship may not negate the carcinogenicity of an agent.

In addition to these criteria, it must be recognized that any epidemiological study will have confidence limits around estimates of association or relative risks (e.g., around Standardized Mortality Ratios etc). In a study reported as "negative", the upper confidence limit may fall at a relative risk considerably above unity and thus the study cannot be regarded as negative but only as excluding a relative risk that is above this upper limit. Finally a "negative" epidemiological study may be relevant only to dose levels within or below the range of those observed in the study and is pertinent only if sufficient time has elapsed since first human exposure to the agent. Experience with human cancers of known etiology suggests that the period from first exposure to a chemical carcinogen to development of clinically observed cancer is usually measured in decades and may be in excess of 30 years.

Epidemiologic evidence must be viewed in its entirety. Such evidence is strengthened when similar findings are repeated or occur in different settings and environments. Accordingly, after discussing and analyzing individual studies, OSHA draws its conclusions based on all studies taken as a whole, scientific opinion, and OSHA policy.

B. RESPIRATORY CANCER

Two significant studies became available before the fact-finding hearing. The first, a study by Ott, Holder, and Gordon (Ex. 1A 3-1) concerning the relationship between respiratory cancer and occupational exposure to dry arsenicals was submitted to OSHA by the Dow Chemical Company in response to the advance notice of proposed rulemaking (39 FR 10494). According to the study report, the dry arsenicals to which the workers were exposed were the following, listed in order of decreasing production: lead arsenate (59 percent), calcium arsenate (34 percent), copper aceto-arsenite (5 percent) and magnesium arsenate (2 percent).

The Dow study compared the proportionate mortality rate of arsenic-exposed employees with that of non-exposed employees over a 37-year period (1919–1956). The "exposed" employee group included those workers who had spent 1 or more days in the arsenical production area, while the "control" group had never worked in the arsenic exposure area.

An increased percentage of cancer deaths was observed among the exposed worker population (32.9 percent) versus the nonexposed (20.7 percent). The authors' analysis of the data indicated an approximate three-fold increase in lung cancer for the exposed population (16.2 percent) over the nonexposed (5.7 percent). Lymphatic cancer occurred 2.5 times the expected rate (3.5 percent versus 1.4 percent). Fewer cancers of the digestive system were found in the exposed population than were expected.

To supplement the results of the first analysis, Ott also performed a cohort analysis by examining mortality data for 603 men who had worked for at least 1 month in the exposure area. Ott observed 35 cancer deaths among the exposed group versus 19.4 deaths expected on the basis of the U.S. white male age-calender time-cause specific rate. Of the 35 total cancer deaths among the exposed population, 20 lung cancer deaths were observed where only 5.8 would have been expected. Additionally, there were 5 deaths attributable to lymphatic cancer where 1.3 were expected. Thus, the results of the cohort analysis confirmed the findings of excess respiratory cancer mortality in the earlier analysis.

Of interest was the fact that of 173 deaths recorded for workers in the exposed population, 138 of the workers had worked in the exposure area for a period of less than 1 year, and of these 138, 16 died of lung cancer.

The National Academy of Science (NAS) report (Ex. 180, p. 313) noted that 60 percent of the respiratory cancer deaths reported in the Ott study were observed among those workers who had worked in the plant 1 year or less. Since the study included only those workers who remained with the company, the report recommended that the excess in this group be verified by following all short term workers. The report also noted that while the excess respiratory cancer mortality among these short-term workers might or might not be ascribable to arsenic, 4- to 6-fold excess respiratory cancer mortality was observed among the longer-term workers.

OSHA agrees it is conceivable that the excess among the short-term workers might not be ascribable to arsenic. However, there is no data to support this hypothesis and the long-term workers were at elevated risk of dying of respiratory cancer. OSHA thus accepts the study findings of excess respiratory cancer mortality among workers in the Dow plant.

The Allied Chemical Corp. submitted an epidemiological study to OSHA which contained findings of an excess of respiratory and lymphatic cancer deaths similar to the Dow studies (Ex. 1A-24). The Allied facility had also been engaged in the manufacture of dry arsenicals for pesticides. Further, like the Dow process, arsenic trioxide was the starting compound for the subsequent synthesis of lead arsenate, calcium arsenate, and other chemicals.

The Allied study, performed by Baetjer et al., compared the mortality experience of retired arsenic workers with that of the general population of Baltimore, Md., the location of the Allied pesticide facility. It focused on 27 deaths occurring between 1960 and 1972. Of the total deaths, 19 were due to cancer, including 10 from respiratory cancer and 3 from leukemia or lymphosarcoma. The expected numbers of deaths, however, based on figures adjusted for the combined age, race, and sex-specific relative frequencies of the general population of Baltimore, were only 5.6, 1.5, and 0.18, respectively.

When an analysis was made of mortality among only male retirees from the pesticide plant, Baetjer found even greater differences between observed and expected deaths from all types of cancer, as well as respiratory and leukemia-lymphatic cancers. Specifically, there were 17 deaths from all forms of cancer versus 1.35 expected, 10 respiratory cancer deaths versus 0.4 expected, and 3 deaths from leukemia-lymphatic cancers versus 0.05 expected.

OSHA recognizes that the Baetjer study is a preliminary study which will be followed by a more thorough analysis. OSHA agrees with Arthur D. Little, Inc. (Ex. 26B, p. 36) that the study does not eliminate other potential associations of workers with respiratory cancer such as smoking, common ethnicity or demography. As ADL noted, the lack of such analysis weakens the inference of a relationship between the plant environment and death by cancer. However, OSHA concludes that the magnitude of the excess of respiratory cancer mortality (28 and 17 times the expected Baltimore rates for 1960 and 1970, respectively) makes this study strong evidence of excess risk among workers exposed to arsenicals.

The studies by Ott et al. and Baetjer et al. because of their significant impact on the assessment of carcinogenic risk to exposure to arsenicals, have come under the most detailed scrutiny of any studies in the record. In the context of deciding the issue of carcinogenicity of pentavalent arsenic, many analyses have focused on the fact that workers were exposed to both trivalent and pentavalent arsenicals as well as other chemicals. In April 1975 OSHA asked the Allied and Dow Chemical Companies what chemicals the workers in the two studies were exposed to and what was their estimate of the degree and duration of exposure to each chemical (Ex. 101, Ex. 102).

Allied responded "we cannot establish with certainty the exact nature of exposures to which our people were subjected. Some were predominantly exposed to arsenic trioxide plus sodium arsenite, Paris Green and the Arsenates, while the female packers (not included in the Baetjer Phase I study, but among whom is a cancer survivor in remission) were exposed only to calcium arsenate, lead arsenate, and Paris Green." (Ex. 55.)

Dow responded:

> Unfortunately, at this time we cannot assess the relative importance of trivalent vs pentavalent arsenic. The men were exposed to the following materials: arsenic acid, lead arsenate, calcium arsenate, copper acetoarsenite, acetic acid, gum arabic, Rhodamin B, and finally lead oxide.
>
> Since the insecticide department was somewhat seasonal in its operation, the turnover of employees was considerable. It was, for many, the entry job into the company from which a considerable number of employees went on to other jobs with other exposures. The random nature of this movement is such that it is impossible to establish any pattern of exposure to other chemical entities. (Ex. 102.)

Ott's response to a question at a 1975 symposium on the health effects of arsenic and lead helps clarify this further.

> Arsenic trioxide was present in one building which was apart from the packaging building where most of the employees worked. Lead oxide was mixed with the arsenic trioxide and the arsenic was converted to the pentavalent form in the first building. The material was then pumped over to the finishing building in a slurry and dried and processed for packaging. (Ex. 182.)

Furthermore, as noted earlier, nearly 95 percent of the arsenicals produced in the Dow plant were pentavalent arsenicals.

Based on the Allied and Dow responses, it appears that the workers in the Allied study were primarily exposed to trivalent arsenic while those in the Dow study were primarily exposed to pentavalent arsenic. It is the case that workers in these two studies were exposed to other chemicals besides inorganic arsenic. However, their primary exposure was to trivalent and pentavalent arsenic, as these were the primary starting materials and primary products of the two plants. At the same symposium, Ott later stated:

> We have evaluated, using proportionate mortality techniques, every production unit in that location. The judgment was made, based on having looked at all these production units in relation to the arsenicals one, that the experience in the arsenicals area was unique to that unit. This is not to say that those people did not have other observed chemical exposure and I do not think we attributed all the effects to arsenicals. It was felt that regardless of whether there was some synergism present or not, the experience we were seeing was unique and not duplicated in any other production. (Ex. 182E, p. 314.)

While exposures to other chemicals (none of which are known to be carcinogenic) may have contributed to the excess cancer mortality observed, OSHA believes that is is appropriate to conclude that inorganic arsenic is the primary causal agent for the excess cancer mortality observed because of the large magnitude of excess risk and because the predominant exposure was to arsenicals. As discussed below, the conclusion is reinforced by the other studies indicating excess risk among arsenic-exposed workers.

For further presentation and analysis of the data in the Ott study see section IV-D of this preamble.

In 1969, Lee and Fraumeni, (Ex. 5D) in an effort to clarify the role of arsenic in human carcinogenesis, studied and compared the mortality data of 8,047 white, male Anaconda copper smelter workers in Montana exposed to both arsenic trioxide and sulfur dioxide and other co-contaminants during 1938-1963, with that of the white male population in the State of Montana. As of December 1963, 5,397 of these 8,047 workers were known to be alive; 1,877 were deceased; and 773 were unknown status. When compared to the control population (white, male Montanans) there were 1,877 observed smelter worker deaths as contrasted with 1,634 expected deaths (P less than 0.01).

The authors analyzed the study group according to duration and degree of exposure to arsenic trioxide and sulfur dioxide. The excessive lung cancer mortality among the copper smelter workers was found to increase consistently with increasing lengths of employment at the smelter. These increases ranged from 2.03 times the expected for those employed from 1 to 4 years, to 4.7 times the expected rates for those employees working 15 years or more prior to 1938.

Lee and Fraumeni further divided the groups into "heavy," "medium," and "light" exposures to arsenic trioxide, based on the amount of arsenic trioxide to which the employees had been exposed. According to testimony given by H. F. Morris (Ex. 28B) the Anaconda workers studied by Lee and Fraumeni would have been exposed to the following average levels of arsenic trioxide from 1943 to 1957: heavy—11.27 mg/m^3; medium—0.58 mg/m^3; light—0.29 mg/m^3. As Morris stated, respirators were supplied in the heavy and some of the medium exposure areas and "used with varying degrees of faithfulness."

Additionally the authors discovered that lung cancer mortality increased consistently with increasing degree and duration of exposure in each of the "heavy," "medium," and "light" categories. Lung cancer mortality ranged from 4.4 to 8 times expected in the "heavy" exposure group, 2.63 to 6.7 times expected in the "medium" group, and 2.1 to 2.5 times expected in the "light" exposure category. Further, it is significant that the 2,862 men who worked less than 12 months in their category of maximum arsenic exposure category, were found to have an incidence of lung cancer 2.86 times that of the control population.

Similarly, workers were grouped according to the duration and degree of their exposures to sulfur dioxide. Again, excess lung cancer mortality was found with increasing exposure to sulfur dioxide. The greatest excess of lung cancer was found among the workers exposed to both high concentrations of arsenic trioxide and medium or high concentrations of sulfur dioxide. Lee and Fraumeni concluded that their findings were "consistent with the hypothesis that exposure to high levels of arsenic trioxide, perhaps in interaction with sulfur dioxide or unidentified chemicals in the work environment, is responsible for the threefold excess of respiratory cancer deaths among smelter workers." For a more detailed analysis of this dose—response data in this study, see section IV-D of this preamble.

The finding of excess lung cancer mortality is of great significance because this study meets most of the criteria of an ideal epidemiological study. The study carefully followed up the population at risk for a substantial period of time. The size of the population at risk, allowed for both a high degree of statistical significance, as well as for breakdown into large exposure categories for gradients of risk of exposure to arsenic trioxide and other agents to be examined. The exposure categories were further substantiated by contemporaneous measurements, which were submitted to the record of this proceeding.

Certain other factors such as smoking and place of birth were only qualitatively evaluated. However, as discussed below, these were not of sufficient magnitude to eliminate the excesses observed.

The strength of the Lee and Fraumeni study was also discussed by Arthur D. Little, a consulting firm hired by Kennecott Copper, to review the evidence. ADL, in comparing this study to other studies discussed in the body of the study pointed out the other "studies which neither in volume, duration or methodological excellence could compete with this exceptional investigation." (Ex. 26B, p. 32).

There have been three studies which examined the mortality experience of ASARCO, Tacoma, Wash., copper smelter workers. The first, Pinto and Bennett (Ex. 3Z) suffers from the inappropriate choice of nonexposed control groups for the arsenic-exposed population (ATR 772-73). The second study, Milham and Strong (Ex. 1A-7H) shows excess lung cancer mortality. The third, by Pinto and Enterline (Ex. 29B and Ex. 111, Attachment 4) presents the most thorough examination of ASARCO, Tacoma worker mortality. Consequently, only the latter study is examined in detail.

At the April 1975 rulemaking hearing, Pinto and Enterline (Ex. 29B) presented results of a mortality study of retirees receiving pensions from ASARCO, Tacoma. The retiree population included those who were alive on January 1, 1961, and who had reached age 65 prior to December 31, 1973 (Ex. 29B). An updated report (Ex. 111, Attachment 4) included pensioners who were alive as of January 1, 1949, and who had reached age 65 before December 31, 1960. For the years 1949 to 1973, 324 deaths were recorded, with 69 due to cancer. Of the 69 cancer deaths, 32 were due to lung cancer, a rate 3 times that of the Washington State population.

Pinto and Enterline considered the lifetime arsenic exposure of each member of the study population from two aspects—total exposure duration and average exposure—the exposure values being constructed from separate departmental averages of a large number of employee urine samples taken in 1973. These levels were used to calculate an arsenic exposure index for each pensioner studied. The pensioners were then divided into four groups based on their exposure indexes.

Pinto and Enterline found that respiratory cancer was related to the average urinary arsenic levels. No excess lung cancer mortality was observed in workers employed less than 25 years prior to retirement, who had average urinary arsenic levels less than 200 micrograms/liter. However, statistically significant excess lung cancer mortality was observed in all groups exposed 25 years or more.

On the basis of their findings Pinto and Enterline concluded, "results thus far indicate that there is a relationship between exposure to arsenic trioxide, or associated agents in the smelter atmosphere, and increased risk of respiratory cancer."

In the updated report (Ex. 111, Attachment 4), the authors also analyzed the effect of smoking on a population of 419 retirees alive on January 1, 1961. Among the 377 workers in this group for whom smoking histories were available, 191 were smokers and 186 were not (nonsmokers were defined as those who had not smoked in the last 10 years). Respiratory cancer mortality rates for the smoking retirees were compared with smokers in the general population of Washington State (1961-70) and the rates of nonsmoking retirees were compared with nonsmokers in the general Washington population. As a result, the authors were able to provide a numerical estimate of the adjustment for smoking on the lung cancer mortality rates observed in the study.

It should be noted that the Pinto and Enterline study, like the Lee and Fraumeni study, is an excellent study and deserves considerable credence. The study was based upon careful followup of a group of long-term exposed workers. Exposure indices, based on 1973 values, provided for a maximum utilization of the data. The consistent dose-response relationship between 1973-based urinary arsenic levels and lung cancer mortality strengthens the association of the disease with worker exposure to arsenic. Thus, OSHA accepts, the overall findings of excess lung cancer mortality observed in the study. The data from this study is analyzed in greater detail in Section IV-D of this premble.

There was considerable analysis in the record of the effects of smoking and place of birth on the findings of Pinto and Enterline, and Lee and Fraumeni, and other studies. Pinto and Enterline found the lung cancer rate among the smoking retirees to be 2.6 times that of the general population smokers, and the rates of the nonsmoking retirees to be 4.6 times that of the general population of nonsmokers. Pinto and Enterline, on the basis of a 1975 survey of current worker smoking habits, calculated that a 17 percent adjustment of lung cancer mortality was necessary to adjust for the smoking patterns of present Tacoma smelter workers. Dr. Enterline concluded:

> There appears to be some interaction between smoking and arsenic exposure, but not the multiplying effect observed for some other substances. Smokers have slightly higher total arsenic exposures at retirement, but definitely not enough to account for the added deaths. Table 3 (of the study) provides only very rough estimates, but it

does suggest that the excess in SMR's for respiratory cancer are not due to smoking.

As noted by Dr. Weir (Ex. 29N) smoking should be considered in the evaluation of the Lee and Fraumeni and Pinto and Enterline studies. Dr. Weir has coauthored several studies which investigated the smoking patterns of various occupational classes of workers. Weir indicated the greatest adjustment necessary to account for increased degree of smoking among the skilled occupational laborers studied was 18 percent. In these circumstances, OSHA is unwilling to assume that smoking alone accounted for more than a 17 percent excess in lung cancer mortality.

OSHA accepts the fact that some adjustment to standardized mortality ratio in other studies, needs to be made, as in the case of the Tacoma workers to take into account for possibly higher smoking pattern (relative to the general population) among smelter workers. But if the 17 percent adjustment at Tacoma is typical, this would not significantly modify the findings of 2 to 8 times excess mortality found in this and other studies. Therefore, OSHA agrees with Dr. Fraumeni (ATR 182) that smoking could not account for the excess mortality in the "light" category of the Lee and Fraumeni study and of course, would not account for the larger excesses in the "medium" and "heavy" exposure categories.

Another factor known to affect excess respiratory cancer observed in the two studies is place of birth (Ex. 29N, 26B). As noted and displayed in table 7 of the Lee and Fraumeni study, foreign-born workers had higher SMR's for respiratory cancer than native-born workers, but exhibited similar gradients by degree and duration of exposure. Lee and Fraumeni stated,

> The greater excess of respiratory cancer mortality among foreign-born workers can be attributed, at least in part, to the fact that the periods of employment were generally longer than those for the native-born. In addition, the extent of the overall excess of respiratory cancer and the mortality gradients associated with specific exposures in the smelter cannot be explained by other factors which affect cancer mortality, such as socio-economic status, genetic susceptibility, availability of medical care, accuracy of death certificates, and urbanization. (Ex. 5D pp. 1049-50.)

Because the paper provided no data to assess the effect of duration of employment on foreign born worker respiratory cancer mortality, Weir analyzed the effect of birthplace on mortality risk for all causes. Weir stated that the figures based on mortality risk of all causes do not necessarily mean that the authors were incorrect in assigning the excess respiratory cancer risk to occupational exposure. However, if these two groups are similar, Weir calculated that as much as 15 percent of the respiratory cancer risk could be reassigned to place of birth (Ex. 29N, p. 21). It should be noted that this is only an approximation. The approach one would prefer (assuming one had access to the original data) would be to assess the influence of birth on the disease being assessed, lung cancer, and not make approximations based upon deaths from all causes. Since 33.7 percent of the deaths of Lee and Fraumeni and approximately 40 percent in the Pinto and Enterline were among foreign-born, Weir believed that the effect was at least as great in the Pinto and Enterline study (Ex. 29N, p. 21).

OSHA accepts Weir's analysis that this birthplace variable may influence the excess respiratory cancer mortality among these workers in these two studies. The exact degree is unknown but 15 percent seems a reasonable high-side estimate. As Weir later noted, the absolute value of the risk gradients by exposure level, would be reduced, the relative values would be unchanged.

Even if the adjustments for smoking (17 percent) and upper bound estimate for place of birth (15 percent were applied; there still would be a substantial excess respiratory cancer mortality in all categories (heavy, medium, and light) of the Lee and Fraumeni study and those in which a statistically significant excess lung cancer mortality was observed in 3 categories in the Pinto and Enterline study.

It can be speculated that these adjustments should be higher and that therefore a greater portion of the excess mortality in the exposed groups is accounted for by smoking and place of birth. But such speculation is not supported by concrete data. OSHA does not judge it appropriate when analyzing studies for the purpose of adopting health standards to apply all speculative hypotheses that might reduce reported risk. Accepting such hypotheses is, in effect, a bias against worker protection. Thus, OSHA concludes that the evidence indicates that some adjustment to the mortality rates is needed to take into account smoking and place of birth. But even allowing for adjustment for smoking and place of birth, there is still substantial excess respiratory cancer mortality among the exposed workers in the Lee and Fraumeni, and Pinto and Enterline Studies. Exposure to arsenic still remains the best explanation for the observed excess risk.

A two-part investigation of the worker population of an English factory which manufactured a sodium arsenite sheep dip was published in 1948. The first part of this study, reported by Hill and Faning, (Ex. 5B) compared mortality data of the factory worker population with that of workers in other occupations in the same community, during the years 1910 to 1943. Hill and Faning found 22 cancer deaths (29.3 percent) among 75 deceased workers, compared to 157 cancer deaths (12.9 percent) among 1,216 deceased workers from other occupations. The percentage of cancer deaths due to cancer of the respiratory system was 31.8 percent for the sodium arsenite workers compared to 15.9 percent for the control group, and from skin cancer, 13.6 percent compared with 1.3 percent for workers from other occupations.

The second part of the study, reported by Perry et al. (Ex. 5C), consisted of a clinical and environmental investigation of the same factory during 1945 and 1946. Although the study was limited in scope and design, Perry's results showed some correlations between the levels of arsenic found in the hair and urine of workers, and the levels of airborne arsenic contamination to which workers were exposed.

The Hill and Faning study is an example of a carefully done case-control study. The control group, a group of comparable socio-economic status with that of the exposed group, provided for internal control of many variables (smoking, place of birth) important for the evaluation of relative risk due to exposure to chemicals. The excesses, although based on a small sample size, are given added importance when considered in conjunction with the findings of the Ott and Baetjer studies (discussed previously) and taken together strongly supports the findings of excess cancer mortality risk among nonsmelter workers exposed to arsenicals.

In 1951 Snegireff and Lombard (Ex. 5E) conducted a statistical study of cancer mortality in the metallurgical industry. They concluded that the frequency of cancer deaths of all types among the employees of a plant handling arsenic trioxide was not significantly different from that of a control population (workers in a plant stated to be identical to the first except that it handled no arsenic trioxide). As a result of this lack of statistical significance, the authors concluded that arsenic trioxide was not carcinogenic.

Both NIOSH (Ex. 99, p. 32-35) and ADL (Ex. 26B, p. 15-20) analyses found the author's statistical analysis and conclusions to be of questionable validity. Using a number of assumptions, NIOSH observed that both worker populations were subject to large excess respiratory cancer mortality. NIOSH concluded that the authors should have chosen a more suitable control population, and focused their analysis on respiratory cancer mortality. ADL in a detailed analysis of the statistics of the paper noted several serious misapplications of statistical analysis as well as errors in interpretation (Ex. 26B, p. 18-20). OSHA concludes along with ADL and NIOSH that the statistics and analysis do not support the authors' conclusions. Accordingly, OSHA places no weight on this study.

In October 1974, the Kennecott Copper Corporation (KCC) submitted a survey of mortality from respiratory diseases observed among its active and retired employees for the period 1950 to 1972 (Ex. 1A-30). The study, performed by Milby and Hine, compared the ratios of observed employee deaths to the expected deaths and the proportion of deaths due to cancers of all types, respiratory cancer, and nonmalignant respiratory diseases among KCC employees with corresponding data for the United States and for the State of Utah. They found that the proportion of respiratory cancer deaths among KCC employees was not very different from either the total U.S. respiratory cancer death rate or that of the State of Utah.

Both NIOSH (Ex. 99, p. 47-8) and ADL (Ex. 26B, p. 38) noted that a major flaw in the Milby-Hine study was the inclusion of all workers from all Kennecott facilities in the mortality analysis. NIOSH noted that approximately 80 percent of the study population were miners, concentrator workers, and refinery workers. Miners and concentrator workers were not exposed to arsenic but rather to complex ore in which arsenic is bound in such a manner that workers are exposed to the "ore" and not free, unbound arsenic compounds. The arsenic in such ores might not be biologically available and therefore might not elicit a carcinogenic response. As noted in the Rencher-Carter study, none of these groups of workers have been shown to be at increased risk. This resulted in a significant dilution effect in which the mortality experience of smelter workers was masked by the inclusion of workers at other work sites. NIOSH also noted that insufficient time may have elapsed to allow for the latency period of arsenic-associated carcinogenesis. Thus, NIOSH felt that the study did not reliably evaluate the effects of exposure at the Kennecott, Utah, smelter.

OSHA concludes that the overbroad inclusion of workers at work sites not at excess risk, diluted results which would have been associated with smelter workers. Additionally, more information than provided in the study is necessary to evaluate whether sufficient time has elapsed to allow for latency period. In view of these difficulties, less weight can be placed on the findings of the Milby-Hine study, particularly in relation to the Lee and Fraumeni, and Pinto and Enterline studies.

A study by Kuratsune et al. (Ex. 1A-7G) published in 1974, reported a high frequency of respiratory cancer mortality among workers at a Japanese copper smelter. On the basis of Kuratsune's findings, the Japanese Ministry of Labor judged that the cases of lung cancer were due to occupational exposure to arsenic trioxide and other compounds released during the smelting of copper ores. Kuratsune's study is consistent with the findings of excess mortality among workers in some American smelters.

In 1976 Tukadome and Kuratsune (Ex. 191), in a follow-up to their 1974 study, published a study of the mortality in an experience of 2,675 male Japanese smelting and refinery workers for the period 1949 to 1971. The workers were divided into 5 cohorts according to their jobs, considering both the areas and tasks to which they were assigned. Standardized Mortality Ratios (SMR's) were calculated by applying the age-specific death rates to the mid-year populations by each year from 1949 to 1971 and summing over all calendar years.

Among copper smelter workers, statistically significant mortality excesses were observed for cancer of all sites, cancer of the colon and lung cancer. The ratio of observed to expected deaths for lung cancer was 11.9 (29 deaths observed, 2.44 expected) cancer of the liver 3.4 (11 observed, 3.26 expected), and cancer of the colon 5.1 (3 observed, .59 expected). In contrast, no excess cancer mortality was observed in any of the other cohorts.

The authors then grouped the copper smelter workers by duration (length of employment) and degree of exposure to arsenic and other compounds. These relative exposure designations were made without any quantitative exposure data, but were based on the relatively high arsenic content of the ores and judgments of persons familiar with the process. The excessive risk of lung cancer mortality was found to increase consistently with increasing length of employment at the smelter. This risk ranged from 5.63 times the expected for those working 1 to 9 years, to 19 times the expected for those working 20 or more years. Similarly, mortality increased consistently with increasing degree of exposure to arsenic ranging from 6.35 times the expected in the "light" exposure category to 14.9 times the expected in the "heavy" exposure category.

While noting the excess mortality due to liver cancer; the authors stated, "Since the majority of these deaths were unspecified malignant neoplasms of liver without adequate diagnostic validity, any further reference can hardly be made with confidence. It seems highly desirable that similar epidemiologic studies with particular attention to this site of cancer should be made at other copper refineries."

Based on their findings, the authors concluded that the findings of increased lung cancer mortality and demonstrable dose-response relationship supports the findings of Lee and Fraumeni and Ott et al. of increased lung cancer risk among workers exposed to arsenicals (Ex. 191, p. 315).

Kennecott Copper stated (Ex. 190-1) the Tukudome study provided no further information beyond the other studies previously examined which indicate a causal relationship between inorganic arsenic and respiratory cancer. Kennecott further noted that there was no environmental data available to indicate what chemicals and to what degree workers were exposed, and that the authors appeared to rely solely on their judgment in deriving the relative exposure classifications. Finally, Kennecott noted that the authors had no data to support their judgment that arsenic compounds and sulfur dioxide as well as possibly other carcinogens such as polycyclic aromatic hydrocarbons are responsible for the excess respiratory cancer observed.

OSHA accepts some of the above criticisms of the study. One of the weaknesses of the study is there is no quantitative exposure data. Thus, great weight cannot be placed on the exposure classifications used. What is useful, however, is the fact that only the cohort of smelter workers were subject to excess risk. Consequently in the absence of exposure data and in light of the relatively primitive processes used in the plant from 1919 to 1946, one can state that these findings are consistent with the findings of other studies of excess respiratory cancer mortality among smelter workers exposed to arsenic trioxide and other compounds.

ASARCO suggested that employees placed in the cohort of refinery workers observed to have no excess mortality, may indeed have had some exposure to arsenic based on analogy with similar operations at their Tacoma plant (Ex. 190-3). Again little weight can be placed on this suggestion because no quantitative data is available to confirm the degree and duration of exposure.

In January 1975, OSHA received the Rencher-Carter (BYU) study of worker mortality in the Utah Division of the Kennecott Copper Corp. (Ex. 5F). For the period 1959 to 1969, 965 deaths were identified and divided into four categories: Smelter workers, mine workers, concentrator workers, and others. The authors then calculated the percentages of deaths from specific causes in each category, and compared their findings with the 1968 mortality data for the State of Utah.

Smelter workers were found to have the highest percentage of deaths due to lung cancer (7 percent), while mine and concentrator workers had 2.2 percent of deaths due to lung cancer. As noted earlier in the discussion of the

Milby-Hine study, it is uncertain whether mine and concentrator workers are exposed to biologically available arsenic. No lung cancer deaths were observed in the "other" category (refinery, office, and research center workers). The corresponding 1968 lung cancer mortality figure for Utah was 2.7 percent.

Next, the authors investigated the influence of smoking on lung cancer mortality. Based on a complete survey of the smoking habits of the deceased smelter workers, and random samples of the deceased mine and concentrator workers, they found that nearly the same percentage of all three groups were smokers (approximately 60 percent). After dividing each of the three groups into smokers and non-smokers, Rencher and Carter observed that both smoking and non-smoking smelter workers had lung cancer mortality rates in excess of their counterparts in the mine and concentrator groups.

After determining the age of the workers at death, the authors calculated age-adjusted death rates and compared them to the State rates. Smelter workers were found to have a rate of lung cancer mortality three times that of the State population (10.1 versus 3.3). The mine workers had a lower lung cancer rate than the State population (2.1 versus 3.3). An examination of work histories revealed that all but one of the smelter workers who died of lung cancer had worked in one of four plant areas having the highest average exposure levels for five contaminants (arsenic, sulfur dioxide, sulfuric acid mist, lead, and copper). After calculating cumulative exposure indices for each smelter worker, for each contaminant, and averaging each category, it was found that all five average cumulative exposure indices were higher for the lung cancer group. This indicates that these smelter workers had either worked longer at the smelter or in areas of higher exposure. The findings of this study are consistent with findings of excess lung cancer mortality of smelter workers exposed to arsenic.

In 1973, W. C. Nelson et al. (Ex. 1A-28) of the Environmental Protection Agency (EPA), published a followup mortality study for a cohort of 1,231 individuals in Wenatchee, Wash., who had participated in a 1938 mortality survey of the effects of exposure to lead arsenate insecticide spray (Neal et al., Public Health Bulletin 267; 1941). The population surveyed was classified by spray exposure, duration of exposure, age and sex. Additionally, three exposure groups were identified: Orchardists, those having the highest exposure; consumers, those having no exposure; and a third group, having intermediate exposures.

Nelson located over 97 percent of the original 1938 study group. The Standard Mortality Ratio (SMR) technique was used to compare the total death rate to the expected death rate in the State of Washington. The authors concluded that excess mortality did not occur consistently with the degree of exposure to lead arsenate spray. In fact, the orchardists, the most highly exposed group, had the lowest SMR of the three groups analyzed.

The American Wood Preservers Institute (AWPI) (Ex. 115, p. 15-18) and others suggest that the Nelson study provides convincing evidence that lead arsenate specifically, and pentavalent arsenic in general, are not carcinogenic. They indicated that the study is a careful followup of the cohort of orchardists studied by Neal et al. (Ex. 62) exposed to substantial quantities of lead arsenate spray during their working lives. Due to the "substantial" exposure and careful methodology, AWPI concluded that lead arsenate is not carcinogenic (Ex. 115, p. 18).

NIOSH on the other hand stated:

> We question also the pertinence of the study by Nelson et al. All that is known about the exposure of those people to arsenates is that during 1938 they were exposed for 8-14 hours per day for not more than 12 weeks, and some for as little as 2 weeks, to airborne concentrations of arsenic somewhere between 0.02 and 261.2 mg/10 cu m. The group considered to be the most heavily exposed orchardists, had a mean concentration of arsenic in their urines at some unspecified time during the day and at unspecified dates in relation to their actual contacts with arsenic that was about 2.2× that in the urines of a control group. We know nothing about their previous or later exposures to arsenates and cannot assume that they continued to have annual exposures to similar environmental concentrations of arsenate throughout the 30 years from 1938 to 1968, when the retrospective study was performed. The exposure during 1938 could be the only one that some of the subjects ever had. The finding of no excess cancer in the most heavily exposed group cannot be assigned any high significance in consideration of the many unknown factors in the study (Ex. 192A).

In its analysis of this paper ADL noted (Ex. 26B, p. 45) "The most serious deficiency of this study deals with the difficulty in identifying the actual level and duration of lead arsenate exposure of its subjects. Frequent and serious errors in such classification of subjects relative to their exposure can mask a relationship that might exist between exposure and mortality."

OSHA concludes that the Nelson study is not a valid basis for judging the potential carcinogenicity of lead arsenate. While it was a careful followup of persons included in the 1938 study, the exposure classifications were based solely on measurements made in 1938. As the authors noted (Ex. 1A-28, p. 110) the 1938 categories were kept constant, regardless of subsequent work or retirement. As NIOSH indicated, exposures may have differed dramatically from those measured in 1938.

Especially noteworthy, also, is the authors' discussion of their own study design. In this discussion, the authors noted that it was difficult to be sure of the exposure dosage categories, and that they lacked data for individual exposure measurements. Nelson stated that they could not be positive about whom the most exposed individuals were, and that the dosage levels were especially a problem for the intermediate group, who had the most heterogeneous exposures. Nelson also stated that it is difficult to interpret the study results due to the relatively small number of individuals involved. In fact, Nelson stated that some of the more suggestive excesses in mortality cannot be considered significant because of small numbers and that many of the volunteers in the 1938 study "are still too young to have reached high risk mortality age" (Ex. 1A-28).

NIOSH attempted to independently evaluate the Nelson study findings using two types of data sources, the first data being occupational mortality data for adult white males in the State of Washington for the period 1950-71 (Ex. 1A-34). The other source reviewed was the age-adjusted mortality rates for specific types of cancer for the three-county area from which the Nelson orchardist sample was drawn. Here again, because of many unknown factors, including lack of data necessary to determine degree and duration exposure to lead arsenate as well as documented use of a variety of other pesticides (Ex. 31C), OSHA feels that this data cannot be relied on to make a judgment on the carcinogenicity of pentavalent arsenic.

In July 1976, American Wood Preservers Institute submitted the finalized form of a mortality study of Hawaiian carpenters, conducted for AWPI by the Pacific Biomedical Research Center of the University of Hawaii (Ex. 137-6). Preliminary results of the study had been submitted during the April 1975 hearings. (Ex. 31C, Attach. 71) The study was undertaken to analyze the mortality experience of carpenters in Hawaii before and after the introduction of water soluble arsenical wood preservatives.

In making this study, the death records of 227 carpenters who died between June 1947, and May 1951 (Group A), and 293 carpenters who died between January 1970, and December 1973. (Group B), were matched with the death records of non-carpenters of the same sex, race and age (within 5 years). Although arsenical wood preservatives had been used in Hawaii since 1935, prior to World War II the use of arsenate-treated wood was negligible. After World War II, however, according to this study, most of the lumber used in construction was treated. Therefore, the investigators assumed that the carpenters who died in the early period (Group A) constituted an unexposed control group with respect to arsenate-treated wood, and that the carpenters who died in the later period (Group B) had substantial exposure to arsenical-based preservatives.

Comparison of the death rates among carpenters with the total death rate in the general population showed a significant increase in deaths among carpenters. The relative risk for all causes of death for carpenters was 2.15 for Group A and 2.29 for Group B. The relative risk for cancer death among carpenters was 3.58 for Group A and 2.72 for Group B. The authors concluded that there was no significant difference in cancer mortality between Group A and Group B. Similarly, the authors found that there were no significant differences in cancer of trachea, bronchus and lung, or lymphatic and hematopoietic system between the carpenters and non-carpenters and that the differences between Group A and Group B were not significant.

Based on their findings the authors concluded, "Our study is in agreement with Milham's and others with respect to excess cancer deaths among carpenters. However, the relative risk for cancer among carpenters exposed to arsenate-treated wood does not show a significant excess for the periods studied."

Unfortunately, there is no data on individual carpenter exposure of the exposed group. Thus, we cannot define who was "exposed", who was "nonexposed", and what the degree of exposure was. Specifically, it is not clear that the Group B carpenters had higher exposures to inorganic arsenic than the "nonexposed" group. Additionally, there is some question whether the Group B carpenters had been followed for a sufficient number of years to allow for the long latency period (20 years or more) observed in other studies for the development of arsenic-related respiratory cancer. (See also the analyses of this study by E. Baier of NIOSH, Dr. Kraybill of NCI, Dr. Lloyd of the Steelworkers (Ex. 192).) Consequently, the conclusions of this study are not sufficiently documented to support a conclusion that pentavalent arsenic is not a carcinogen. As discussed in the scope and application section, however, OSHA has concluded that it is not appropriate to include arsenically treated wood within the scope of this standard.

In 1969, Denk et al. (Ex. 109C-87) reported the autopsy findings of 100 Moselle vineyard workers exposed to arsenical pesticides. From 1923 until 1942 vines were sprayed from May to June with "Urania Green" and "Silesia Green", two pesticides containing 54 to 56 percent arsenic trioxide, and also with calcium arsenate. In addition to inhalation exposure, workers consumed large quantities of "home brew" (a wine residue) containing 2.0 to 8.9 mg arsenic trioxide per liter.

Cases were selected from among those petitioning from 1960 to 1966 to the Rhine Agricultural Professional Society for recognition of the effects of arsenic as an occupational disease. One hundred cases were chosen, without regard to expert evaluation, from among those autopsied for which precise medical diagnoses were available for evaluation. Cancer was listed as cause of death in 75 of the 100 cases, and as a secondary disease in 10 others. The 85 cases were distributed over the various organ sites as follows: 65 cases of lung cancer, 29 cases of skin cancer, 3 of laryngeal cancer, 2 of stomach cancer and 2 of pancreatic cancer, and one each for 8 other sites.

In 1957 and 1958, Roth (Ex. 65, 109C No. 88) published the results of his autopsy findings of vine growers from the Moselle region in Germany who were exposed by inhalation of pesticides containing 4.3 to 56 percent arsenic trioxide and by drinking wine containing 1.5 to 8.2 mg arsenic trioxide per liter. In the 1958 report, cancer was listed as the cause of death in 30 of the 47 cases (64 percent), 18 of which were due to lung cancer (38 percent), 6 to liver sarcomas (12.8 percent), 5 to cancer of the esophagus (10.8 percent), and 1 to bile duct cancer (2.1 percent). Arsenic cirrhoses were listed as the cause of death in 8 of the 47 cases and were observed in 15 other cases. Roth also found 10 cases of multiple tumors of the skin and 4 cases of melanoses of the skin. Roth also surveyed the lung cancer mortality rate in the general population of vineyard and nonvineyard areas of the Moselle and vineyard areas of the Ahr districts of Germany. In general, Roth found higher rates of lung cancer mortality in vineyard areas using arsenical insecticides than in all other areas.

The Denk and Roth studies have been discussed in detail, because of the considerable analyses on them made during the record of this proceeding. The major route of exposure for these pesticide workers was ingestion of arsenic contaminated wine. These studies thus, provide further evidence of the carcinogenic potential of inorganic arsenic by another route of exposure, ingestion.

C. LYMPHATIC CANCER

With the exception of the Allied and Dow studies, no excesses of lymphatic cancer mortality were reported in the arsenic epidemiological literature. In many studies, no analyses were made for the risk of lymphatic cancer. In letters to Allied (Ex. 101) and Dow (Ex. 102) OSHA asked whether they had any reason to suspect exposure to a particular agent or agents used in their plants, and not found in the environment of nonferrous smelters, as a causative agent or agents for lymphatic cancer. Allied responded,

> That the difference is either due to route of exposure (skin contact versus inhalation) or to the specific properties of sodium arsenite and/or Paris green (copper aceto-arsenite). In our earlier reviews and reports to you, we did not recognize the significance of the fact that sodium arsenite was produced concurrently as a product in a separate operation in the arsenic acid plant area, and was also used as a raw material in the insecticide plant. Doctor Baetjer advises us that the clinical literature supports the position that sodium arsenite is a systemic carcinogen, whether by skin absorption or by ingestion.
>
> We have also learned from personal interrogation that at least some of the people contracting non-pulmonary cancer had prior conditions of arsenical keratoses subsequent to skin irritation or contaminated wounds. We have determined that among the dry products only the Paris green acted as a skin irritant under normal conditions of personal cleanliness and hygiene. The arsenates of lead and calcium were essentially non-irritating. We are somewhat reassured by the fact that both skin irritation and keratoses are historical in nature, and that no new keratoses have been logged for at least twenty years. This corresponds roughly in point of time with our revisions to the arsenic acid/sodium arsenite processes and to our termination in 1947 of Paris green manufacture and packaging.

The Allied response continued,

> We consider it significant that arsenites were involved in the two American studies and the English "sheep dip" study, whereas arsenates were apparently not involved in the British experience. According to Hunter ("Diseases of Occupations: 4th Edition, pp. 337-342) both Paris green and sheep dip have produced skin cancers by contact, some of which progressed to other sites.
>
> We have also been able to retrieve two rather ancient clinical studies: Archives of Dermatology and Syphilology 32: 218-33 (1935), Montgomery: Arsenic as an Etiologic Agent in Certain Types of Epithelioma, and American Journal of Cancer 22: 287-207 (1934) Franseen and Taylor: Arsenical Keratoses and Carcinomas. These papers, which relate mainly to medicinal use of sodium or potassium arsenites, both comment on the fact that a significant fraction of those patients with skin cancer at the site of arsenical keratoses later developed lymphatic and other "metastases" after apparently successful removal of the original lesions.
>
> These reports, considered jointly, all seem to corroborate the inferences we have drawn from the limited number of cases among our own people on which we have been able to secure reasonably complete case histories: i.e. that there is no objective evidence that arsenates have produced human cancer when arsenites were not also present, and that irritation, generally followed by keratoses resulting from skin contact, is an important factor in non-pulmonary arsenical cancers. (Ex. 55)

Dow Chemical Co. responded that they could not identify any agent responsible. (Ex. 102)

Thus, based on the above limited data and data from the clinical literature, it appears that copper-acetoarsenite, sodium arsenite, and potassium arsenite may be the causal agents in the observed lymphatic cancer cases. By regulating inorganic arsenic for purposes of reducing respiratory cancer mortality, exposures will be maintained sufficiently low so that the potential risk of lymphatic cancer will also be minimized.

D. DOSE-RESPONSE

Two of the epidemiologic studies (Pinto and Enterline, and Lee and Fraumeni), provide evidence of a dose-response relationship for the carcinogenic effects of arsenic, i.e., higher exposures for longer periods is associated with higher incidence of disease.

As discussed earlier, Pinto and Enterline conducted a mortality study of retirees receiving pensions from the ASARCO Tacoma smelter. Pinto and Enterline considered the lifetime arsenic exposure of each member of the Tacoma smelter study population from two aspects, total exposure duration and average exposure. The exposure values were constructed from departmental averages of a large number of urine samples taken in 1973. These levels were used to calculate an arsenic exposure index (μg/1-years) for each pensioner studied. The pensioners were divided into 4 groups based on their exposure indexes.

Pinto and Enterline found that respiratory cancer mortality was related to both the arsenic exposure index and the average intensity of urinary arsenic value. This is clearly demonstrated by data presented in Table 1 and 2 of their study (Attachment 4, Exhibit 111) which showed that SMR's for respiratory cancer increased consistently with increasing arsenic exposure index.

TABLE 1 (EXCERPTED)

Urinary arsenic exposure index (yrs-μg/1 urine)	Observed deaths	SMR
Under 3000	5	165.6
3000-5999	11	279.4**
6000-8999	7	306.9**
9000-11999	4	568.5**
12000+	5	810.5**

**Significant at the 5% level.

Respiratory cancer mortality also increased consistently with increasing average intensity of exposure and duration of exposure.

TABLE 2 (EXCERPTED)

1. EXPOSED FOR LESS THAN 25 YEARS

Average Intensity (μg/1 Urine)	Number of Retirees	Observed Deaths	SMR
50-199	99	2	95.6
200-349	77	4	257.2
350 and over	25	3	595.3**

2. EXPOSED FOR 25 YEARS OR MORE

Average Intensity (μg/1 Urine)	Number of Retirees	Observed Deaths	SMR
50-199	191	10	237.7**
200-349	106	8	368.7**
350 and Over	28	5	859.5**

** Significant at the 5 pct level

There is a weak to moderate correlation between urinary arsenic levels and airborne arsenic levels. This is discussed in exhibit 111 attachment 4, which indicates that a urinary level of 100 μg/1 is roughly equivalent to 31 μg/m[1] in air. As shown above, no excess lung cancer mortality was observed in those workers employed at the smelter less than 25 years having average urinary arsenic levels less than 200 μg/1 (mean of 123 μg/1). However, excess lung cancer mortality was observed in all groups of pensioners who had worked at the smelter for 25 years or more.

From the results of this study Pinto and Enterline concluded, "results thus far indicate that there is a relationship between exposure to arsenic trioxide, or associated agents in the atmosphere, and increased risk of respiratory cancer."

On December 5, 1975, Dr. Enterline submitted a further analysis of the evidence of the existence of a threshold for arsenic exposure.

"As you know, the tables we prepared on retired smelter workers show no excess for men working less than 25 years and with mean urinary arsenic values less than 200. The SMR of 95.6 for this group, while based on only 2 observed deaths, is supported by SMR's in adjacent intensity exposure levels. The relationships appear to be linear with 97 percent of the variation in SMR's explained by the combination of intensity and duration. Thus, the findings for men exposed less than 25 years (mean 20.1) and at levels between 50-199 μg/1 (mean 123) seem to be real enough (if linear relationships exists). This is not to say, however, that our data are ideal. Any interpretations must be conditioned by their limited nature (e.g.; older males, unknown cigarette smoking histories, etc.).

There are at least two interpretations that can be placed on our data for men working less than 25 years with urinary arsenic under 200:

(a) Exposure at the level produces cancer but we simply were unable to follow these men long enough to observe an excess or;

(b) This truly represents a threshold limit value.

In support of the first interpretation, there are data which suggest that latency in cancer is a function of dose, with low doses requiring very long latent periods (e.g.: t=(1/d)⅓ power). The low dose retirees were followed an average of 8.7 years after retirement and since they had worked an average of 20.1 years, the mean latent period observed is 28.8 years. For most carcinogens with which I am familiar, 20 years is long enough to observe effects in humans. If arsenic exposure which cause mean urinary levels of 123 over a period of 20 years also cause lung cancer, the median latent period must be very long indeed in this population of older males probably longer than they're likely to live.

In support of the second interpretation, an examination of SMR's among retirees for respiratory cancer by age shows a decline with time since termination of exposure (retirement) so that further follow-up may not show any effect:

Age	Observed	Expected	SMR
65 to 69	14	4.1	345.0
70 to 74	11	3.5	315.5
75 to 79	5	2.0	250.0
80 plus	2	1.0	200.0

This looks like the experience with cigarette smoking. That is, lung cancer risk for persons who stop smoking seems to approach normal with the passage of time. Do I think there is a TLV for airborne arsenic? It's unfortunate that we must have an answer at this moment. We have now microfilmed personnel records at the Tacoma smelter for all men who worked a year or more during the period 104-01963 and in about a year should have the answer. The only relevant data now available, however, suggests that there is a TLV for men who retired from the smelter, and if the effects of arsenic tend to disappear with time (as cigarettes) this may apply to other age groups as well." (Ex. 133)

For an analysis of the threshold question, see the analysis below.

In 1969 Lee and Fraumeni published a study of the mortality experience of 8,047 white male smelter workers who had been employed at the Anaconda, Montana smelter for at least 1 year prior to 1957. From January 1, 1938 to December 31, 1963, 1,877 deaths were recorded, 147 deaths of which were due to respiratory cancer, a rate 3.3 times the respective rate in the Montana population (p less than 0.01).

For each year of the study period, workers were assigned to one of five cohorts on the basis of duration of their employment in smelter. These cohorts were defined as follows:

Cohort 1, 15 or more years with 15th year completed before 1938
Cohort 2, 15 or more years with 15th year completed 1938–1963
Cohort 3, 10 to 14 years
Cohort 4, 5 to 9 years
Cohort 5, 1 to 4 years

The study group was further divided according to heavy, medium and light exposure to arsenic trioxide, sulfur dioxide and other chemicals based on measurements made at the smelter at the time of the study. The authors stated, "While measurements in work areas may have varied over time, it seems reasonable to assume that these 3 broadly defined categories denoting relative exposure remain fixed." This statement was supported by testimony presented by H. F. Morris, Consulting Engineer for Anaconda (Exhibit 28B). Based on measurements made by Anaconda, the mean arsenic exposure from 1943 to 1959 were as follows: Heavy (11.27 mg/m3), medium (0.58 mg/m3), and light (0.29 mg/m3). Thus, as the authors stated, these categories appear to represent relative exposures.

Lee and Fraumeni found that respiratory cancer mortality increased consistently with increasing duration and degree of exposure to arsenic trioxide. This gradient is clearly demonstrated by data presented in Table 5 of their study.

Cohort	Respiratory cancer mortality	Maximum exposure to arsenic (12 mo or more)		
		Heavy	Medium	Light
All cohorts combined	Observed	18	44	45
	Expected	2.7	9.2	18.8
	SMR	*667	*478	*239
1	Observed	8	22	14
	Expected	1	3.3	5.6
	SMR	*800	*667	*250
2	Observed	6	12	9
	Expected	.9	2.2	2.9
	SMR	*667	*545	*310
3 to 5 combined	Observed	4	10	22
	Expected	.9	3.8	10.3
	SMR	**444	**263	*214
Number of persons in arsenic category***		402	1,526	3,257

*Significant at the 1 pct level.
**Significant at the 5 pct level.
***The remaining 2,862 men in the study worked less than 12 mo in their category of maximum arsenic exposure and had an SMR of 236*.

Sulfur dioxide exposure and respiratory cancer mortality were also positively related, with observed deaths ranging from 6.0 to 2.6 times expected in the heavy, medium, and light categories. This is demonstrated in table 6 of the study.

Cohort	Respiratory cancer mortality	Maximum exposure to SO_2 (12 or more months)		
		Heavy	Medium	Light
All cohorts combined	Observed	46	23	39
	Expected	7.7	8.0	15.2
	SMR	*597	*288	*257
1	Observed	24	10	12
	Expected	3	1.7	5.1
	SMR	*706	*588	**235
2	Observed	13	6	8
	Expected	1.7	2.4	2.2
	SMR	*765	250	*364
3 to 5 combined	Observed	9	7	19
	Expected	2.6	3.9	7.8
	SMR	*346	179	*244
Number of persons in SO_2 category***		1,144	1,506	2,444

*Significant at the 1 pct level.
**Significant at the 5 pct level.
***The remaining 2,953 men in the study worked less than 12 mo in their category of maximum SO_2 exposure and had an SMR of 283*.

The authors stated, "exposures to both arsenic trioxide and sulfur dioxide were found to be associated with an excess of respiratory cancer deaths in this study. It is difficult to separate the effects associated with these two exposure variables, since most work areas having "heavy" arsenic exposure were also "medium SO_2" and conversely, all jobs with "heavy SO_2" exposure were "medium arsenic". However, further investigation revealed that persons with heaviest exposure to arsenic and moderate or heaviest exposure to SO_2 were most likely to die of respiratory cancer" (Ex. 5D, p. 1047).

As described in detail in section IV-B of this preamble, Ott, Holder and Gordon showed that workers exposed to primarily pentavalent inorganic arsenic were at a 3.5-fold excess risk of dying of respiratory cancer and 3.8-fold excess risk of dying of lymphatic cancer. (Ex. 1A 3-1)

The authors divided the arsenical workers into 4 groups based on estimated arsenic exposures. This data is presented in Table 1 (page 251 of the study) which is reproduced below.

TABLE 1.—*Estimated arsenic levels by job category*

Job category	8-hr TWA[1]
Group 1	5.0
Group 2	3.0
Group 3 (jobs associated with arsenical production out of the area of high dust exposure)	1.0
Group 4 (jobs involving either the formulation of nonarsenicals within the production unit or requiring only intermittent time in the areas of high exposure)	0.1

[1]Mg As/m³.

The authors described the derivation of these categories as follows:

"Over the course of 37 years, numerous modifications in job classification terminology were encountered. Fifty different job titles were identified, including those later found to refer to the same job. Next, job descriptions and exposure measurements were used to combine the jobs into four exposure classifications. Time-weighted average concentrations were assigned to the various groupings with emphasis on maintaining properly spaced ratios between the exposure groups. The estimates shown in Table 1 were obtained through the consensus of two industrial hygienists familiar with the processes, the available industrial hygiene data, and job descriptions.

The concentrations of arsenic experienced by employee while in group 1 jobs were quite variable, and included the likelihood of brief exposures to very high levels. Respirators were available, but were not worn consistently. Individuals on group 2 jobs were exposed to dust levels generally at lower, less variable concentrations, but over longer periods of time. Some employees, for example, spent up to 6 hours a day performing tasks near the packaging machines. Few measurements were available for group 3 or group 4 jobs because the exposure was apparently thought to be of relatively less concern. Thus, the greatest subjectivity was used in estimating time-weighted average concentrations for these groups. Since no adjustments were made for the wearing of respirators, or for the fact that production occurred on a somewhat intermittent basis, it is likely that actual exposure dosages were overstated rather than understated by the above estimates. However, the imprecision in the time-weighted average estimates would not be expected to lead to appreciable distortions in the relative dosage exposure rankings, since duration of exposure, which was determined quite precisely, varied considerably from individual-to-individual."

In a letter submitted to Mr. David Miller, an attorney for ASARCO (submitted as Exhibit 29(0)), Dr. Gordon presented a further breakdown of respiratory cancer mortality by exposure intensity group. This data is reproduced below.

SUMMARY OF 173 DEATHS BY EXPOSURE INTENSITY GROUPS

Highest exposure intensity	Total decedents	Respiratory malignancy deaths
Total	173	28
Group 1	30	8
Group 2	92	14
Group 3**	44	6
Group 4	7	0

**Groups 3 and 4 include individuals exposed only at those levels.

Groups 1 and 2 include individuals who experienced limited exposure intensities, as a result of having changed jobs during their employment in the arsenicals production unit.

In a subsequent letter to Dr. Gordon, OSHA asked whether he considered the findings of 0 respiratory malignancy deaths among the 7 decedents in Group 4 to be evidence of a threshold effect. Dr. Gordon responded, "The small number of individuals in Group 4 does not permit the establishment of a threshold; however, it encourages one to think that a threshold may exist." (Exhibit 102.)

Using a six-term equation, Ott et al., calculated the number of respiratory cancer deaths and ratio of observed to expected respiratory cancer deaths in various arsenic exposure categories (see table 4 of the study). The authors described this derivation as follows:

The expected proportion of deaths due to respiratory malignancy in relation to year of death and age of death was estimated based on a weighted least squares analysis of the control population. The 1,809 deaths among the controls were categorized by 10-year age groups and intervals of 5 calendar years within each age group. A six-term equation, utilizing age and year of death, explained 57 percent of the variability between the categories and provide a reasonable fit to the data in the region of interest.

The limitations inherent in data contained in table 4 must be analyzed. As stated previously, 16 respiratory cancer deaths were observed among the 138 decedents who had worked in arsenic exposure areas for 1 year or less. Consequently, it is not appropriate to extrapolate short-term dosages in terms of long-term "equivalent" career dosages.

Furthermore, as ADL noted (Ex. 26B) although work histories seemed well documented, the quantitative exposure could not be accurately specified. The authors based the four daily exposure categories on limited exposure data and a consensus judgment among individuals familiar with the operation. ADL stated, "They fail to acknowledge here that their most dramatic conclusion relates excessive incidence of death by respiratory cancer to a distribution of career dosages, where both the death excess and the career dosage depend on the value assumed by the four daily exposure levels" (Ex. 26B, p. 33). ADL also noted that the six-term regression equation which yielded the weights for the least squares fit of dose-response was not sufficiently documented to permit evaluation.

OSHA agrees with the ADL analysis. We have no way of evaluating individual worker exposure for potential error. Application of the six-term equation to this data, thus can provide no acceptable data for an estimate of dose-response. In contrast to the Lee and Fraumeni and Pinto and Enterline studies, we have insufficient exposure data to provide verification of exposure categories. Accordingly, OSHA cannot rely on the dose-response data or analyses thereof as a basis for the final standard. As noted in section IV-B of this preamble, OSHA does rely however on the study findings of excess mortality risk among arsenic-exposed workers.

As discussed in respiratory cancer section of this preamble, both the Lee and Fraumeni and Pinto and Enterline studies meet many requirements of an ideal epidemiological study and great weight can be placed on their findings. Their further finding of a consistent dose-response relationship provides strong and convincing evidence of the carcinogenicity (or co-carcinogenicity) of some inorganic arsenicals. As also discussed above, the exposure classifications and analyses thereof in the Ott study and therefore the Blejer-Wagner analysis of the Ott study (Ex. 99, p. 55-6) have major methodological limitations and therefore it is not appropriate to draw firm conclusions as to the exact nature of the dose-response curve. However, the Ott study provides firm evidence of excess lung cancer mortality of workers exposed to arsenicals.

Based upon the above data, several participants at the hearing believed that there was a threshold level, below which no increased cancer risk would be observed. Representative of this discussion, was the following discussion by ASARCO (Ex. 118, p. 42-3):

In the Dow study it was estimated that employees in Group 4 had a time-weighted average exposure to inorganic arsenic of 100 µg/m³. As we have previously noted, none of the employees who remained in Group 4 for their employment period in the study died of lung cancer. While there are only seven persons in this group and their experience does not conclusively establish a threshold, it encourages one to think that a threshold may exist.

Similarly, the Pinto and Enterline data suggest the existence of a safe level. The group whose exposure index was under 3,000 in table 1 of Dr. Enterline's letter (Ex. 111, Attach. 4) had a SMR of 165.6 for respiratory cancer, a value not different statistically from 100 * * *.

The group in table 2 whose average intensity of exposure was under 200 μg/l and who worked less than 25 years had an SMR for respiratory cancer of 95.6. The data concerning the experience of retirees from 1961-1973, who probably had lower exposures than the 1949-1973 group, contain SMR's even closer to the norm (Ex. 29B). The SMR for respiratory cancer for the group whose exposure index was under 3,000 was 130.6, and for those with an average intensity of exposure under 175 with 25 years or less experience the SMR was 117.4—neither figure being significantly different from 100 by standard statistical tests.

ASARCO concluded, citing the Dow and Pinto and Enterline studies as the best available evidence. "Those materials would support a finding that there is a no-effect level, or at least a level of respiratory cancer risk reduced to the insignificant, at inorganic arsenic concentrations of about 100 $\mu g/m^3$ in air or 250 μg/l in urine" (Ex. 118, p. 45).

A number of witneses, however, gave their expert opinions that there is not yet enough knowledge about the mechanisms of carcinogenicity to determine a threshold level.

Dr. Kraybill stated:

There is a general policy or concept among epidemiologists that there is no safe level. Why do we say that? Because we have no scientific method as of yet—1975—to prove otherwise (ATR p. 186).

This was Dr. Radford's view also (ATR 562).

Dr. Wagoner concluded:

I think the overwhelming body of scientific judgment in the United States and internationally is of the opinion—and it has been very aptly put by the Surgeon General's ad hoc Committee on low level environmental carcinogens—that the present state of technology does not permit the determination of safe levels for a carcinogen (ATR 334-335).

OSHA believes it is not appropriate to set an exposure limit based on the belief that a threshold may exist because of these considerations. As noted above, OSHA does not regard the exposure categories of the Dow study to be sufficiently supported to make further judgments on dose-related effects. Furthermore, the last category (Group 4), composed of seven deaths, is far too small for conclusions as to a threshold to be made.

The Pinto-Enterline data is more satisfactory (Ex. 29B). However, workers exposed more than 25 years in all exposure categories including those with average intensity less than 200 μg/l had statistically significant excess respiratory cancer mortality. In this study, as well, the limited number of workers in the exposure category in which no excess was observed is far too small to statistically test whether a threshold exists for the entire population at risk (arsenic-exposed workers). Therefore, no level has been satisfactorally demonstrated that will eliminate increased lung cancer mortality among all arsenic-exposed workers.

Further, this limited amount of epidemiologic evidence is not sufficient to overcome the substantial body of scientific opinion that there is not sufficient knowledge to determine a threshold for a carcinogen.

In view of OSHA's obligation to protect workers and the substantial body of scientific opinion that no safe level of exposure to a carcinogen can be shown, OSHA must exercise its discretion in favor of assuring worker protection. OSHA and other Federal agencies responsible for protecting individuals from the hazards posed by carcinogenic substances have consistently followed the view that no safe level of exposure can be established based on current scientific knowledge.

E. ANIMAL STUDIES

In its 1973 criteria document, NIOSH evaluated 18 animal studies involving inorganic arsenic exposures. However, only two of these were studies of the effects of exposure to airborne concentrations, and neither of these were designed to observe lung cancer.

The first was an inhalation study, by Rozenshtein (14), of albino rats exposed to arsenic trioxide for 24 hours per day, for 3 months. The study was designed to observe the effects of atmospheric pollution. The second study, by Bencko and Symon (2), involved an evaluation of hairless mice exposed to fly ash containing 0.1 percent arsenic trioxide. The authors observed an accumulation of arsenic in the animals' livers and kidneys from exposure to the fly ash.

Dr. Kraybill of the National Cancer Institute presented testimony at both the fact-finding and April 1975 hearings in which he discussed the failure of experimental animal studies to confirm the epidemiological findings concerning arsenic exposure. Some of the reasons for this failure could be, according to Dr. Kraybill, that "(a) the proper animal model has not been tried, (b) the proper route of administration has not been tried, i.e., inhalation, (c) sufficient numbers of animals have not been in the study for statistical validation of results, and (d) the role of arsenic as an interactant or synergist and establishment of it as a possible co-carcinogen has not been determined" (Ex. 16A). Dr. Kraybill stated during the fact-finding hearing, "Arsenic stands out as the one substance for which human carcinogenicity has been demonstrated, but for which an animal model has yet to be found to reproduce this effect" (FTR p. 40).

Though there are no positive animal studies which confirm the epidemiological findings of excess respiratory cancer mortality among workers exposed to inorganic arsenic, OSHA believes that the epidemiological studies clearly establish the carcinogenicity of inorganic arsenic. Once epidemiological findings are found to be convincingly related to exposure to particular substance(s), OSHA must regulate in such a manner to minimize such risk to workers.

F. VALENCE CONSIDERATIONS

The acute toxic effects of inorganic arsenic compounds on man following ingestion are well known. It is also known, that the severity of toxic reaction varies significantly with inorganic arsenic's valence states. According to the published literature (Ex. 31C-41) and testimony by Drs. Wacker and Peoples (Ex. 31A and 31D), trivalent arsenic (arsenite) is more toxic when ingested than pentavalent arsenic (arsenate).

Schroeder and Balassa (Ex. 31C-41) and Wacker (Ex. 31A) and Peoples (Ex. 31D) stated that trivalent arsenic's greater toxicity is due to its rapid binding with sulfhydryl groups. This binding results in the inhibition of many important enzymes such as alcohol dehydrogenase, enzymes which synthesize the components of DNA and RNA, and enzymes which synthesize DNA and RNA. In contrast, pentavalent arsenic (arsenate) does not react with sulfhydryl groups, but is known to inhibit the synthesis of ATP, an important metabolite, by uncoupling oxidative phosphorylation.

Based on his evaluation, Dr. Wacker concluded, "I find the conclusions reached by OSHA in its proposal (to treat both pentavalent and trivalent inorganic arsenic as carcinogens) to be highly implausable on scientific grounds, considering the chemical and toxicological characteristic of the various arsenical compounds in question. Indeed, I am baffled by the absence of any extensive consideration of the chemical and toxicological differences between these compounds as the differences are so great. I am convinced * * * they should be considered separately." (ATR 845.)

Dr. Radford commented (Exhibit 192B) that, "the acute toxicity of pentavalent arsenic compounds given parenterally is much less than for trivalent compounds. This well-accepted difference implies that if pentavalent compound are reduced to trivalent compounds in the body, either the conversion is slow, or they are converted to inactive forms or the distribution of the trivalent compounds is to relatively insensitive issues (i.e. conversion in the kidneys and rapid excretion in the urine). Another interpretation possible is that no significant conversion to trivalent arsenic occurs, and pentavalent forms have toxic actions different from trivalent."

Dr. Radford later stated, "We do not know the mechanism of action of arsenites as carcinogens, but it is at least conceivable that they act by conversion to the pentavalent form and displacing phosphate in nucleic acids as Rosen has suggested." (Ex. 192B, p. 3.)

Dr. Kraybill of NCI concluded, "Doctors Wacker, Peoples and perhaps others have made interesting comments on the relative toxicity of the trivalent and pentavalent arsenic. The proposition concerning the relative avidity of trivalent and pentavalent ion SH groups (sulfhydryl groups) or glutathione as the protective mechanism is a most attractive and interesting concept. While this appears attractive to us on theoretical grounds, we would like to see some basic data (biochemical, pharmokinetic) in this area which would be helpful in describing the relative carcinogenic potential of trivalent and pentavalent arsenic on a mechnistic basis. Having such information and data could provide some evidence to better assess the significance of epidemiological studies. Perhaps this is the strongest reason for doing some good studies with appropriate animal models and using relevant routes of administration." (Ex. 192C.)

The most thorough analysis of the issue whether pentavalent arsenic is converted in the body to trivalent arsenic was presented by Dr. Peoples (Exhibit 193, Attachment B). Dr. Peoples reviewed findings by Winkler that after feeding rats trivalent arsenic, arsenic in their liver was largely pentavalent. When fed pentavalent arsenic, no trivalent arsenic was found in rat livers. He reported that the findings of Ginsburg (Ex. 63, Ex. 64) in which he reported some reduction of pentavalent arsenic to trivalent arsenic in the kidney of dogs after feeding with arsenate, could not be relied on because the analytical method was not accurate in the range of the reported sample size. Finally, he reviewed the findings of Crecelius (Exhibit 193, Attach. B) that no trivalent arsenic was found in the urine of a human who had drunk water containing 200 μg of pentavalent arsenic. He stated, "The level of As(III) remained at the control level. There was an increase in As(V) peaking at 5 hours then returning to normal in 10 hours. The mono methylarsonate remained near the control but the dimethylarsonate (cacodylic acid) rose to a high level and remained so during the 80-hour observation period. In other words, As(V) is not reduced in the body to As(III). It is almost entirely metabolized to cacodylic acid."

Thus OSHA concludes, that the presently available evidence indicates that there is little or no conversion of pentavalent to trivalent arsenic in the body. Given the unknown relevance of acute toxicity and biochemical reactions of trivalent and pentavalent arsenic to the assessment of carcinogenic risk and the findings that pentavalent arsenic is not converted to trivalent arsenic, OSHA concludes that it must, principally rely on the findings of the epidemiological studies, expert opinion, and general policy considerations in determining whether to regulate pentavalent arsenic as a carcinogen.

G. CONCLUSIONS

(1) *Trivalent Arsenic.* Based on the entire set of studies, OSHA believes that exposure to trivalent arsenic has been shown to cause respiratory cancer. Studies in the copper smelting industry (Lee and Fraumeni, Pinto and Enterline, Rencher, and Carter) have shown statistically significant increased lung cancer mortality among workers exposed to arsenic trioxide, sulfur dioxide and other cocontaminants released during the smelting of copper ores. As Lee and Fraumeni stated, it is impossible to differentiate in these cases between the effects of exposure to arsenic and these other cocontaminants. However, the finding that lung cancer mortality increased consistently with degree and duration of exposure to arsenic trioxide provides substantial evidence that exposure to trivalent arsenic is a cause of respiratory cancer (as was discussed in detail in the dose-response section). This data, particularly that of Lee and Fraumeni and Pinto and Enterline has been discussed in detail in section IV-D of this preamble and accordingly will not be repeated here.

The findings of studies by Baetjer et al. and Hill and Faning serve as positive controls for the findings in the smelting industry. That is, these workers studied by Baetjer et al. were exposed principally to trivalent and some pentavalent arsenicals, and Hill and Faning sodium arsenite (a trivalent arsenical); and to a limited number of other chemicals (Ex. 5B). They were not exposed, however, to most of the other cocontaminants found in the smelter environment.

There have been many analyses by experts during the hearing. Both Dr. Fraumeni (ATR 168) and Dr. Kraybill (ATR 161) stated that inorganic arsenic is strongly incriminated as an occupational carcinogen. NIOSH recognized that each epidemiological study alone has its limitations, but stated: "However, when all reports of occupational exposure to inorganic arsenic are considered together, NIOSH believes it undeniable that there have been carcinogenic effects which must be attributed to inorganic arsenic." (ATR 54-5).

During April 1975, Dr. Enterline was asked whether, based on the whole constellation of studies, inorganic arsenic is a carcinogen. Dr. Enterline responded:

> Yes, I think that it's certainly related to respiratory cancer based on reading these studies. Obviously, I can't tell whether it's something that goes with it or it's arsenic itself. But, the studies—and particularly the more recent studies, the Allied and Dow studies, the Allied in particular—are very impressive studies. They present in my mind pretty overwhelming evidence. (ATR 775.)

Dr. Weir of the Johns Hooper Foundation on the basis of his evaluation stated that there is an association of moderate overall magnitude between arsenic exposure and respiratory cancer (ATR 1381). He based his conclusion on a detailed analysis of the epidemiologic studies and on his evaluation of seven general factors for evaluating whether exposure to chemical agents such as arsenic and observed health outcomes (i.e., lung cancer mortality) is a causal relationship (Ex. 29N). These seven factors are as follows:

(1) Strength of association.
(2) Time sequence.
(3) Consistency with findings in other research areas.
(4) Failure to find alternative explanations.
(5) Gradient of risk.
(6) Consistency of association over several studies.
(7) Specificity.

In summary, Dr. Weir noted that the strength of association between exposure to arsenic and lung cancer mortality was moderate (2 to 3 times expected lung cancer mortality). He noted that lack of an animal model somewhat lessened the confidence which one could place on the degree of association. He further noted that the association is strengthened by the occurrence of a gradient of risk (dose-response), repeated findings over several studies and settings, and failure to find other explanations which could account for the excess risk. He concluded:

> The surest route to reducing unnecessary mortality is to apply standards on the belief that arsenic is a probable cause of mortality increase, and is, therefore, the best available factor by which we can expect to successfully intervene in the causal network, and then to proceed expeditiously to make whatever commitment of human and financial resources is necessary to establish with reasonable scientific certainty the definitive factor in the observed association. (ATR 1385-6.)

Arguments have been made that the relationship between arsenic and respiratory cancer cannot be presently stated to be causal (ATR 1381-6, Ex. 26B, p. 5) due to the fact that workers were exposed to other workplace contaminants. OSHA agrees, at least in the case of the copper smelting industry, that one cannot conclude with complete certainty, that the association is causal. The degree of association is strengthened by the findings in pesticide plants (Baetjer et al., Ott et al., Hill, and Faning). OSHA recognizes that, these workers too were exposed to other chemicals. However their work environment was substantially different from that of smelter workers and they were not exposed to most of the other chemicals to which workers are exposed in the smelting industry (compounds of lead, antimony, cadmium, sulfur, etc.). The fact that workers exposed to arsenic in substantially different environments were subject to excess respiratory cancer mortality is strong evidence that arsenic was an important etiologic factor in the observed excess mortality. OSHA cannot rule out the possibility that these other chemicals may have influenced excess respiratory cancer and lymphatic cancer mortality. However, even if it should later be shown that arsenic is not the sole factor, the regulation and resultant minimization of worker exposure to inorganic arsenic will, we believe, intervene in the causal network and reduce, to the extent feasible, worker risk of lung cancer. Thus in agreement with experts from NCI, NIOSH and industry, OSHA has concluded that trivalent arsenic must be regulated as an occupational carcinogen.

Confirming animal studies would be helpful, but OSHA believes that the best available evidence is the observed effects on man, himself as a compelling indication of risk and the lack of an animal model does not detract from this conclusion.

(2) *Pentavalent arsenic.* One of the most controversial and difficult issues during the arsenic hearings is whether pentavalent arsenic should be regulated as a carcinogen. The National Cancer Institute and NIOSH have recommended that pentavalent arsenic should be treated as a carcinogen; while the American Wood Preservers Institute has argued that the evidence is not strong enough for such a determination to be made. Three types of evidence have been submitted in the record: epidemiologic evidence, chemical evidence, and opinions of experts in the field.

A brief review of the epidemiological studies may be helpful. The Ott study showed a substantial excess cancer mortality among workers exposed principally to pentavalent arsenicals. The study includes a reasonable analysis of exposed and nonexposed workers. The AWPI suggested that pentavalent arsenic should not be implicated as a causal factor because there was some degree of exposure to trivalent arsenic and suggests that further research be done. On the other hand, NIOSH stated:

> With relation to the paper by Ott et al., it seems to be a reasonably valid study of the results from exposure to arsenates. Although it is true that the employees involved were exposed to both arsenites and arsenates, the authors state that 95 percent of the exposure was to arsenates and only 5 percent to arsenites. It seems not to be illogical or unjustified to attribute most, if not all, the excess of malignancies in the exposed group (incidence rate almost 60 percent greater than that in the control group) to the pentavalent arsenical compounds (Ex. 192A).

OSHA agrees with NIOSH that in view of the relative degree of exposure to pentavalent arsenic in comparison to trivalent arsenic, it is reasonable to accept the Ott study as evidence that pentavalent arsenic should be regulated as a carcinogen.

The Baetjer study also shows excess cancer mortality, but it is clear that many of these workers were exposed primarily to trivalent arsenicals. Because the predominant exposure was to trivalent arsenic, it would be inappropriate to implicate pentavalent arsenic on the basis of this study. In this instance, all one can state is that exposure to inorganic arsenic is the most reasonable explanation for the observed excess cancer mortality.

The AWPI places principal reliance on 2 studies, Nelson and Budy-Rashad, where excess respiratory cancer mortality was not observed. But the former study suffers from the deficiency that actual degree and duration of exposure to lead arsenate was not identified. In the Budy-Rashad study, the carpenters were not exposed to pentavalent arsenic, but rather to a stable arsenic-wood complex. Thus, carpenter exposure to this arsenic-wood complex cannot be considered a priori, equivalent to exposure to unbound pentavalent arsenic. No data is available on individual carpenter exposures to verify degree and duration of exposure. Additionally, insufficient time has elapsed to allow for sufficient latency period, for arsenic induced respiratory cancer. For the above reasons, it is difficult to make conclusions based upon these two studies.

Although the epidemiologic evidence does not as clearly indicate the carcinogenicity or cocarcinogenicity as in the case of trivalent arsenic, the Ott study provides epidemiologic support for the proposition that pentavalent arsenic, for the purposes of regulatory action to protect employees should be treated as a carcinogen.

The chemical questions discussed in the record principally relate to the differences in biochemical mechanisms between trivalent and pentavalent arsenic, and whether pentavalent arsenic is converted to trivalent arsenic in the body.

Peoples and Wacker discussed the well-accepted fact that while trivalent arsenic reacts with sulfhydryl groups, pentavalent arsenic can substitute for phosphate groups, thus decoupling oxidative phosphorylation. Peoples reviewed his studies and the literature and concluded that pentavalent arsenic is not converted to trivalent arsenic in the body. Studies by Ginsburg suggest that there is some conversion.

OSHA believes that the Peoples studies are more extensive and analytically reliable and therefore are more convincing. However, as the causal mechanisms of arsenic-related carcinogenesis are not known, OSHA must conclude that the fact that trivalent and pentavalent arsenic have different biochemical mechanisms, is not in itself sufficient evidence to indicate that respiratory cancer is not caused by both. The actual mechanism(s) may be substantially different from any of those suggested.

Dr. Peoples and Wacker stated that in view of the different mechanisms, pentavalent arsenic should not be treated as a carcinogen. Dr. Radford concluded:

> Because inorganic pentavalent arsenic is not yet known to produce cancer in man either directly or from conversion to trivalent arsenites, I do not believe that arsenates should be included with the inorganic trivalent forms as carcinogens. Thus a separate standard may be appropriate for pentavalent arsenic, just as is required for arsine. It may be that a reevaluation of the distinction between the two valence states of arsenic in relation to their exposure limits may be necessary as better evidence is obtained. It would seem to be imperative to obtain more experimental and epidemiologic data to resolve the questions concerning the health effects of pentavalent arsenic. (Ex. 192B.)

On the other hand, NIOSH stated that while trivalent arsenic is clearly a carcinogen, pentavalent arsenic should be so treated until convincing evidence is presented to the contrary (Ex. 192A). Similarly, Dr. Kraybill stated:

> But in essence the sorting out of trivalent from pentavalent arsenic with regards to their carcinogenic activity on the basis of the epidemiological studies is not facilitated since several studies impugned pentavalent possibly confounded with trivalent exposures. Thus, at the present time, we are left with a situation wherein we cannot help but implicate the pentavalent arsenic ion.
>
> Doctors Wacker and Peoples present some interesting toxicological evidence on the relative difference between trivalent and pentavalent arsenic. These postulates of the "tri" and "penta" states although interesting do not provide the actual verification in animal carcinogenicity studies. If we have overlooked some reports in the area, we would welcome them for our review. Until then, we have to make our assessments on the basis of available data and specific evidence. (Ex. 192C.)

The situation presented is identical to the one in *I.U.D.* v. *Hodgson:*

> "the questions involved are on the frontiers of scientific knowledge and consequently as to them insufficient data is presently available to make a fully informed factual judgment. Decision making must in that circum-

stance depend to a great extent upon policy judgments and less upon purely factual analysis * * *.

For example, in this case the evidence indicated that reliable data is not currently available with respect to the exposure to asbestos dust; nevertheless, the Secretary was obligated to establish some specific level as the maximum permissible exposure. After considering all the conflicting evidence, the Secretary explained his decision to adopt, over strong employer objection, a relatively low limit in terms of the severe health consequences which could result from over-exposure. Inasmuch as the protection of the health of employees is the overriding concern of OSHA, this choice is doubtless sound, but it rests in the final analysis on an essentially legislative policy judgment, rather than a factual determination, concerning the relative risks of underprotection as compared to overprotection.

In summary the Ott study provides epidemiologic evidence that pentavalent arsenic is a carcinogen, and a significant body of expert opinion including representatives of the National Cancer Institute and the National Institute for Occupational Safety and Health recommends that pentavalent arsenic be regulated as an occupational carcinogen. Further, in view of the long latency period and irreversible nature of lung cancer, it is OSHA's policy to act in the manner most protective of employee health. Although there are chemical differences between pentavalent and trivalent arsenic, viewing all the considerations and evidence as a whole, including the strong evidence that trivalent arsenic is a carcinogen, OSHA believes it necessary to regulate pentavalent arsenic as a carcinogen. Further research is always useful, but there has to be a stage when a decision is taken, since there always remain byways of possible research.

(1) A. Baetjer, M. Levin, A. Lillienfeld—"Analysis of Mortality Experience of Allied Chemical Plant," unpublished.

(2) V. Bencko and K. Symon—"The Cumulative, Dynamics in Some Tissue of Hairless Mice Inhaling Arsenic," Atmos. Environ., *4*, 157-61 (1970).

(3) A. M. Budy, M. N. Rashad—"Cancer Mortality Among Carpenters in Hawaii," presented at the Third International Symposium on Detection and Prevention of Cancer, New York, April 29, 1976.

(4) R. Denk, H. Holzmann, H. Lange, D. Greve [Concerning the Long-Term Effects of Arsenic as Seen From Autopsies on Moselle Vineyard Workers], Mediz. Welt, 11:557-67 (1967).

(5) A. B. Hill, E. L. Faning—"Studies in the Incidence of Cancer in a Factory Handling Inorganic Compounds of Arsenic—I. Mortality Experience in the Factory," Br. J. Ind. Med., *5*, 1-6 (1948).

(6) M. Kuratsune, S. Tukodome, T. Shirakusa, M. Yoshida, Y. Tokumitsu, T. Harano, M. Seita—"Occupational Lung Cancer Among Copper Smelters," Int. J. Cancer, *13*, 552-8 (1974).

(7) A. M. Lee and J. F. Fraumeni, Jr.—"Arsenic and Respiratory Cancer in Man—An Occupational Study," J. National Cancer Institute, *42*, 1045-52 (1969).

(8) T. H. Milby, C. H. Hine, "A Survey of Mortality Due to Respiratory Diseases Among Employees of the Kennecott Corporation" (October 4, 1974), unpublished.

(9) S. Milham, Jr., T. Strong—"Human Arsenic Exposure in Relation to a Copper Smelter," Environ. Res. 7, 176-82 (1974).

(10) W. C. Nelson, M. H. Lykins, J. Mackey, W. A. Newill, J. F. Finklea, D. I. Hammer—"Mortality Among Orchard Workers Exposed to Lead Arsenate Spray: A Cohort Study," J. Chron. Dis., *26*, 105-18 (1973).

(11) M. Ott, B. Holder, H. Gordon—"Respiratory Cancer and Occupational Exposure to Arsenicals," Archives of Environmental Health, *29*, 250-5, (1974).

(12) K. Perry, R. G. Bowler, H. M. Buckell, H. A. Druett, R. S. F. Schilling—"Studies in the Incidence of Cancer in Factory Handling Inorganic Compounds of Arsenic," Ind. Med., *5*, 6-15 (1948).

(13) S. S. Pinto, B. M. Bennett—"Effect of Arsenic Trioxide Exposure on Mortality," Arch. Environmental Health, *7*, 583-91 (1963).

(14) S. S. Pinto, P. E. Enterline—"Mortality Study of ASARCO Tacoma Smelter Workers," unpublished.

(15) S. S. Pinto, C. M. McGill—"Effect of Arsenic Trioxide Exposure in Industry," Ind. Med. Surg., *22*, 281-7 (1953).

(16) A. C. Rencher, M. W. Carter—"A Retrospective Epidemiological Study at Kennecott's Utah Smelter" (April 1971), unpublished.

(17) F. Roth [Concerning the Long-Term Effects of Chronic Arsenical Poisoning of Moselle Vineyard Workers], Dtsch. Med. Wschr., *6*, 211-16 (1957).

(18) F. Roth [Bronchial Cancer in Vintners Suffering from Arsenic Poisoning], Virch. Arch, *331*, 119-37 (1958).

(19) I. S. Rozenshtein—"Sanitary Toxicological Assessment of Low Concentrations of Arsenic Trioxide in the Atmosphere," Hgy. Sanit., *35*, 16-21 (1970).

(20) L. S. Snegireff and O. M. Lombard—"Arsenic and Cancer Observations in the Metallurgic Industry," Arc. Ind. Hyg. Occup. Med., *4*, 199-205 (1951).

(21) S. Tukodome, M. Kuratsune—"A Cohort Study on Mortality from Cancer and Other Causes Among Workers at a Metal Refinery," Int. J. Cancer, *17*, 310-17 (1976).

V. Permissible Exposure Limit

The final standard establishes a permissible exposure limit (PEL) of 10 $\mu g/m^3$ averaged over an eight hour period. This represents the lowest level which OSHA believes is feasible. In determining the appropriate PEL, OSHA relies in part on the record of the proceeding and in part on policy considerations which lead the Agency to conclude that in dealing with a carcinogen or other toxic substances for which no safe level of exposure has been demonstrated, the permissible exposure limit must be set at the lowest level feasible. Such a determination OSHA believes is justified by the nature of the hazard being dealt with, and the intent of the Act.

As already discussed, insufficient evidence has been introduced into this proceeding to demonstrate the existence of a safe level of exposure to inorganic arsenic. In the absence of a demonstrated safe level, OSHA will not assume that one exists because of the irreversibility and long latency period for lung cancer. An erroneous determination that a threshold exists would cause an irreversible illness leading to death. This would be inconsistent with OSHA's statutory responsibility to set a level that will assure that no employee will suffer material impairment of health.

The statutory requirement also mandates that OSHA set a feasible level. A zero level, although ideal, is not feasible given arsenic's utilization in large scale, high temperature processes which cannot be completely enclosed. The record indicates that 10 $\mu g/m^3$ is the lowest level which generally can be achieved in most copper smelters and many of the other processes in which inorganic arsenic is used primarily by joint use of engineering and work practice controls.

OSHA has determined that the 10 $\mu g/m^3$ exposure limit is the level which properly balances the above factors and most adequately assures to the extent feasible, the protection of workers exposed to inorganic arsenic. This level will provide a dramatic reduction in the lung cancer mortality of workers exposed to inorganic arsenic. It is also a level which is generally achievable through engineering and work practice controls, the preferable control strategy. This level is achievable almost entirely through engineering and work practice controls at 11 of the 16 U.S. copper smelters, and for the large majority of employees in other industries and facilities. Moderate or limited use of respirators will be needed in 4 copper smelters, and in a relatively few locations in other industries. One smelter will require extensive respirator use and is discussed at length below.

The scientific and policy determinations underlying the regulation of inorganic arsenic as a carcinogen were mentioned in the preamble to the proposal and were discussed in the course of this rulemaking. These determinations are consistent with other OSHA regulatory actions for carcinogens made after considerable scientific debate. For example, see the preambles to OSHA's carcinogen standard, applicable to 14 selected substances, 29 CFR 1910.1003-1910.1016 (39 FR 3758) aff'd. *Synthetic Organic Chemical Manufacturers Assn.* v. *Brennan*, 503 F. 2d 1155 (3rd Cir. 1974); the vinyl chloride standard, 29 CFR 1910.1017 (39 FR 35892), aff'd, *The Society of the Plastics Industry* v. *OSHA* 509 F. 2d 1301 (2nd Cir.) cert. den. 421 U.S. 992 (1975); the coke ovens emissions proposal (40 FR 32268 (1975)) and final, 29 CFR 1910.1029 (41 FR 46742 (1976)), aff'd. *American Iron and Steel Institute, et al.* vs. *OSHA*, No. 76-2358 (3rd Cir., 3-28-78); and the DBCP emergency temporary standard, 29 CFR 1910.1044 (42 FR 45536 (1977)).

OSHA has followed a similar course on regulation of carcinogens, including a detailed discussion of the scientific evidence supporting such regulation, in the proposed rules on identification, classification, and regulation of toxic substances posing a potential occupational carcinogenic risk ("Cancer Policy") which was published in the FEDERAL REGISTER on October 4, 1977 (42 FR 54148). In the proposed Cancer Policy, OSHA restates the determination that as a prudent policy matter, in the absence of a demonstrated safe level or threshold for exposure to a carcinogen " * * * (o)nce a qualitative presumption of carcinogenicity has been estabished for a substance, any exposure to the substance must be considered to be attended by risk when considering any given population. No exception to this point has yet been demonstrated." (42 FR at 54166).

The record of the arsenic proceeding independently clearly supports this general policy. Dr. Wagoner concluded:

> I think the overwhelming body of scientific judgment in the United States and internationally is of the opinion—and it has very aptly put by the Surgeon General's ad hoc Committee on low level environmental carcinogens—that the present state of technology does not permit the determination of safe levels for a carcinogen. (ATR 334-5.)

Dr. Kraybill stated:

> There is a general policy or concept among epidemiologists that there is no safe level. Why do we say that? Because we have no scientific method as of yet—1975—to prove otherwise. (ATR 186.)

This was Dr. Radford's view also (ATR 562). And NIOSH has taken the position that in regulating cancer-causing substances it is not possible to determine a safe exposure level (Revised Arsenic Criteria Document, 1975 (Exhibit 99)).

The exposure limit is based upon what can be achieved by the affected industries taken as a whole using available technology, or technology looming on todays horizon. Alternatives to this approach have been considered in the context of the arsenic proceeding. As will be discussed, arsenic exposure in the most affected industry, copper smelting varies significantly among the 16 U.S. copper smelters due to variability in smelting conditions and variability of arsenic content in the ore.

Difficulties which may arise at individual facilities or processes in particular plants will be considered at the compliance level which is specifically oriented to consider problems at individual locations. The compliance plan process provides the mechanism to resolve these problems.

One alternative would be to establish the lowest feasible level for each of the 16 smelting plants as well as for each of the many other plants in the other affected industries. Such an approach would be extremely difficult to implement. It would strain limited agency resources including trained manpower and time. By concentrating on the arsenic issue, the Agency would have to reduce efforts in other important health areas. Accordingly, this feasibility determination is based upon analysis of the entire affected industries taken as a whole.

Another alternative would be to base the determination on a worst case basis, that is those situations where the level is most difficult to meet. This alternative is also unacceptable. It would allow most workers to be exposed to much higher exposure levels, than could generally be achieved through engineering and workpractice controls and thus subject them to a potentially increased risk of arsenic-induced lung cancer.

A third alternative is to set the level based on what could be achieved by these facilities with the least problems. In the case of the copper smelters, this would be based on the level achievable for those smelters with the lowest arsenic content in the feed and with the processes most adaptable to control. Such an approach would make it impossible to achieve such a limit for the majority of affected workers in the majority of plants without resort to full time respirator use by most employees. Because of problems inherent in their use (see Section on Respiratory Protection), this alternative is not ideal, though in certain circumstances it may be necessary to give needed health protection.

The approach OSHA believes appropriate and has chosen for this and other standards is the lowest level achievable through engineering controls and work practices in the majority of locations. This approach is intended to provide maximum protection without excessively heavy respirator use. Respirator use in the interval when engineering controls are being installed is more acceptable because their use is temporary. Further, their use is acceptable for those employees in peak exposure areas. Adequate supervision can be given if respirator use is concentrated in a few peak exposure areas and programs can be devised for a relatively few locations to minimize the full time use of respirators. (See the discussion of the Tacoma smelter below where such a strategy is outlined.)

The level achievable is based on available engineering controls and those controls which can be adapted from other uses or which are looming on the horizon and can reasonably be expected to be developed. The OSHA Act is a technology forcing act as discussed in Section II of this preamble. However, OSHA does not interpret this to mean an open ended commitment to research and develop unforeseeable new technologies, but rather the adaptation and development of controls from existing known practices and principles.

OSHA contracted for two detailed studies of technological and economic feasibility considerations:

1. D. B. Associates (D.B.), "Feasibility and Estimated Costs of Compliance for Three U.S. Smelters," (Ex. 18).
2. Arthur Young & Co. (AY), "Technological Feasibility and Inflationary Impact Statement," (Ex. 135A).

The AY study was based upon analysis of data in the D.B. report, industry studies and data from industry sources. The AY analysis was further amplified in the document entitled, "Detailed Account of Certain Compliance Costs," (Ex. 148A, 173A). Testimony indicated that certain costs were under-estimated in the D.B. study. AY corrected for those underestimates.

ASARCO, Inc. commissioned a study by Industrial Health Engineering Associates (IHEA, Ex. 29M) which presented a detailed analysis of technical feasibility and costs of engineering controls at ASARCO facilities. Additionally, ASARCO hired Arthur D. Little, Inc. (ADL Ex. 111-7) to integrate the cost data of IHEA with other cost data provided in testimony by ASARCO management and to estimate the proposed standard's impact on its Tacoma smelter and on ASARCO as a whole.

The Anaconda Co. presented a report by Phillip A. McKee & Associates (Ex. 28B). Kennecott Copper supplied a less detailed estimate of the costs of compliance and Phelps Dodge supplied an overall estimated cost figure without supplying any documentation (Exs. 12, 156A, 157). A combined cost estimate for these four major copper smelting firms was presented in Exhibit 156A.

Industries other the copper smelting, generally did not submit specific studies, but did give some testimony on feasibility issues. In addition to specific studies, a substantial amount of testimony and some written submissions addressed feasibility questions.

The copper smelting industry is the industry most affected by the standard. Analysis of feasibility in that industry is complicated not only because exposure varies significantly between processes in a given smelter but they also vary substantially among smelters. A major reason is the differing percentages of arsenic in the smelter feed ranging from 5 percent to under 0.001 percent. The following Table indicates that variation.

TABLE I.—*Percent arsenic in feed, U.S. copper smelters*

Smelter	Percentage arsenic in— Overall feed	Copper concentrates	Approximate annual tons copper concentrates, 1971-73
ASARCO:			
El Paso, Tex	0.8	0.21	290,000
Hayden, Ariz	0.04	0.005	520,912
Tacoma, Wash	5.2 (12.8 max)	4.2	273,603
Phelps Dodge:			
Ajo, Ariz	Not available	Less than 0.005	206,471
Douglas, Ariz	do	0.1 to 0.3 pct	680,609
Morenci, Ariz	do	0.001 pct	810,000
Tyrone, N. Mex	do	Not detectable	(1)
Kennecott:			
Garfield, Utah	0.135	0.15	780,542
Hayden, Ariz	0.015	0.016	298,282
Hurley, N. Mex	0.005	Less than 0.006	205,442
McGill, Nev	Not available	Not available	283,196
Inspiration: Miami, Ariz	do	do	282,200
Magma: San Manuel, Ariz	do	0.007	798,500
Anaconda: Anaconda, Mont	0.96	0.97	647,870
Copper Range: White Pine, Mich	0.002	0.003	247,100
Cities Services: Copper Hill, Tenn	Not available	Not available	(1)

[1] Not available.

Other factors also affect existing levels such as layout of plant, smelting process, and age of equipment. Some smelters use a roasting process, which results in additional sources of arsenic exposure during roasting and during transfer of the hot roasted material (calcine). Some of the recently modernized or new smelters make use of processes such as the Noranda Process or electric smelting which reduce the number of sources of exposures or make the control of such emissions less difficult. Exposures are also affected by the uniformity of the arsenic content. A uniform feed usually results in a smelting process which is easier to control and this tends to make it easier to control emissions.

There is a substantial body of evidence on the record to aid in analyzing feasibility in copper smelters. In addition to the DB, IHEA, AY, and McKee studies mentioned above, fairly extensive exposure data is available in Exhibits 6, 7, 12, 28A, 29G, 31C, and 188. Further, Burton of DBA, Caplan of IHEA, and Brazie of AY specifically addressed these points in their testimony.

The Arthur Young, Inc. analysis indicated that the 4 $\mu g/m^3$ level could be achieved with engineering controls and extensive use of respirators at Tacoma, moderate use of respirators in smelters which they grouped into categories 2 and 3, very limited use of respirators in category 4 smelters and essentially without respirators in category 5 and 6 smelters. Sometimes they gave specific estimates of the number of employees required to wear respirators. In other instances their estimate can be approximately computed by dividing $4,000 into their estimate of respirator annual costs.

Brazie of AY also pointed out that in those smelters with low levels of arsenic in the material stream, very low levels of exposure can be achieved solely be engineering and work practice controls (STR 120). The details of the AY analysis can be found in Exhibits 148A and 173A. Their smelter categories are listed on page 2 of Exhibit 148A.

Caplan, an ASARCO witness, indicated the difficulties in achieving 50 $\mu g/m^3$ for the Tacoma smelter with engineering controls alone and stated that extensive use of respirators would be needed to reach a 4 $\mu g/m^3$ level there and at the El Paso smelter. He also discussed generally the difficulty of reducing exposures to 50 $\mu g/m^3$ in uranium processing and compared this to copper smelters. At various places he seemed to imply that these difficulties could apply to copper smelting generally.

It is accepted that at Tacoma engineering controls in a number of places (though not all) will have difficulty reducing exposures below 50 $\mu g/m^3$. It is also accepted that in large scale, high-temperature, heavy-industry processes, reducing exposure levels below 50 $\mu g/m^3$ may be difficult for substances which are present in relatively high percentage in the material streams. This analysis is clearly applicable to Tacoma with 5 percent arsenic in the concentrate feed. But Caplan's analysis has only very limited applicability in smelters with approximately 1 percent arsenic in the feed and is not applicable at all to smelters with feed typically ranging from 0.1 percent to .001 percent arsenic, where the large majority of exposure levels are already lower than 50 $\mu g/m^3$ and still further reductions are clearly achievable. Caplan himself has stated (ATR, p. 1310) that lower levels are achievable when toxic substances are present as only a small fraction of the material stream. Further this report did not cover in detail those smelters with lower percentages of arsenic in the feed, nor did it take into account the existing lower levels of exposure (see Ex. 12 for example) for many employees.

Burton of D. B. Associates did not make specific judgments as to levels achievable but did make predictions as to whether there was a good, fair, or poor chance of reaching a 4 $\mu g/m^3$ level with engineering controls alone at various locations in the three smelters he studied. Generally his analyses indicated a greater likelihood of reaching a 4 $\mu g/m^3$ level through engineering controls alone than Caplan's analysis.

Burton also testified as to general degree reduction in exposure achievable through engineering controls. He stated that as a rule of thumb, 95 to 99 percent reduction in the concentration of an air contaminant is possible for emissions from definable sources, while 80 percent reduction in emissions may be achieved when more sources and more ill-defined sources are added (STR 278). Given the age of most smelter facilities, and the numbers of the major emission sources, OSHA believes it prudent to utilize Burton's lower estimate of the effectiveness of engineering controls. It should be noted, however, that as smelters are modernized and newer more continuous processes are adopted, engineering controls should succeed in reducing exposures to lower levels.

In some operations the 80 percent reduction will be achieved, and in others it will not. It is not possible to predict the exact degree of improvement to be obtained from engineering controls until they are actually implemented. Further, the degree of additional control possible depends on how extensive existing controls are.

Applying the above testimony and principles to the data presented in the record, the Tacoma smelter will require extensive respirator use at the 10 $\mu g/m^3$ level. Because of that, a specific compliance strategy is discussed below which will alleviate the hardships of wearing respirators and reduce as much as possible full time use of respirators.

At the ASARCO El Paso smelter, a substantial number of employees are exposed in the range of 50 $\mu g/m^3$ (Ex. 29G, App. 3). Applying Burton's estimate of 80 percent reduction in exposure, a significant number of those employees in this range will have their exposures reduced to 10 $\mu g/m^3$. Employees in this group whose exposures are not reduced below 10 $\mu g/m^3$ through engineering controls still may have their exposures reduced sufficiently low so that in conjunction with clean rooms respirator use will be limited. Engineering controls alone are not anticipated to reduce exposures to 10 $\mu g/m^3$ for those employees working in the high exposure areas such as the roasters and reverberatory furnaces where existing exposures are sometimes as high as several hundred micrograms per cubic meter. Therefore respirator use will be necessary to reduce exposures to 10 $\mu g/m^3$ level for the limited number of employees working in these areas. As discussed in the Tacoma section full time use of respirators can be avoided even for many of these employees. Much smelter work is of an intermittent or watching nature so employees can go into clean rooms or filtered air pulpits during part of the day and be protected without wearing respirators.

Arthur Young estimated that 70 employees would need to wear respirators at the 4 $\mu g/m^3$ level at El Paso. Utilizing Burton's 80 percent analysis, OSHA believes that the 70 number might be on the low side at 4 $\mu g/m^3$ proposed level but that it may be a reasonable estimate at the 10 $\mu g/m^3$ level set by this standard. It is possible that the number will be higher than this. See the economic considerations section for a discussion of ASARCO's estimate of respirator use at the 4 $\mu g/m^3$ level which is not broken down by facility.

It is accepted that it is a major engineering task to accomplish these goals at El Paso. But installation of the engineering controls discussed in the AY and IHEA studies will substantially reduce exposure levels.

At the Anaconda smelter many exposure emissions from the traditional copper smelting technology have ranged between 10 $\mu g/m^3$ and 50 $\mu g/m^3$ with a few somewhat higher (Ex. 28, p. 165). Applying the above principles to these exposures, 10 $\mu g/m^3$ would be a challenging engineering task which should be achieved a significant percentage of time with engineering controls and work practices alone. Some employees will need to wear respirators to achieve 10 $\mu g/m^3$. The same principles discussed for El Paso will limit respirators use to part-time for most employees who need to use them. The difficulty in achieving 10 $\mu g/m^3$ may be lessened due to the installation of the electric furnace, although that may not reduce the problems in the converter aisle where exposures average approximately 46 $\mu g/m^3$.

The Kennecott-Garfield smelter is being completely rebuilt utilizing the Noranda Process. Accordingly, a feasibility analysis of the new smelter is difficult. But, based on the fact that arsenic in the feed is between the levels existing at Anaconda and El Paso on the one hand and ASARCO-Hayden on the other, and the limited exposure data supplied by Kennecott in higher exposure process areas, the problems of compliance should be less than those at Anaconda and El Paso. The new Kennecott smelter's continuous and more enclosed process should improve conditions as well.

At the ASARCO-Hayden smelter many exposures are in the 10 $\mu g/m^3$ range such as at the converter aisle and acid plant (Ex. 29A, App. 4). However, exposures in the reverberatory furnace area are in the 100-200 $\mu g/m^3$ range and are approximately 75 $\mu g/m^3$ by the roasters. The 10 $\mu g/m^3$ will be achievable for the employees in the low exposures area with engineering controls and will require some respirator use for employees exposed in the higher range. AY estimated that 45 employees would need to wear respirators at a 4 $\mu g/m^3$ level. The ASARCO data is discussed in economic considerations.

Arthur Young used Hayden as the basis for its analysis for the four other smelters in Group 4. However, it is quite possible that AY has underestimated the success that engineering controls will have in achieving the permissible exposure limit at those four smelters and that even the limited use of respirators which AY estimated at those smelters is an over estimate. In addition to the increase in the permissible exposure level, those four smelters have much lower levels of arsenic in their feed than ASARCO-Hayden ranging from .015 percent to .002 percent in comparison to the .04 percent at Hayden. Therefore, though there is little exposure data supplied by those smelters, it seems likely that they will find it easier to comply than ASARCO-Hayden.

On the other hand, Arthur Young may have placed Phelps-Dodge's Douglas smelter in too low a group. The level of arsenic in its feed is higher than at other smelters in Groups 4 and 5. Exposure data in Exhibit 12 indicates that most exposures are near 10 $\mu g/m^3$. However, a few exposures readings are between 10 and 80 $\mu g/m^3$.

In all the remaining smelters most exposures are quite low and concentrate levels are less than 0.02 percent. Those smelters can clearly meet the the 10 $\mu g/m^3$ level in virtually all of the places most of the time. Arthur Young estimated that very few if any of the employees at those smelters (in Groups 5 and 6) would need to wear respirators on a regular basis in these smelters at a 4 $\mu g/m^3$ level.

In summary, the three expert witnesses, Caplan, Burton and Arthur Young agreed that a 4 $\mu g/m^3$ level was technically achievable with engineering and work practice controls and respirators use, though varying on the extent of their estimates of respirator use. However, the 10 $\mu g/m^3$ level comports more clearly with the concept of technical feasibility, especially in the smelter environment. It provides a very high degree of protection with less extensive respirator use. Certainly a higher number would give less protection and lead to less respirator use. A lower number possibly might provide more protection and certainly would substantially increase respirator usage.

The 10 $\mu g/m^3$ level is achievable at 11 of the smelters with engineering and work practices and only very limited use of respirators. Limited use of respirators will be needed at the ASARCO-Hayden smelter, moderate use at the El Paso smelter and Anaconda smelters, and the Kennecott Garfield smelter will probably fall in between the two groups in terms of respirator use. The Tacoma smelter will require extensive respirator use and an appropriate compliance strategy to mitigate the problems created is discussed below.

Exhibit 5G contains a discussion of new technologies which may become available in the future. These, because of their more enclosed and continuous nature or because of their use of newer technology will ultimately lead to still lower exposures. However, those technologies (some of which are unproven) commonly require building a new smelter which may cost in the $150 to $250 million range. Since these new technologies are generally not yet looming on the horizon, the feasibility analysis has not been based on them.

The Arthur Young study (Ex. 148A) also considered other affected industry groups. However, those industries which are covered by this final standard did not specifically submit any detailed studies themselves though they made a few comments.

AY estimates the 4 μg/m³ was achievable with engineering and work practice controls alone in zinc smelters. Arthur Young and Arthur D. Little (Ex. 111-7, p. 37) clearly considered the 4 μg/m³ level feasible at primary lead smelters though it is unclear to what extent limited respirator use might be needed.

Arthur Young estimated that the glass, and desiccant manufacturer industries could achieve 4 μg/m³ with engineering controls alone. They estimated that the herbicide and pesticide manufacturers, wood preservative manufacturers and lead arsenical industry could achieve 50 μg/m³ with engineering controls alone but would require some respirator use to achieve 4 μg/m³. As the former two industries are chemical industries where enclosed processes can often be utilized, OSHA believes that the 10 μg/m³ level can be achieved without respirator use. There may be limited use of respirators needed at the 10 μg/m³ level in the lead arsenical segment.

In conclusion, the 10 μg/m³ exposure level is the lowest feasible level for exposure to inorganic arsenic. It minimizes, to the maximum extent feasible, excess lung cancer deaths resulting from exposure to inorganic arsenic. It is achievable generally through engineering and work practice controls. Limited respirator use will be needed to achieve the limit in some locations in some facilities, and one facility will require extensive respirator usage. The absolute degree of control of work exposure will be certain only after inplementation of engineering and work practice controls. What is clear is this standard will provide significant protection of workers from arsenic-induced lung cancer.

VI. Economic Considerations

In setting standards for toxic substances, the Secretary is required by section 6(b)(5) of the Act to give due regard to the question of feasibility. Section 6(b)(5) mandates that final standards be set which most adequately assure employee safety and health "to the extent feasible, on the basis of the best available evidence" and further requires that, in the development of occupational safety and health standards, "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."

While the precise meaning of feasibility is not clear from the Act, it is OSHA's view that the term may include the economic ramifications of requirements imposed by standards. The determination that OSHA has the authority to consider economic feasibility factors in developing standards has been endorsed by the courts. *Industrial Union Dept., AFL-CIO* v. *Hodgson*, 499 F. 2d 467 (C.A.D.C., 1974); *AFL-CIO* v. *Brennan*, 530 F. 2d 109 (C.A. 3, 1975); *American Iron & Steel Inst.* v. *OSHA*, No. 76-2358 (3rd Cir., 3/28/78). As pointed out by the D.C. Court of Appeals, Congress did not intend the Secretary to promulgate standards which drive entire industries or large numbers of employers out of business. On the other hand, "standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely". Further, the Court said, the concept of economic feasibility does not "necessarily guarantee the continued existence of individual employers." *Industrial Union Dept., AFL-CIO* v. *Hodgson, supra*, at page 478. In accordance with the Secretary's position, it has been OSHA's practice to analyze the economic impact of proposed standards where significant impact on employers covered by the proposals seem likely. OSHA then makes, such analyses available to affected parties for comment and subsequent hearing prior to issuance of final rules, and invites the submission of other information on the economic impact and feasibility of proposed standards. In developing a final standard OSHA evaluates the economic impact of the final standard on the basis of the entire rulemaking record, including the information developed by its own studies of the proposal and submissions by the public. On the basis of the best available evidence, therefore, OSHA has determined, as explained in detail below, that the permanent standard is economically feasible.

A number of studies were done of economic considerations resulting from an arsenic standard. The Arthur Young study (Ex. 135A) contracted for by OSHA considered economic factors for all affected industries. Other studies submitted concentrated on the copper smelting industry. These are listed in section V of this preamble. In addition the matter was specifically considered in testimony at the hearings.

The copper smelting industry is the most affected industry. Table 2 summarizes the Arthur Young and industry cost estimates for a 4 μg/m³ level and Arthur Young's estimates for a 50 μg/m³ level. However more than half of the industry's total cost estimate was comprised of hypothesized worker rotation costs for Anaconda and Kennecott. The industry hypothesized that the OSHA proposal required that industry use employee rotation, rather than respiratory protection, if engineering controls and work practices were sufficient by themselves to achieve the proposed 4 μg/m³ exposure level. Although it is true that Arthur Young's cost estimates includes in a few instances a limited amount of worker rotation, the proposal does not contain any language specifying worker rotation. Like the proposal, the final standard contains no requirement that worker rotation be used rather than respiratory protection when engineering and work practice controls do not succeed in reaching the permissible exposure limit (sometimes referred to in this document as the PEL or TWA limit). Therefore OSHA does not consider it appropriate to include worker rotation costs and Table 2 also presents the industry estimate adjusted to exclude worker rotation costs.

TABLE 2.—*Cost of compliance for copper smelters*

[Millions of dollars]

Source of estimate	50 μg/m³			4 μg/m³		
	Capital	Annual	Annualized	Capital	Annual	Annualized
AY (Ex. 135A)	85.9	6.2	23.5	103.9	11.2	32.0
Industry (Exs. 156a, 111-7)				224.2	153.7	198.8
Industry adjusted				224.2	49.6	94.7

Annual costs include the additional costs resulting from the standard for fuel, medical examinations, monitoring, maintenance, etc., as well as potential loss of efficiency through respirator use. Annualized capital costs are 20 percent of initial capital costs. These are then added to annual costs to derive annualized costs.

The industry cost figures cited in Table 2 do not include costs for four of the 16 U.S. primary copper smelters which are not owned by the four major companies. The Arthur Young estimate includes costs for all 16 U.S. primary copper smelters. The ASARCO estimates, included in the overall industry cost figure includes costs of compliance for some of their non-copper operations as well as their copper smelters and thus to that extent the industry figure overstates costs which are attributable to copper smelting alone.

OSHA believes that at the 10 $\mu g/m^3$ level the adjusted industry cost estimates are too high. Respirator costs will be reduced substantially from the 4 $\mu g/m^3$ level because engineering controls will succeed in reaching the 10 $\mu g/m^3$ level more frequently. There will be a limited reduction in the cost of engineering controls at the 10 $\mu g/m^3$ level at Kennecott and Phelps-Dodge. The Phelps-Dodge capital costs estimate of $80 million, supported by no underlying data, seem, much too high relative to other industry estimates. They had originally estimated $22 million (Ex. 12). Kennecott, with higher exposures and a larger scale of operation, estimated capital costs at $28.5 million.

Kennecott's estimate of $9.9 million in annual energy costs to reheat stack gasses is unsubstantiated. Anaconda's estimate of $30 cfm estimate for ventilation controls is approximately double other estimates used for ventilation controls on the record (Ex. 29 m, Ex. 148A).

The ASARCO cost estimate includes annual costs of $10.57 million for loss of efficiency from respirator use and $231 million for respirator expenses at the 4 $\mu g/m^3$ level. These figures are based on approximately 900 employees at Tacoma and approximately 2000 employees at other ASARCO facilities wearing respirators full time. Loss of efficiency through respirator use is computed by ASARCO at 20 percent or $3600 per man year. Respirator costs are estimated at approximately $800 per man year.

OSHA believes these ASARCO figures are substantial over-estimates at the 10 $\mu g/m^3$ level. As analyzed in detail below, in the Tacoma section, ASARCO's estimate of employees on respirators at Tacoma is probably double the correct figure and the 20 percent estimate of loss of efficiency for respirator use is probably more than double the correct estimate. Therefore the loss of efficiency through respirator use at Tacoma is probably more than $2.43 million too high.

OSHA believes that substantially fewer than 2,000 employees will need to wear respirators full time at non-Tacoma ASARCO facilities at the 10 $\mu g/m^3$ level. ADL does not make clear how this figure is derived, but it appears to be based on all production employees at El Paso, Hayden, East Helena and possibly other ASARCO facilities wearing respirators at the 4 $\mu g/m^3$ level. However ASARCO Exhibit 29G indicates that many employees at those locations (except El Paso) have exposures already below 10 $\mu g/m^3$ and other are exposed at levels sufficiently close to 10 $\mu g/m^3$ so that engineering controls will in many instances succeed in reducing exposures below 10 $\mu g/m^3$. In any event full time use of respirators by many of these employees is not likely to be necessary.

Further David Burton and AY estimated that approximately 50 employees would need to wear respirators at Hayden at the 4 $\mu g/m^3$ level. (Ex. 18, p. 67, Ex. 173A). Arthur Young estimated that approximately 70 employees at El Paso will need to wear respirators full time at the 4 $\mu g/m^3$ level (Ex. 173A). These estimates would indicate much lower respirator use than the ADL estimate at 4 $\mu g/m^3$.

Based on the change to the 10 $\mu g/m^3$ level, existing exposure levels, the effectiveness of engineering controls and estimates of other experts, OSHA believes that fewer than 500 employees will be wearing respirators at ASARCO's non-Tacoma facilities. Further as discussed below in the Tacoma section, the 20 percent figure for loss efficiency through respirator use is too high and 10 percent may be a more reasonable high side estimate. Therefore the ASARCO estimate of $8.86 million in total respirator expenses at non-Tacoma facilities ($7.33 million loss of efficiency plus $1.54 million respirator costs) is probably overstated by a factor of seven-eighths. In any event, full time use of respirators by many of these employees is not likely to be necessary. However to be certain that respirator costs are not underestimated, it will be assumed for purposes of this analysis that these respirator costs are overestimated by three-quarter or $6.65 million. Therefore the total ASARCO estimate for respirator expenses is overestimated at least $9 million per year at the 10 $\mu g/m^3$ level ($2.43 million overestimate at Tacoma and $6.65 million non-Tacoma). The ASARCO capital cost figure will also be reduced in the short and middle term by the likelihood of less capital investment at Tacoma as discussed below. In the longer term that investment will be necessary.

The above overestimates come to $32.1 million per year in annualized costs. Subtracting the overestimates from the industry estimate of $94.7 million leaves a balance of $62.6 million in annualized costs. The computations to derive the $32.1 million figure are as follows: Capital costs at Phelps Dodge should be no more than the Kennecott estimate of $28 million, saving $52 million in capital costs from the Phelps Dodge $80 million estimate or $10.4 million in annualized costs. Even the $28 million figure is likely to be an overestimate for Phelps Dodge since Exhibit 12 indicates that existing exposures are low. Caplan, an ASARCO witness estimated $16 per CFM for difficult ventilation jobs. Applying that figure to the Anaconda estimate of 1 million CFM results in costs of $16 million rather than the $30 million Anaconda estimate. This saves $14 million in capital costs or $2.8 million in annualized costs. Arthur Young believed the $30 CFM figure was too high but nonetheless utilized it in their analysis. They believed the capacity required was overestimated as well. Also subtracted are $9 million in excess respirator costs at ASARCO and $9.9 million in excess fuel cost at Kennecott. (10.4+2.8+9.0+9.9=$32.1 million in overestimates).

Changes in the standard from the proposal will also result in substantial cost savings from the industry estimates. Monitoring costs will be reduced by approximately two-thirds due to the reduction in monitoring frequency. Medical, laundering and hygiene costs will also be reduced significantly by the change in the definition of covered employees and the reduction in laundering frequency. These savings have not been subtracted from the various estimates.

It also should be noted that both industry and Arthur Young figures are based on a 20 percent factor covering interest and depreciation to annualize capital costs. A figure commonly used in other OSHA proceedings has been

15 percent. To the extent that the 15 percent figure is more realistic, all of the estimates have exaggerated the annualized cost figures.

The Arthur Young cost estimates are reasonably detailed and based to a substantial extent on detailed underlying data. Caplan of IHEA testified that AY did not always give sufficient reasons when choosing the DBA report as the basis for estimates rather than selecting the IHEA estimates. (STR p. 629.) Nonetheless, the choice was made by qualified persons and general considerations and sometimes specific reasons were given in Exhibits 148A and 173A. The DBA costs, when chosen, were detailed and made by a qualified expert. DBA estimates were adjusted by AY to fully account for overhead costs.

Some of the AY costs based on DBA estimates may be too low. For example, in OSHA's experience the estimate of $5,350 for enclosing, filtering, and air conditioning an overhead crane (Ex. 148A, p. 8) may be too low. Also, the AY computation of costs for Phelps-Dodge smelters may be too low based on exposure levels at the Douglas smelter and interpolation of AY cost data. These underestimates are at least in part compensated for by the lessening of costs at the 10 $\mu g/m^3$ level from the 4 $\mu g/m^3$ level.

It therefore appears to OSHA that the AY 4 $\mu g/m^3$ estimate is a reasonable estimate at the 10 $\mu g/m^3$ level. It also appears that the industries adjusted figure for the 4 $\mu g/m^3$ level is high at a 10 $\mu g/m^3$ level, though an estimate in between those two figures of approximately $63 million would also be a reasonable high-side estimate. The adjusted industry figure with some of the probable overestimates substracted would come out to approximately $63 million in annualized costs.

The smelters not included in the industry compilation will probably have costs in the lower range in comparison with other smelters at the 10 $\mu g/m^3$ level since exposures are already in the lower range. In addition, it is not unreasonable to assume that as they did nbot actively participate in the hearing process, they did not believe it difficult to comply. It also should be noted that the profit figures used below do not include profits for the other smelters and therefore understate industry profits.

In considering economic impact, it is inappropriate to assume that the industry will have to absorb all these costs. Some of the increased costs will be offset by increases in smelting charges. Since the early 1970's smelting charges have risen from about 6 cents to 12 cents per pound of copper and combined smelting and refining charges have increased from about 10 cents to 20 cents per pound in response to higher energy, environmental and other costs. (Ex. 111-7, p. 24-25.) Also ASARCO has successfully increased smelting charges to independent mines to assist in offsetting costs of environmental controls. (STR. pp. 457-458.) Notes 1 and 6 of the 1975 ASARCO Annual Report indicate that ASARCO has been receiving approximately $12 million per year in environmental surcharges.

A. D. Little suggested that those costs of controls which affected most smelters can be passed on to consumers by smelting operations without disruption in time of "normal" copper prices. (Smelting charges are normally assumed by copper analysts to be paid by the mine which takes the gains and losses from rises and falls in copper prices.) ADL estimated that 2 cents per pound of copper could be passed along. (Ex. 111-7, pp. 35-37.) Arthur Young estimated that there would only be a "negligible" increase in copper prices based on the low impact of the proposal on some smelters, ADL's estimate that there is a surplus of smelting capacity abroad, and that their study was directed at long-term impacts. (Ex. 135, p. VI-10, Ex. 184.)

A 2 cent increase in smelting charges would result in increased revenue to smelters of $60 million per year and a 1 cent increase of $30 million per year based on a typical figure of 1.5 million tons of copper smelted per year in the U.S. In view of past increases in smelting charges to cover increased costs, OSHA believes some part of the increased costs of the regulations can be recovered by the smelters in increased smelting charges to mitigate the impact of the cost of arsenic controls. There are costs in shipping copper from overseas and some overseas smelters are also facing increased environmental costs. Therefore despite a possible surplus of overseas capacity, OSHA believes that a part of the cost increases can be recovered in increased smelting charges.

The average annual pretax profits over the 10 year period 1966-1975 for the four largest copper smelting companies total $525 million excluding extraordinary items (Standard and Poors). Industry profits need to be averaged over a period of time because of their historically large fluctuations. It is appropriate to compare costs against pretax profits since depreciation and interest are tax deductible. (Such a comparison may still overstate the impact of the costs because there is a tax credit for capital investment that would have the effect of reducing net capital outlays.)

Using the industry's adjusted estimate of costs of $94.7 million and a low estimate at increased smelting charges of 1 cent per pound ($30 million), the copper smelting industry would be left to absorb $64.7 million of costs, or 12.3 percent of average pretax profits. As discussed above, that percentage is probably too high at a 10 $\mu g/m^3$ level because the $94.7 million cost figure appears to be too high. Using the AY figure of $32 million in costs and the 1 cent per pound increase in revenues, the costs to be absorbed by the industry would be a negligible $2 million. This net figure is probably low. At the $32 million cost figure only a lower increase in smelting charges would probably be passed on because of the different cost impacts of the standard on different smelters.

An intermediate analysis would be to consider costs at the 10 $\mu g/m^3$ level as midway between the AY and industry adjusted estimate or $63 million. With increased smelting charges of 1 cent per pound this would result in the industry absorbing $33 million in increased costs, or 6.3 percent of historical pretax profits.

It would appear to OSHA that these percentages indicate that the cost of the arsenic standard is well within the economic capabilities of the copper smelting and refining industry as a whole. It is true that the copper smelting industry is also being required to spend substantial sums on environmental controls. However, no witnesses have testified that costs of this magnitude would be infeasible for the copper smelting industry as a whole.

This conclusion is consistent with the conclusions of A. D. Little, ASARCO's witness, that the cost to the copper and lead smelting industries can be passed on without any major dislocations except in times of abnormally low metal prices (Ex. 111-7, p. 37). They believed the exception to this was the additional compliance costs to ASARCO at their Tacoma and El Paso facilities over and above the level of costs at other smelters.

OSHA is aware that subsequent to the close of the record in this rulemaking, that copper prices have been very low and some copper companies have been in a loss position on their copper operations. It is also true that subsequent to the close of the record Kennecott received a very large sum in cash from the sale of Peabody Coal Co., Anaconda was purchased by Atlantic-Richfield and Bendix has invested in ASARCO. The Financial Press has speculated about high copper prices in the 1980's.

OSHA has not considered these factors in its analysis. However at the compliance level, feasible compliance plans are worked out for specific facilities. To the extent that a specific company can prove that serious economic feasibility difficulties exist, the compliance plan can be adjusted to include a more extended period for the installation of required engineering controls with more extensive use of respirators in the short term.

It is not appropriate to reopen the record each time the state of the economy or the price of a specific commodity changes. These fluctuations are frequent and it would become difficult ever to close a record and issue a final standard. In consequence needed health protection for employees would be further delayed. Such changes are better addressed at the compliance level where more detailed information is available. See *Atlantic and Gulf Stevedores* v. *OSHA*, 534 F. 2d 541 (3rd Cir. 1976). No party has petitioned to reopen this proceeding.

LEAD AND ZINC SMELTERS

The IIS estimated annualized costs to primary lead smelters of $9.3 million and of $940,000 to zinc smelters at a 4 $\mu g/m^3$ level. It found no economic impact of sufficiently great magnitude to create questions of economic feasibility or supply problems. In addition no detailed industry analyses were made indicating that any problems of economic feasibility existed.

ECONOMIC IMPACT—OTHER INDUSTRIES

Interested parties in other industries did not bring to OSHA's attention major problems of economic feasibility. The IIS estimated substantial ($30 million annualized) costs of compliance at the 4 $\mu g/m^3$ level in the glass industry but did not indicate that difficult economic feasibility questions existed. The costs are distributed broadly across a reasonably large industry. In addition arsenic use in glass has been going down as substitutes have been developed. Manufacturers are continuing to reduce the already small percentage of arsenic in glass and to develop complete substitutes which will reduce the costs of compliance. The costs will be further reduced by the change to the 10 $\mu g/m^3$ level.

The IIS estimates $6.7 million in annualized costs for secondary lead smelters. It suggests that a few of the smaller firms may have some difficulty in raising capital to meet the costs of controls though no smelters have presented specific evidence on this point. This evidence indicates that the standard is feasible for the industry as a whole.

The IIS estimates that annualized costs of compliance were not over $1 million at the 4 $\mu g/m^3$ in any of the other industries studied. Although the IIS suggests that one or two individual plants may have difficulty in raising capital, no specific evidence has been presented to OSHA. In view of the relatively small amounts involved at a 4 $\mu g/m^3$ level, no significant questions of economic feasibility appear to be presented for these industries as a whole at a 10 $\mu g/m^3$ level.

BENEFITS

The legislative history and language of the Occupational Safety and Health Act, as distinguished from some other environmental and safety legislation, clearly indicate that Congress has already arrived at a judgment concerning the balancing of cost and benefit, with the result that worker safety and health are to be heavily favored over the economic burdens of compliance. Specifically, Section 6(b)(5) of 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 upon research, demonstrations, experiments and such other 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.

Thus, while feasibility is an appropriate consideration, the Secretary is directed to set standards which attain the "highest degree of health and safety protection for the employee * * *."

This does not mean, however, that a systematic evaluation of costs and benefits is not to be encouraged within the limits of the estimation techniques. In considering the issue of feasibility in this rulemaking, as in others, OSHA has carefully evaluated the cost of compliance which may be incurred by the directly affected employers and their ability to comply. Additionally, OSHA believes that a standard for a substance which has been found to pose a cancer risk to workers, in this case inorganic arsenic, must assure maximum benefit (i.e. prevention of serious illness or death), constrained only by the limits of feasibility.

There is general agreement that inorganic arsenic exposure causes cancer. In spite of the certainty of this conclusion, and that there is a reasonable dose-response relationship for exposures in the hundreds of micrograms per cubic meter, there does not exist an adequate scientific basis for determining a quantitative dose-exposure relationship at the lower levels of exposures necessary to reduce the risk as much as is feasible. The uncertainty in both the actual magnitude of expected deaths and in the theory of extrapolation from existing data to the exposure level set by this standard places the estimation of benefits on "the frontiers of scientific knowledge."

While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number is likely to be appreciable. A dose-response relationship, that is a lower incidence of excess risk at lower levels of exposure is likely to exist at lower as well as higher levels of exposure to inorganic arsenic. Therefore reductions in exposure to lower levels is accompanied by a reduced risk, even though a precise quantitative relationship cannot be established.

The epidemiologic studies discussed in the health effects section give an indication of the magnitude of the excess risk which will be reduced by this standard. For example, the excellent Lee and Fraumeni study considered the employees at one copper smelter. This study indicated that over a 25 year period, there were 147 lung cancer deaths where only 45 deaths would be expected (Ex. 5D, Table 3, p. 1048). Exposures of groups of employees showing excess risk were both above and below the existing 500 $\mu g/m^3$ limit. It is clear that the new standard would contribute very substantially to reducing the 102 excess lung cancer deaths at that one copper smelter. In light of the uncertainties in this area of scientific knowledge, OSHA believes that it is required by the statutory mandate to adopt a highly protective posture in considering the evidence for health benefits.

We recognize that in view of the latency period usually associated with the induction of cancer, significant reductions in mortality may not be seen for many years. However, unless exposures are reduced now, OSHA believes that the mortality rate will not decline and employees exposed to inorganic arsenic will continue to suffer excess mortality.

Based upon the foregoing and the record as a whole, OSHA finds that compliance with the standard is well within the financial capability of the covered industries. Moreover, although the benefits of the standard cannot rationally be quantified in dollars, OSHA has given careful consideration to the question of whether these substantial costs are justified in light of the hazards of exposure to inorganic arsenic. OSHA concludes that these costs are necessary in order to effectuate the statutory purpose of the Act and to adequately protect employees from the hazards of exposure to inorganic arsenic.

In making judgments about specific hazards, OSHA is given discretion which is essentially legislative in nature. In setting an exposure limit for a substance like inorganic arsenic, OSHA has concluded that it is inappropriate to substitute cost benefit criteria for the legislatively determined directive of protecting all exposed employees against material impairment of health or bodily function. Where the health effectiveness of alternative approaches are extremely uncertain and likely to vary from situation to situation, OSHA believes it is appropriate to adopt the compliance strategy which provides the greatest certainty of worker protection even if the approach carries with it greater economic burdens for the affected employers.

In the case of the inorganic arsenic standard, the evidence in the record indicates that the costs of compliance are not overly burdensome to industry. Having determined that the benefits of the proposed standard are likely to be appreciable, OSHA is not obligated to carry out further exercises toward more precise calculations of benefit which would not significantly clarify the ultimate decision. Previous attempts to quantify benefits as an aid to decisionmaking in setting health standards have not proved fruitful (41 FR 46742).

IMPACTS ON PRICE INDEXES

Both the IIS (Ex. 135, p. VI-5) and the Council on Wage and Price Stability (STR, pp. 845-6) estimate that the overall impact on general price indexes of the inorganic arsenic standard indexes will be "negligible." Arsenic products have a very small weight in these indexes and even substantial increases in individual arsenicals would have no significant impact. The likelihood of a 50 percent increase in the price of arsenic trioxide is discussed below. But such an increase would have very little impact on the prices of finished chemicals, cotton, or preserved wood because the cost of the arsenic trioxide is generally a small part of the cost of the finished product. See the discussion in the Final EIS of how even a 100 percent increase in the cost of arsenic trioxide would only have a negligible impact on the cost of cotton production, the largest user.

This preamble utilizes a 1 cent per lb increase in the price of copper as a low side estimate of the increase in price of copper for purposes of estimating impacts on copper smelters. ADL originally suggested a 2 cent increase in price. At the September 1976 hearing they suggested the possibility of a 5 cent increase if the Tacoma smelter shut down. As discussed below OSHA believes a compliance strategy exists which will assist in maintaining the continued viability of the Tacoma smelter.

OSHA does not believe that sufficient evidence has been introduced to permit it to evaluate the validity of ADL's second prediction. No doubt a 5 cent increase in the price of copper is not insignificant to copper users. However the market price frequently fluctuates by much greater amounts in the course of a year. Such an increase would still have a negligible impact on general price indexes, $150 million in a $1.5 trillion plus GNP. If it did occur, it would interestingly make the copper industry as a whole much more profitable and substantially improve its capabilities for paying for needed environmental and occupational safety controls.

THE ARSENIC MARKET

A. D. Little speculated that if Tacoma closes, the other producers of arsenic, Sweden, Mexico and Southwest Africa may form a cartel and force up the price of arsenic (Ex. 167A, p. II-16). Arthur Young points out that their speculation is not "obvious" though the IIS did not specifically consider this contention. (Ex. 184, p. 15)

The compliance strategy suggested for Tacoma will assist in maintaining its continued viability, so the basis for ADL's speculation may not occur. In any event OSHA believes the ADL suggestion is based on mere conjecture and is highly speculative. Further the flue dusts of many copper smelters are rich in arsenic and precious metals. These dusts, which in some cases now are stored, might very well become additional sources of arsenic if price relationships were suitable.

THE ECONOMETRIC MODEL

The 115 includes an econometric model. Arthur D. Little presented extensive criticisms of the model (Ex. 167, 167A, 186, 190(3)). Arthur Young responded to the criticisms in Ex. 173B and 184. OSHA has made its own independent interpretation of economic considerations in this preamble based on the data in the record. Therefore, it has not found it necessary to attempt to resolve the differing views on the econometric model.

VII. THE TACOMA SMELTER

The above analysis indicates that the final arsenic standard is feasible for the industries affected. However, the record also indicates that for copper smelters the magnitude of the task to achieve compliance will vary substantially among the different facilities in the industry. As discussed above, OSHA believes that it is inappropriate to make feasibility determinations based on those few facilities which have the most difficult compliance problems. To do so would deny necessary and achievable health protection to the majority of employees in facilities where a much lower level can be achieved.

When there are some facilities which cannot comply with the standard in the medium term using principally engineering controls, for technical reasons or because of serious economic difficulties, then a more elaborate compliance plan is required. Such a plan is to achieve compliance with the exposure limit in the near term through a carefully planned mix of feasible engineering controls, work practices and personal protective equipment. The plan should set priorities for the adaptation and installation of further engineering controls which will be put in place as soon as possible. It should also include strategies for reducing the difficulties in using personal protective equipment.

Normally, these situations will be dealt with at the compliance level. Considering the unusual circumstances at a few locations in a general rulemaking hearing would excessively lengthen the hearing with its many participants, and would reduce resources available to respond to major health questions with broad implications. Also solutions to the compliance problems are best incorporated in the compliance plan for a specific location so they can be tailored to specific difficulties.

However, a substantial amount of evidence has been placed on the record in regard to the Tacoma smelter of ASARCO, Inc. which has the most difficult compliance problems. OSHA has spent a substantial amount of time analyzing those data and members of its standards staff have visited the Tacoma smelter. Therefore, to assist the compliance process to more quickly and effectively reduce exposure levels, the evidence is analyzed here. This discussion will also provide useful information for other facilities. The outline of a feasible compliance plan is also described. Such a plan will permit compliance with the final standard including the 10 $\mu g/m^3$ level, substantially reduce the elevated lung cancer mortality reported among workers at the Tacoma smelter and alleviate the hardships of respirator use. It will assist in maintaining the continuing viability of the Tacoma smelter and the employment for its approximately 1,000 employees.

The details and changes based on new evidence will be worked out at the compliance level where the most recent evidence will be available to closely scrutinize compliance efforts and capabilities. Also, a joint EPA and OSHA study will be available which will integrate and set priorities for occupational and environmental health controls.

The evidence indicates that Tacoma is principally a copper smelter and similar to the other 15 in the United States. Like many of the others it is an older facility which smelts copper through a high temperature pyrometallurgical process involving the open transference of molten and fuming mineral complexes between and from furnaces. The employees at Tacoma carry out many tasks in a manner similar to other copper smelters. Compliance, as at other smelters, requires principally enclosure, hooding, and ventilation to the extent feasible at the various steps in the process.

However, the record indicates that the degree of difficulty to achieve compliance is greater at Tacoma. Two reasons principally account for this. First, the level of arsenic in Tacoma's copper concentrate feed (4 to 5 percent overall) is five times that at the two smelters with the next highest levels of arsenic in their feed and at least 40 times greater than the other smelters. Second, Tacoma is the only domestic producer of arsenic-trioxide.

Both Knowlton Caplan, expert witness for ASARCO (Ex. 29m, pp. 66-67; ATR p. 1314) and David Burton, expert witness for OSHA (Exs. 18, 150; STR p. 279), suggested that in a number of areas at Tacoma, ventilation and enclosure controls by themselves would have a low probability of reducing exposures below 50 $\mu g/m^3$. Arthur Young did not specifically express a judgment on this point, but did suggest that to reach a 4 $\mu g/m^3$ level, engineering controls would have to be coupled with substantial use of clean rooms, respiratory protection and some worker rotation.

Arthur Young estimated that the capital cost of all technically feasible engineering controls at Tacoma would be $31 million and that the annualized cost would be $10 million at the 4 $\mu g/m^3$ level. A. D. Little estimated capital costs at $41 million and annualized cost at $16 million at that level. Costs of all technically feasible engineering controls would be similar at the 10 $\mu g/m^3$ and 4 $\mu g/m^3$ levels at Tacoma because of the high current exposure levels. ASARCO stated that pretax profits at Tacoma had averaged $1.9 million per year but supplied no underlying data (STR, p. 439). ASARCO's pretax profits have averaged $92 million in the 10 year period 1966-1975 (Standard and Poors). As discussed below, Tacoma is integrated into other ASARCO operations. This evidence indicates that part of the costs of controls should be borne by ASARCO as a whole.

The standard requires that employers install at the earliest possible time but no later than December 31, 1979, necessary engineering controls except to the extent the employer can show that those controls are not feasible. Unless the evidence supplied by ASARCO does not represent the current circumstances, ASARCO may be able to show that installing all of the technically feasible engineering controls discussed in the IHEA, DBA and Arthur Young studies are not feasible in that period at Tacoma. In addition, substantial respirator usage will be required.

If this is the case, the standard requires ASARCO to develop a compliance plan for installing the most effective feasible controls in the near term, mitigate the difficulties of substantial respirator use and provide a framework for complete compliance in the long term. ASARCO is obligated to install additional engineering controls as they become feasible.

The most effective types of engineering controls to be installed by December 31, 1979, would include the following three types of controls. Controls should be installed which would most effectively reduce background levels of arsenic contamination at the smelter. This includes enclosure, hooding, and ventilating sources of arsenic contamination which are currently uncontrolled or only partially controlled. Possible examples are controls at the roaster flue cleanout and enclosure of the fine ores bin. Other examples are hooding and ventilation of sources of arsenic emissions at the roaster, and during charging and tapping at the reverberatory furnaces and convertors to the extent that current systems are insufficient or incomplete. Also, some steps in the arsenic-trioxide production process are basically uncontrolled at present and reasonable controls should be installed to reduce background contamination. For example, hand tools are used in the open to "pull" (remove) arsenic-trioxide out of the "kitchens" (condensers) with little in the way of even basic forms of enclosure, ventilation or mechanization leaving a visible residue of arsenic-trioxide.

Lowering background arsenic levels makes controls at other specific locations easier to devise and reduces the need for full time use of respirators. It lessens respirator use in those areas of the plant where little arsenic is emitted and where most exposure is from background sources. Such controls by reducing fugitive arsenic emissions, reduce the spread of arsenic outside of the plant boundaries. They thereby reduce potential exposure in the surrounding community. These types of engineering controls must necessarily be coupled with good housekeeping practices such as promptly cleaning up spills, cleaning larry car tops and furnace doors for better seals, and cleaning of maintenance shops. A conscientiously carried out program of such practices can substantially reduce background levels of arsenic.

Secondly, those engineering controls which will reduce exposures below the 10 $\mu g/m^3$ limit for significant numbers of employees should be installed. This will eliminate the need for respirator usage in those locations.

Thirdly, filtered-air pulpits and clean rooms should be utilized where appropriate. Many production jobs in a smelter are of a tending or intermittant nature. A clean room or filtered air pulpit provides an environment below the 10 $\mu g/m^3$ level, where the employee can stay with his respirator off in between tasks, or while monitoring controls. As a result, the employee's exposure is substantially reduced without the full-time use of respirators.

Both D. B. Associates and Arthur Young emphasized the importance of these controls, which are effective at moderate cost and which in OSHA's experience are commonly used by industry. Caplan testified that at Tacoma, clean rooms might not succeed in reducing exposures to the 4 $\mu g/m^3$ because of high background levels. OSHA believes that well designed clean rooms will succeed in keeping exposures below the 10 $\mu g/m^3$ level. Good design includes adequate filtration and vacuums for the employee to dust himself off before entering.

The above discussion is not intended to be determinative, but to provide general guidance. The specific plan for setting installation priorities for engineering controls needs to be worked out at the compliance level where all necessary details can be taken into account. It is clear that such a plan can be devised. Caplan testified that he indeed could develop a compliance plan which would rationally set priorities for the installation of engineering controls, and that the study which he submitted to the record did not do that (STR, pp. 642-643). Similarly, the D.B. Associates study did not prioritize controls, but Burton himself did indicate the beginnings of a plan to do that in his testimony (STR, pp. 270-281).

In conjunction with the installation of the most effective feasible engineering controls, substantial respirator use will be necessary in the medium term to meet the 10 $\mu g/m^3$ exposure limit. Therefore, the standard requires the compliance plan to include provisions for a respiratory protection program designed to reduce the burden on the employees of widespread respirator use as well as assuring the effective use of respirators.

The plan for engineering controls discussed above is the first step in such a respiratory protection program. It will provide a basis for reducing the need for full time respiratory use. Many employees will be able to spend part of the day in clean rooms and pulpits where they may remove their respirators. Another part of the day, the employee will have to wear a respirator. However, properly fitted and selected respirators in many circumstances will reduce exposures substantially under 10 $\mu g/m^3$. That, in conjunction with a general lowering of background exposure levels, will permit employees to spend part of the day not wearing respirators outside of the clean room and still maintain 8 hour time weighted average under the 10 $\mu g/m^3$ limit set by the standard.

The standard also requires quantitative fit testing for facilities with widespread respirator use. Such testing will permit a more accurate assessment of the degree of protection the respirator is giving each employee. It will also permit determination of what part of the day the employee may go without wearing his respirator, and still be under the exposure limit.

The standard also gives the employees the option of wearing powered air purifying respirators and requires employers to furnish them when requested. Those respirators, as discussed below, are often more comfortable for the employee and can provide a higher degree of protection than negative pressure respirators. In addition, the process of developing new and more comfortable forms of powered air purifying respirators continues. OSHA is willing to consider granting experimental variances or other appropriate action to permit use of such respirators or other respirators which increase comfort and reduce safety problems before certification by NIOSH is granted, if quantitative fit tests indicate they are providing proper protection in the Tacoma environment.

A compliance plan for Tacoma following the above outlines will mitigate the hardships of respirator use at Tacoma. It will reduce the need to wear respirators for the entire work day and will encourage the use of more comfortable types of respirators. It also will be beneficial to ASARCO because the loss of efficiency through respiratory use is less when they need not be worn all day and more comfortable types can be worn. It is recognized that for some employees, such as crane chasers, electronic communication equipment needs to be incorporated into the respirator to permit adequate communication.

The feasible compliance plan for Tacoma would not be appropriate in most other circumstances. As explained above, the substitution of respirators for feasible engineering controls is not acceptable because of the difficulties in properly fitting and insuring that they are used. Moreover many types of respirators are uncomfortable to wear, and it is inappropriate to place the burden of compliance on the employee when it is the employer who has not removed toxic substances from the workplace.

Further a program of averaging exposures with the respirator on and off to prevent full time use is also not acceptable in most circumstances. It is difficult to administer such a program, enforce it and insure that employees are not over exposed.

However Tacoma presents difficult circumstances. There are serious health and feasibility problems. In these limited circumstances, the above program is appropriate despite its difficulties. If carefully administered by ASARCO, it will provide needed health protection for the employees and respond to the feasibility questions.

In the longer term installation of additional engineering controls, modernization of the Tacoma facility and technological development will reduce exposure levels. As this occurs less reliance on respiratory protection will be needed.

The case of *IUD* v. *Hodgson* (supra) suggests that consideration may be given to setting a different exposure level for different industries. Such a response does not seem proper in these circumstances. OSHA does not believe that the carcinogenic risk at higher worker exposure levels is acceptable, and an approach is available which can provide the Tacoma employees with the same level of protection as other employees, although in a less satisfactory manner. In addition Tacoma is primarily a copper smelter and does not constitute a separate industry.

The rulemaking record includes analyses of economic feasibility for Tacoma by Arthur D. Little, Inc., Arthur Young & Co., Dr. Arvil Adams, and ASARCO management officials. Based on this record OSHA believes ASARCO is in position to spend a substantial capital sum towards the installation of effective engineering controls and carry the provisions of the compliance plan described.

Final determination of the most effective economically feasible schedule for installation of engineering controls will be determined at the compliance level. Latest information and internal financial data will be available at that stage. This information is discussed here to assist in a more rapid determination at the compliance level and to give guidance to the parties.

Tacoma is integrated into other ASARCO operations as pointed out by Strauss, ASARCO's Executive Vice-President (STR, p. 443) and by A. D. Little, ASARCO's own witness (Ex. 111-7, pp. 29-30). Although ASARCO supplied little evidence upon which to estimate the value of the services it performs for other ASARCO facilities, they involve treating $30 million in metal values per year (Ex. 111-7, p. 30). ASARCO has stated it would involve new capital expenditures to perform those services at its El Paso smelter (STR. p. 443). On this basis and because of the serious health problems at Tacoma it is appropriate that the initial capital investment for engineering controls should be in major part charged to ASARCO as a whole, and not specifically come only from Tacoma resources.

ASARCO recently completed an $18 million program for reduction of environmental sulfur dioxide emissions at Tacoma. It has committed itself to spending $6 million for environmental arsenic controls there, knowing about the pendency of OSHA arsenic regulations. The expenditure of sums in this range will go a long way towards completing, or complete by 1980 the installation of those most effective engineering controls describes above. Obviously ASARCO management has considered it economically feasible to invest sums of this size in environmental controls in the recent past at Tacoma. However, in view of the severe health hazards, it is OSHA's view that a substantial sum must be invested in engineering controls, no matter what the circumstances, in order to significantly reduce that hazard and indicate that a major effort to reduce exposures is being made.

In considering economic feasibility at Tacoma it is also necessary to take into account additional revenues which will be generated at the smelter as a result of this standard. As discussed above in the feasibility analysis for the copper smelting industry, there will be conservatively an additional 1¢ per pound in copper smelting charges as a result to the standard. Based on approximately 75,000 tons of copper per year smelted at Tacoma, this will come to $1.5 million in increased revenues.

In addition, as a result of this standard Tacoma will receive increased revenues from the sale of arsenic-trioxide over its arsenic-trioxide revenues at the time this record was compiled. Both Arthur Young and A. D. Little analyzed the arsenic market at considerable length in Exhibits 135A and 111-7. Arthur Young suggested that, so long as Tacoma produced arsenic, prices would not increase significantly because of import competition. A. D. Little suggested that ASARCO might raise its arsenic-trioxide approximately 50 percent ($150 per ton) and still sell its entire annual production though not reduce its inventories existing at the time of the report. It is OSHA's understanding that Tacoma arsenic inventories have been substantially reduced and therefore pricing to reduce inventories would not now be necessary.

Foreign prices have in the last several years risen to levels higher than domestic prices. The largest foreign producer, Boliden in Sweden, may currently have less arsenic-trioxide to sell; it's inventories have shrunk with the exhaustion of some of its sources of high arsenic concentrates. Foreign arsenic-trioxide prices have increased about 300-400 percent over the last eight years. More recently domestic prices have risen 200-300 percent and domestic inventories have declined. Foreign prices are now greater than domestic prices. Domestic consumption has been maintained or increased.

The cost of arsenic-trioxide is only a small part of the cost of the finished products in which it is used and for some uses substitutes are less satisfactory. (This aspect is discussed at greater length in the final EIS.) Based on this, many of the purchasers of arsenic compounds should be able to absorb significantly increased prices without reducing consumption substantially.

A 50 percent increase in arsenic prices would increase Tacoma revenues by approximately $1.5 million per year based on 10,000 tons produced per year and a $300/ton price at the time of this record. It would appear to OSHA that a price and revenue increase of this magnitude would be quite possible in view of the recent price history and other reasons discussed above.

This standard will therefore result in additional smelting revenues of $1.5 million and additional arsenic revenues of $1.5 million, or total increased revenues of $3 million annually. ASARCO has stated that Tacoma pretax profits averaged $1.9 million and these two figures total $4.9 million.

The Arthur Young estimate for annual costs at the 4 μg/m³ level is $3.85 million. This number is based on some assumptions based upon the provisions of the proposal and not the final standard. There will be a lower level of operating costs initially as a result of the immediate installation of fewer engineering controls. The increased exposure limit will reduce respirator use, but the installation of fewer engineering controls will increase it. Hence the changes will, at least in part, balance out.

The ASARCO estimate for annual costs at Tacoma is summarized by A. D. Little at page 15 of their Report. The basis of this data is testimony by ASARCO management and Caplan. A. D. Little did not independently review the figures. The figure estimated in $7.68 million. Other figures given are capital charges which are discussed above.

However the ASARCO estimate includes two figures which are substantial over-estimates. The operating expenses for engineering controls given are $2.77 million based on immediate installation of $41.1 million of engineering controls. If for example it is decided at the compliance level that it is only feasible to install one-third of those controls by 1980, then the operating costs of engineering controls would be reduced by approximately two-thirds or $1.84 million to $0.93 million.

ASARCO estimates a $3.24 million annual cost for loss of efficiency from respirator use. This is based on all 900 production employees wearing respirators full time giving protection to the 4 μg/m³ level and an estimated average loss of efficiency of 20 percent. There are other estimates on the record of loss of efficiency of respirator use ranging down to 8 percent. In addition the change in the final standard from the proposal and new developments in respirator protection since that estimate was made, should substantially reduce the loss of efficiency associated with respirator use.

The change to the 10 μg/m³ level and the use of exposure averaging (which would be based on mean exposure levels), will mean that a significant number of employees may not need to wear respirators at all and many employees will only need to wear respirators part time. Further employees need not wear respirators when in clean rooms. In a number of areas at Tacoma, existing mean exposures (based on personal samples as required by the standard if that data is available) are below 20 μg/m³. Exhibit 29G, Appendix 3 supplied by ASARCO indicates that the Acid Plant, Slimes Building, Electric Shop, Fine Castings, Ore Dock, Main Office, Warehouse, Machine Shop, Anode Department, Mobile Equipment Repair and Bucking Room come in this category. The installation of the most effective engineering controls discussed above, good housekeeping and clean up may eliminate the need for respirators in those areas or greatly minimize it.

The ASARCO estimate is based on employees exposed over 4 μg/m³ having to wear fullface piece respirator which ASARCO believes are less comfortable. It is also based on a substantial number of employees wearing airline respirators. These substantially reduce efficiency in jobs requiring mobility because the hoses interfere. It is not completely clear whether the estimated reduction in efficiency includes an element of the very high loss of efficiency in wearing heavy self-contained breathing apparatus. However it appears from the questioning that Mr. Lindquist's estimate of 20 percent loss of efficiency includes some allowance for that. It also should be noted that the study, which Mr. Lindquist stated he relied on for his 20 percent estimate, was not systematic and did not involve any actual time and motion analysis of lost efficiency.

The final standard will permit one-half facepiece respirators to 100 μg/m³ which will reduce loss of efficiency from possible discomfort wearing full facepieces. There is now a certified dust and acid gas cartridge. Therefore when the SO2 limit is exceeded, the employee is permitted to wear a one-half facepiece respirator up to a concentration of 100 μg/m³ of arsenic and 10 times the sulfur dioxide limit.

In addition there is now available a portable, battery operated certified powered air-purifying respirator (PAPR) which weights only 5 pounds, mostly carried at the belt. Because the face fit is loose, there is a cooling air stream, no breathing resistance and light weight, this type of respirator creates a loss of efficiency substantially below 20 percent and probably below the low end (8 percent) estimate on the record. These respirators may be used where exposures do not exceed 10,000 μg/m³ thus offering the opportunity for replacing airline respirators, negative pressure respirators and self-contained breathing apparatus in the vast majority if not all locations. (See Table 1, paragraph g of standard)

In view of all these factors, OSHA believes that the loss of efficiency from respirator use will be, at most, no more than one-half of the ASARCO estimate. Further OSHA believes that with the increase in the permissible exposure level to 10 μg/m³ and the compliance strategy described, approximately one-half of the number of full time equivalent employees will need to wear respirators as ASARCO estimated. Therefore the loss of efficiency through respirator use is likely to be reduced three-quarters or $2.43 million from ASARCO's $3.24 million estimate.

In view of these two factors, OSHA believes that the ASARCO estimate of annual compliance costs should be reduced by $4.27 million ($2.43 million respirator efficiency plus $1.84 operating costs engineering controls over-estimates) to $3.41 million. OSHA, however, would expect that ASARCO would spend several hundred thousand dollars more on improved housekeeping than the $0.14 million ASARCO estimated.

Based on the above analysis. OSHA believes that the operating cost of the compliance plan described will be within the resources of the Tacoma smelter including its $1.9 million historical annual profits and $3 million additional revenues as a result of this standard and that overall the compliance plan described is feasible. Obviously to the extent conditions change or better analyses become available, suitable adjustments can be made at the compliance level.

The question of future operations at Tacoma in uniquely the decision of ASARCO's management. Evidence on this record indicates that the continuing viability of the smelter depends on many factors beyond the control of OSHA or anyone, such as copper prices, availability of British Columbia concentrates, Japanese subsidy policies, and a number of other considerations. Nor as a matter of policy or of law does OSHA believe it appropriate to ignore health considerations because difficult feasibility questions may exist. ASARCO figures indicate a substantial excess of lung cancer deaths at Tacoma. Certainly, major efforts are required to reduce this risk.

Consideration of additional capital investment for engineering controls in the early 1980's, is best analyzed in compliance proceedings at that time, in the light of the circumstance and available resources then existing. In addition as engineering controls succeed in reducing exposure levels, respirator use will be reduced. The resulting savings in respirator costs will make available additional sums for further engineering controls.

VIII. SUMMARY AND EXPLANATION OF THE STANDARD

The following sections discuss the individual requirements of the standard. The sections include an analysis of the record evidence, the recommendations of NIOSH, and the policy considerations underpinning the decisions on the particular provisions of the standard. As discussed in the PEL section above, the final standard sets a permissible exposure limit to inorganic arsenic of 10 μg/m³. Engineering controls and work practices are required where necessary and written compliance plans must be developed. Other portions of the standard including those on respirators, protective clothing, hygiene facilities, and exposure monitoring have been revised and clarified as described in detail below.

It should be noted that the language of many of the standard's provisions and the order of the paragraphs have been changed to be consistent with the drafting in recent OSHA health standards such as the acrylonitrile proposal (43 FR 2608), benzene final standard (43 FR 5913), and the final coke oven standard (41 FR 46784). OSHA believes, to as great extent possible, a similar style should be followed in order to lead to uniformity of interpretation of similar provisions. Section 6(b)(5) of the Act states that health standards shall also be based on "experience gained under this and other health and safety laws."

A. SCOPE AND APPLICATION: PARAGRAPHS (a) AND (b)

This standard applies generally to all occupational exposures to inorganic arsenic. Some of the industries where substantial exposures to inorganic arsenic may occur are non-ferrous metal smelting, glass making, and manufacture of arsenical chemicals and pesticides. There may also be exposures covered by this standard in other areas and industries. Pesticide application, application of arsenical preservatives to wood, use of arsenically treated wood and agricultural uses are exempted. Pursuant to section 4(b)(1) of the OSHA Act, this standard does not apply where other Federal agencies exercise statutory authority to prescribe standards regulating occupational safety or health.

It should be noted that the standard does not cover every place where inorganic arsenic is present. As explained in the background section and FEIS, arsenic is a naturally occurring material and is present in small amounts in many substances. It is therefore inappropriate to cover situations where very low levels of arsenic may be present in substances or products in the workplace, but where they are handled in such a way that the possibility of airborne exposure is minimal. But where the substances containing arsenic are handled or processed in such a way as to create exposure, a possible hazard exists, and the operations come within the scope of this standard.

Several examples may be helpful. If arsenic trioxide is added to glass during manufacture, airborne arsenic is likely to be present and the operation comes within the scope of this standard. However, when that glass is cut or used, airborne exposure is unlikely because the arsenic is bound in the glass, and those operations are outside the scope of this standard. Similarly when gallium arsenide is produced there may be airborne exposures and the operation is covered by this standard. However, when light emitting diodes are assembled into calculators or watches, airborne exposure is unlikely and those operations are outside the scope of this standard.

If the operation comes within the scope of this standard, but exposures are shown to be below 5 μg/m³ after initial monitoring, then there may be no other obligations under this standard except labelling in some circumstances and remonitoring if processes change.

Inorganic arsenic is defined as copper aceto-arsenite and all inorganic compounds containing arsenic except arsine. Copper aceto-arsenite has been specifically noted because of possible confusion on whether it is considered organic or inorganic. As Allied Chemical (Ex. 109) stated copper aceto-arsenite is inorganic. Furthermore, as previously noted it has been implicated as a potential lymphatic cancer agent, which compels its inclusion in this standard.

Arsine has been excluded for several reasons. The proposal did not include arsine and the rulemaking did not consider specifically the special provisions necessary for proper control of exposure and regulation of arsine. Most notably, no suitable sampling technique has been submitted for levels significantly lower than the present standard of 0.05 ppm.

NIOSH and the AFL-CIO suggested that the final standard include arsine. OSHA agrees that arsine has a very high acute toxicity. It has no practical value and exposures occur solely as a result of accidental evolution. It would unnecessarily delay the inorganic arsenic standard to wait for the development of a suitable sampling technique as well as other procedures and there is a current permissible exposure limit for arsine of 0.05 ppm included in Table Z-1 of 29 CFR 1910.1000 to give protection now.

Some parties requested that the scope of the final standard be narrowed and clarified. Spokespersons from several industries expressed their belief that industries handling materials containing less than 0.1 percent arsenic (Exhibits 79, 106, 108, 112) be exempted from the standard. It was their belief that this would provide a reasonable cut-off where exposures would be minimal and provisions such as monitoring need not apply.

OSHA does not feel it is appropriate to exclude those industries handling materials with less than 0.1 percent arsenic from the standard. OSHA feels this standard must be based on the degree of employee exposure to airborne concentrations of inorganic arsenic since the degree of exposure most represents the risk to the employee. It should be noted, for example, that employee exposure in some copper smelters with arsenic levels of less than 0.1 percent in their feed had a number of employees exposed above 10 μg/m³. The inclusion of an action level limits the requirements of the standard (except for initial monitoring and labelling), to employees exposed above 5 μg/m³.

Diamond Shamrock (Ex. 3E) has expressed the view that regulatory activity would be difficult where naturally occurring organic arsenicals may be mixed with inorganic arsenic. They further stated that since they believed there was no analytical method for distinguishing individual arsenic compounds, only total arsenic can be measured. Diamond Shamrock, therefore, recommended that only operations involved in smelting ores, conversion of arsenic trioxide and primary application of arsenical products be included. Dr. Braman (Ex. 145) has demonstrated that there is a sensitive method capable of distinguishing between organic and inorganic arsenic. Natural background levels of arsenic are in the range of approximately 0.01 to 0.04 μg/m³. The higher levels reported in smelter communities cannot be considered natural, and are typically not high enough to interfere with sampling at a 5 μg/m³ action level. In most facilities it can be determined whether workers are exposed to inorganic or organic arsenicals based upon the chemicals present and processes used. In those cases where both are present, a determination at the enforcement level can be made as to the percentage of exposure to organic arsenic, using Dr. Braman's or other methods.

The standard excludes pesticide application from its scope. The EPA regulates most pesticide applications and has a program to extend its regulations as necessary including suitable protection for employees.

The manufacture of pesticides is not considered pesticide application and is covered by this regulation. Most agricultural uses are pesticide application.

As discussed in the background section of this preamble one of the major uses of arsenic is to impregnate wood so as to preserve it from rot and insects. The manufacture of the preservative solution is covered by this regulation as is the manufacture and formulation of other pesticides. However, EPA regulates the impregnation of the wood by the preservative as a pesticide application. EPA is now reviewing the registration of arsenical preservatives and has indicated that it is considering new requirements for application and use including suitable protection for employees. OSHA believes it advisable to avoid duplicative regulation when employees will be suitably protected, and therefore the impregnation of wood with arsenical preservative is not covered by this regulation.

EPA currently does not regulate the use of preserved wood. Based on the evidence in this record the arsenic in the preserved wood is bound tightly to the wood sugars, exhibits substantial chemical differences from other pentavalent arsenicals after reaction, and appears not to leach out in substantial amounts (Exhibits 31 C-2, 5, 6, 7, 21, 36). Therefore OSHA does not believe it appropriate to regulate the use of preserved wood on the basis of the current record.

If further information indicates the need for regulation, and other agencies have not exercised jurisdiction, OSHA will institute proceedings to suitably regulate employee exposure to arsenically preserved wood.

PARTICULATE SIZE

The proposed standard was based on the regulation of worker exposure to all particle sizes of inorganic arsenic. Some parties requested that this requirement be changed so that only arsenical particulates of "respirable size" (less than 10 micrometers mass median diameter) be regulated (Exhibits 3F, 3T, 23A, 106, 108, 109). This position has been summarized by Engelhard Minerals & Chemicals Corp. (Exhibit 3F) as follows:

> Since the Rule clearly refers only to arsenic exposure in terms of mg As/m³ of air in the workplace, it is implicit that the Rule is intended to cover only airborne arsenical particulates or aerosols and should, therefore, indeed be restricted to those only in the *respirable* particulate size range, i.e., less than approximately 10 microns e.s.d., since particles larger than this are non-respirable and physiologically rejected.

There are two major routes of entry of airborne concentrations of inorganic arsenic. The primary route is inhalation. The secondary route, ingestion. Little is known about the absorption and translocation of arsenic in the various regions of the upper respiratory tract, lung and the gastrointestinal tract after inhalation and ingestion. Although the size of particle admitted by the inhalation route is limited by the aerodynamic principle of particle deposition, a similar limitation does not apply to arsenic that may possibly be ingested. Furthermore, too little is known about the absorption and translocation of *differently sized particles* in the lung, upper respiratory tract, lung and gastrointestinal tract to predict with confidence the final body dose. Accordingly, OSHA believes it appropriate to take the most protective stand and provide adequate protection from all particle sizes of airborne arsenic.

B. CEILING LIMIT: DELETION

In contrast to the proposal, the final standard does not provide for a ceiling limit to supplement the permissible exposure limit. In the principally affected industry, copper smelting, there will be brief unpredictable exposure to higher levels of arsenic as a result of the smelting process. OSHA believes that engineering controls now available would not prevent occasional excursions above a ceiling limit though there are practices and controls available which will reduce their frequency and extent.

For the permissible exposure limit of 10 $\mu g/m^3$ to be met, employers will have to implement feasible engineering and work practice controls which will tend to reduce the number and extent of excursions over the permissible exposure limit. In this manner, the standard assures that protection will be provided to employees.

C. ACTION LEVEL: PARAGRAPH (B)

The proposal contained an action level of 2 $\mu g/m^3$ which triggered the monitoring, medical, regulated area, hygiene facilities and protective clothing requirements of the proposed standard. This requirement has been retained in the final standard, but the numerical value has been changed to 5 $\mu g/m^3$ in light of the change of the permissible exposure limit.

Many industry spokepersons believed that the action level was overly burdensome, stating their opinion that if the permissible exposure level were a level that adequately protects workers, no action level should be required (Exhibits 3A, 3W, and 112). Others believed that it was probably impossible to reduce employee exposures to 2 $\mu g/m^3$ in many locations, and therefore felt it should be deleted (Exhibits 3-L, 30, 3v). It was also pointed out that it would be difficult to measure a 2 $\mu g/m^3$ level.

In the absence of a demonstrated safe level for a carcinogen, OSHA has limited employee exposure to the maximum extent feasible by the use of engineering and workpractice controls. OSHA believes it is appropriate to begin some protective actions prior to exceeding the permissible exposure limit. The action level serves such a purpose. Another purpose of the action level is to help to relieve the burden on employers by providing a cut-off point for many of the required compliance activities under the standard. The standard necessarily encompasses some employers whose employees are exposed to levels below the permissible exposure limits. Such employers are required to perform initial monitoring to determine the extent of their employees' exposures to inorganic arsenic. If, on the basis of the results of the initial measurement, exposure is below the action level, the employer may discontinue monitoring and most other compliance activities for that employee. The action level concept thus provides an objective means for an employer to determine what further actions are required for compliance with the standard.

The statistical basis for determining the action level has been discussed in connection with several proposed OSHA health standards (See, for example, "Proposed Standard for Trichloroethylene" (Oct. 20, 1975, 40 FR 49032)). In brief, although all measurements on a given day may fall below the permissible exposure limit, some possibility exists that on unmeasured days the employee's actual exposure may exceed the permissible limit. Where exposure measurements are above one-half of the permissible exposure limit, i.e., the action level, the employer cannot reasonably be confident that his employees may not be overexposed. (Leidel, N. A., et al., "Exposure Measurement Action Level and Occupational Environmental Variability." DHEW, PHS, DCD, NIOSH, DLCK (August 1975)). Therefore, requiring periodic employee exposure measurements to begin at the action level provides the employer with a reasonable degree of confidence in the results of his measurement program.

However, OSHA has reduced the number or requirements and burden of requirements triggered by the action level, while maintaining its major benefits. The action level has been raised from 2 $\mu g/m^3$ to 5 $\mu g/m^3$, thereby reducing the number of workers and number of establishments required to do more than initial monitoring by this standard.

D. REGULATED AREAS AND NOTIFICATION OF USE: PARAGRAPHS (D) AND (F)

The final standard requires that regulated areas (RA) be established and access limited to authorized persons.

This section is to aid in limiting exposure to inorganic arsenic. By limiting access to the RA to authorized persons, the standard requires the employer to prevent those persons who are not authorized to enter the RA from doing so and thereby being exposed to inorganic arsenic. Other purposes of this section are to designate those areas in which precautionary signs are posted, and to designate those employees subject to quarterly exposure monitoring. Additionally, employees working in regulated areas are covered by the washing and showering provisions and certain activities such as smoking and eating are prohibited within regulated areas.

The proposed standard required that the regulated area be established at the action level. Commentors (Ex. 3B, 108, 112) suggested that the regulated area be established in areas in which exposure exceeds the permissible exposure limit (sometimes refered to as the PEL or TWA limit). This suggestion has been adopted for the Final Standard and is consistent with the approach taken in other OSHA standards for carcinogens.

The proposed standard required that a daily roster of all persons who enter the RA be made and maintained for at least forty years or the duration of employment plus 20 years whichever is longer (Ex. 2a, 40 FR 3397, 3400). The final standard does not requiare that a roster be kept.

Commentors have criticized this provision as excessively interfering with day to day operations (Ex. 3B). OSHA has concluded that rosters would be of little use in limiting worker exposure to inorganic arsenic. Other records such as medical records and results of exposure to monitoring required by the standard would provide more useful information and obviate the need for a roster.

The proposed standard prohibited eating, drinking and applying cosmetics in areas where employees were exposed above the action level. The specific prohibition was located in the Hygiene paragraph of the proposal.

The limitation on eating, smoking and applying cosmetics in regulated areas is necessary to prevent the ingestion of inorganic arsenic. As discussed elsewhere in the preamble, the ingestion of inorganic arsenic has been implicated as a cause of cancer. There is the possibility of the translocation of arsenic within the body after ingestion. Further it is OSHA's policy to limit all routes of exposure to carcinogens. Moreover, inorganic arsenic is a skin irritant. Applying cosmetics in its presence would retain arsenic against the skin.

Drinking water is permitted within regulated areas. The possibility of heat stress exists in smelters. Therefore it is necessary to have water readily available.

Paragraph (r) of the proposal required employers with regulated areas to notify OSHA area offices. This requirement has been retained in paragraph (d) of the final standard so that OSHA will be aware of facilities where substantial exposure to arsenic exists.

E. EXPOSURE MONITORING AND MEASUREMENT: PARAGRAPH (E)

The standard requires each employer who has a place of employment where there is exposure to inorganic arsenic as the result of the employers' activities to monitor their employees' exposure to inorganic arsenic over an eight hour period without regard to the use of respiratory protection. Section 6(b)(7) of the Act (29 U.S.C. 655) mandates that any standard promulgated under subsection 6(b) shall, where appropriate, provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees.

There are various reasons which make it appropriate for employers to measure employee exposure to inorganic arsenic. First, exposure monitoring informs the employer whether he is meeting his legal obligation to keep employee exposures below the permissible exposure limit. Second, exposure monitoring evaluates the effectiveness of the installation of engineering and work practice controls and informs the employer whether additional controls need be instituted. Third, exposure monitoring is necessary in order to determine whether respiratory protection is required at all, and if so, which respirator is to be selected.

Fourth, section 8(c)(3) of the Act (29 U.S.C. 657) requires employers to promptly notify any employee who has been or is being exposed to toxic materials or harmful physical agents at levels which exceed those prescribed by an applicable occupational safety and health standard and to inform such employee of the corrective action being taken. Exposure monitoring is necessary in order to determine whether employees are being exposed to inorganic arsenic at levels exceeding that prescribed by this standard and therefore should be notified as required by the Act. Finally, the results of exposure monitoring are part of the information which it is necessary to supply to the physician.

The need to conduct exposure monitoring was generally accepted by participants in the rulemaking process. A requirement that monitoring be done was included in the proposed standard. In view of this support and for the reasons stated above, the standard establishes a requirement for employers to monitor employee exposure to inorganic arsenic. The monitoring of airborne exposure is consistent with the proposal and other health standards.

Some industry spokespersons expressed their preference for biological monitoring (urinary arsenic measurements) (Ex. 29G, Ex. 118) stating that biological monitoring best defines the risk to the employee, that it is equally effective and much less expensive (Ex. 3T). Some feel that this form of biological monitoring can be used as an indication of the total effectiveness of control programs, including the effectiveness of respirator usage and the personal hygiene habits of the employee (Ex. 118). ASARCO (Ex. 29G, App. 7) presented a regression analysis of urinary arsenic levels versus airborne arsenic exposure levels. In this analysis, the average individual employee's urinary arsenic level taken on ten consecutive days were regressed on the corresponding average individual employee airborne arsenic exposure. The data on which this correlation is based is contained in Exhibit 125. Based on the 23 employees so measured, a weak to moderate linear correlation (regression coefficient of 0.528) was observed.

During the April 1975 hearing, NIOSH representatives were asked to evaluate the urinary arsenic determinations as an indicator of worker exposure (ATR 372-6). Dr. Blejer responded:

> From my background as a physician and knowledge of various plants, not smelters, which handle inorganic arsenicals, the urinary excretion of arsenic is an extremely variable and inconstant thing for any individual.
>
> Occupationally, I have learned and I was taught, as well, to treat results—all the results—to group them and take means or average but not on individual bases, because of dietary and many, many other factors.
>
> Therefore, the results of an individual would not be indicative of an exposure and if they were to be enormously high, which would be about the only way that you could tell that they were occupationally related, I would say, then you would be corroborating what would have to be a fairly gross exposure or overexposure. [ATR 373]

OSHA has concluded that it is not appropriate to use urinary arsenic measurements as the primary means for determining employee exposure. Airborne monitoring is effective and is capable of detecting levels over the permissible exposure limit before over exposures to employees occur. Urinary monitoring is variable and the correlation between airborne and urinary levels is only weak to moderate. OSHA has further concluded that it will not require urinary arsenic determinations as a supplement to airborne monitoring. However, employers may use it as an additional monitoring technique if they believe it useful in their particular circumstances.

The requirement for airborne monitoring is limited to employers who have a place of employment where inorganic arsenic is released as a result of their operations. There are trace amounts of naturally occurring arsenic in the atmosphere (.01-.04 μg/m³) and without this limitation, all employers would be required to monitor. (For a discussion of this limitation see the Scope and Application section.)

The standard requires that the measurements be made by monitoring which is representative of each employee's exposure to inorganic arsenic over an eight hour period without regard to the use of respiratory protection. Exposure measurements for each individual employee would, of course, be an indication of that employee's exposure. However, this may be unnecessarily burdensome in some instances, as some industry participants have suggested. Monitoring which is truly representative of an employee's exposure would provide the necessary information and in many instances would involve fewer samples.

The employee exposure measurements are to be made without regard to the use of respiratory protection. In order to use the results of exposure monitoring to evaluate the effectiveness of the required engineering and work practice controls, to determine whether additional controls must be instituted, and to ascertain which, if any, respirator must be used, it is necessary to know employee exposure levels without the use of respiratory protection.

Exposure conditions vary throughout the day (Exhibit 29G). At least one sample is to be taken during each shift in order to ensure that exposure measurements represent exposures of employees on all shifts. Employees working in the same area doing different jobs may have different exposures. Therefore the standard requires sampling for each job classification as well. The samples are to be full-shift samples to give a more accurate indication of an employee's average exposure during a work shift than would sampling for less than a full shift. Short-term samples would tend to be affected by the variability or inorganic arsenic emissions associated with operations such as copper smelting. Full-shift samples tend to average out these variations. As time is needed to issue and retrieve samplers, full shift sampling is defined as sampling for at least seven working hours. The proposed standard did not expressly set forth these requirements for accurate monitoring. The standard has been clarified by requiring these procedures for the reasons stated above. All of those requirements are intended to ensure that the monitoring is truly representative of an employee's exposures.

Paragraphs (d)(1) and (d)(2) of the proposed standard allowed the employer to visually inspect each work place and work operation to accurately determine if any worker was exposed above the action level (Exhibit 2A, p. 3400). OSHA has reconsidered this provision. It is not possible by visual inspection to accurately determine worker exposure. Accurate initial determinations are crucial, particularly when dealing with a carcinogen. Accordingly, this provision has not been included in the standard and the employer must monitor and measure the employee's actual exposures.

The final standard requires remeasurement every 3 months for employees exposed above the TWA limit and every 6 months for those exposed between 5 and 10 μg/m³. In addition a remeasurement is required where the initial measurement is below 5 μg/m³ if there is a significant change in process or materials which could result in additional exposures.

The proposal required monthly measurements for employees exposed above the permissible exposure (TWA) limit and bimonthly for employees exposed between the action level and the TWA limit. Employers criticized these frequencies as being too burdensome in relation to the possible health benefits (Ex. 3A, Ex. 3B, Ex. 118).

There are substantial fluctuations in exposure conditions, hour to hour and day to day at smelters, the largest industry affected by this standard (Ex. 29A, Ex. 29G). The higher the measurement frequency, the higher the accuracy of the employee exposure profile. On the other hand, monthly or bimonthly monitoring of significant numbers of employees at some smelters would require major resources including trained personnel. Monitoring could not be generally concluded during a few days, but would necessarily be carried out over a longer period of time.

Therefore OSHA has lowered the monitoring frequency.

Any choice of a lower measurement frequency is judgmental. OSHA now believes that requiring measurements at 3 and 6 month intervals in the circumstances of the particular industries affected by this standard will reflect employee exposure with sufficient accuracy to assure that suitable precautions will be taken as needed.

The standard requires that in those instances in which measured exposure ranges between 5 and 10 μg/m³, these measurements shall be repeated at least every 6 months. OSHA recognizes that the accuracy of monitoring and measurement will decrease as exposure decreases below 10 μg/m³. Therefore, the standard requires an accuracy of plus or minus 35 percent rather than 25 percent for exposures between 5 and 10 μg/m³. However, periodic measurement is appropriate when exposures are in the 5-10 μg/m³ range because of the possibility that minor changes in process, materials, or weather may raise exposure to above the TWA limit and to compensate for the possibility that such measurements are falsely low.

Periodic monitoring and measurement are not required when initial measurements are below 5 μg/m³. It is unlikely when exposures are at this level that minor fluctuations in process, materials, or weather or measurement accuracy would result in false negative readings below the TWA limit. It would not be appropriate to require periodic measurements in those operations where exposures would be well below the permissible exposure limit. If there is a significant change in materials or process in an area where exposure was under 5 μg/m³, remeasurement would be required.

The standard requires that whenever there has been production, process, or control change which may result in new or additional exposures to inorganic arsenic, or whenever the employer has any other reason to suspect an increase in employee exposure, the employer shall repeat the required monitoring and measurements for those employees affected by such change or increase. A redetermination which was also included in the proposed standard, is required in order to ensure that the most recent monitoring accurately represents the existing exposure conditions. This is necessary so that the employer may take the appropriate actions such as instituting additional engineering controls and providing the appropriate respiratory protection.

Section 8(c)(3) of the Act (29 U.S.C. 657) requires employers to promptly notify an employee who is exposed in excess of the permissible exposure limit. The proposal required that the employee be notified in writing within 10 days of the sampling. OSHA agrees with the statements by some industry participants that 10 days would not allow sufficient time for sample analysis (Ex. 3D). This would be particularly true in such cases where many samples need be analyzed or where samples would be sent to other locations for analysis. Accordingly, the standard requires an employer to notify each employee in writing of that employee's measurement within five working days after the receipt of the results of any required measurements.

ASARCO (Ex. 111, Attach. 10; Ex. 1608) twice sent inorganic arsenic samples for analysis by outside laboratories. In contrast to the second trial, samples were not replicated and were not distributed on a double blind basis in the first trial. Therefore, the results of the first trial are not as significant as those of the second trial.

In the second trial, five laboratories randomly chosen from the 7 laboratories used in the study, were sent one blank, filter three filters containing

2.5 μg arsenic and three filters containing 6.0 μg of arsenic. The two remaining laboratories were sent one blank filter as well as one filter each containing the other two concentrations. The results of the second trial are found in Table III of "Results of Trace Arsenic Analyses Performed by Various Laboratories" (Attached to Ex. 160B).

The results indicated that 5 of the laboratories did not achieve an accuracy of plus or minus 25 percent for the arsenic samples analyzed. However, 2 of the laboratories (including the ASARCO laboratory, Laboratory B in the table) did achieve accuracies of plus or minus 10 percent.

The final standard requires that the method and measurement have an accuracy of plus or minus 25 percent (with a confidence level of 95 percent) for concentrations of inorganic arsenic greater than or equal to 10 $\mu g/m^3$. It requires a method of sampling with an accuracy of plus or minus 35 percent for concentrations of inorganic arsenic between 5 and 10 $\mu g/m^3$.

As noted previously, the standard requires full shift personal monitoring (minimum 7 hours) for the determination of employee exposure. Using personal monitoring pumps at a flow rate of 2 liters per minute, with a 7 hour sampling time, 8.4 μg of inorganic arsenic will be collected if the airborne concentration is 10 $\mu g/m^3$. The equivalent sample at airborne concentrations of 5 $\mu g/m^3$ will be 4.2 μg of inorganic arsenic.

The ASARCO tests indicate that accuracies of plus or minus 10 percent can be achieved by experienced laboratories with samples of between 2.5 and 6 μg of inorganic arsenic. Therefore the minimum amounts of arsenic which would be collected under the final standards requirement fall within the range which can be accurately analyzed by experienced and qualified personnel such as those at ASARCO's own laboratories. It is also sufficiently large so that sample comtamination will not excessively affect the results.

It should be noted that the laboratory methods used by the two laboratories with best results were atomic absorption and colorimetric methods. These methods are relatively simple methods commonly in use by industrial hygiene laboratories. More sensitive methods are available, such as X-ray fluorescence and d.c. discharge emission methods (Ex. 145). These more sensitive methods can be used to analyze with improved accuracy much lower arsenic concentrations. However, these methods are somewhat more difficult and expensive for many laboratories to use and in the typical industrial setting the problem of sample contamination would exist at such lower levels.

ASARCO noted that possible contamination might significantly elevate results at the small sample size range of the proposed action level of 2 $\mu g/m^3$. The potential effects of contamination have been reduced in the final standard due to the increased TWA limit and action level. The sample size collected at the 10 $\mu g/m^3$ TWA limit will be 5 times greater than at the proposed 2 $\mu g/m^3$ action level. Thus a similar level of contamination will only have one-fifth the effect. Similarly, an equivalent level of contamination at the 5 $\mu g/m^3$ action level will have only 40 percent of the effect which would occur at a 2 $\mu g/m^3$ level. Therefore a level of contamination of 0.5 μg suggested by ASARCO as a possibility will not be a major factor relative to the sample sizes resulting from monitoring at the permissible exposure limit and action levels in the final standard.

One question raised was whether particulate sampling methods could efficently collect arsenic released in the smelting environment. It has been suggested that arsenic trioxide has a significant vapor pressure and that it would not be efficiently collected at the elevated temperatures of copper smelting. An ASARCO study (Ex. 160B) indicates the efficient collection is possible at the temperatures of copper smelting. Using millipore personal monitor cassettes (0.8 micron pore size), backed up by midget impinger containing potassium permanganate or sodium hydroxide, ASARCO observed that the millipore filter had better than 95 percent collection efficiency of arsenic in the smelter (Ex. 160 B, Refs. 8, 9). As can be calculated from Table 1, Ex. 160B; capture efficiencies ranged from 98.5 percent to 99.6 percent for total arsenic particulate ranging from 45.6 to 224.8 $\mu g/m^3$. The vapor and/or submicron particulate evading capture ranged from 0.26 to 0.62 $\mu g/m^3$. Thus, assuming that the highest value (0.62 $\mu g/m^3$) was eluding collection with an airborne concentration of 10 $\mu g/m^3$, 93.8 percent collection efficiency would result.

F. METHODS OF COMPLIANCE: PARAGRAPH (g)

The final standard requires that engineering controls and work practices be used to control employee exposure to inorganic arsenic, except to the extent that the employer can show they are not feasible. If all feasible engineering and work practice controls do not succeed in reducing exposure below the permissible exposure limit, they must be supplemented by respiratory protection. This is changed from the proposal which required that all feasible engineering controls be instituted before reliance could be placed on work practices. However, OSHA's experience has been that engineering controls must be coupled with suitable work practices to maximize their effectiveness. Consequently, the final standard allows joint use of engineering and work practice controls. Respiratory protection may be used only during the time period necessary to install engineering controls, where engineering controls may be inappropriate such as during some maintenance operations or in those cases when both engineering controls and work practices do not succeed in reducing exposures below the permissible exposure limit.

This compliance strategy has been consistently OSHA's policy and has been followed in prior standards and proposed standards. This policy is based upon the view that the most effective means of controlling employee exposure is to contain emissions of toxic substances at their source through the use of mechanical means combined with work practices. This is far more effective than reliance on the highly variable human behavior so critical to the successful use of respirators. As discussed below, respirators have many disadvantages which preclude primary reliance or co-reliance of respiratory protection on an equal basis with engineering and work practice controls. Furthermore, the burden of reducing employee exposure should more properly rest on the employer in whose establishment toxic substances are released rather than placing the burden of respirator use on the exposed employee.

ASARCO appeared to propose an alternative compliance strategy (Ex. 29 p. —; Ex. 111-7, p. 19; Ex. 118). Biological monitoring would be used, using an assumed safe urinary arsenic level of 250 μg/liter as a trigger. In those instances in which the urinary arsenic levels were above 250 μg/liter, workers would be removed, and/or engineering controls or respiratory protection would be instituted. ADL (Ex. 111-7) suggested this would be a much less costly approach. However, ADL did not include the costs of engineering controls to reduce exposures in areas in which the urinary levels were consistently above the specified limit. Therefore the ADL cost estimate is only a fraction of the actual costs unless it was proposed that employees be constantly rotated from areas of lower exposure to those of higher exposure and conversely, to reduce high exposures.

OSHA does not believe this is an appropriate compliance strategy. As discussed in the monitoring section, there is a weak correlation between urinary arsenic levels and environmental arsenic levels and there are other difficulties with biological monitoring. The ASARCO proposed urinary arsenic level cannot be shown to be a safe level. Thus, employees exposed for more than 25 years in the lowest urinary arsenic exposure category (exposures under 200 μg/liter) did have excess respiratory cancer mortality (though it is true earlier exposures may have been higher). Further, as discussed in the occupational health implications section, there is a significant body of scientific opinion that it is not possible given present methodology to demonstrate a safe level for a carcinogen. The limited amount of evidence ASARCO has submitted is not sufficiently convincing to adopt their approach.

OSHA also does not believe in many circumstances it is an appropriate compliance strategy to rotate employees into and out of high exposure areas to reduce worker exposures to carcinogens. This approach would present the possibility of increasing the number of workers exposed to higher levels of a carcinogen. If ASARCO proposes to use engineering controls to reduce exposures, then the ADL cost figures are misleading as they just indicate monitoring costs. The actual cost of the ASARCO strategy will be much nearer the cost of the standard compliance strategy since a substantial amount of engineering controls would have to be installed.

The Council on Wage and Price Stability (Ex. 169) and some industry representatives (see Ex. 12 for example) suggested a control strategy involving principal reliance on respiratory protection, to reduce the cost of compliance. However, as will be discussed in a subsequent section, there are many difficulties with respiratory protection as testified by respirator expert Bruce Held (ATR 227-229) as well as some industry representatives (Ex. 29H). Because of the difficulties in face fit, it is difficult to know whether the respirators actually provide adequate protection. Respirators, by interfering with vision, hearing, and mobility, can cause safety problems. Some employees cannot wear respirators because of breathing difficulties. Finally, it is not appropriate to place the burden of compliance principally on the employee, as would be the case if respiratory protection were the principal means of reducing employee exposure. Therefore, OSHA retains in the standard the policy of principal reliance on engineering controls and work practices, except in circumstances where there appears to be no feasible alternative to more substantial reliance on respiratory protection.

Even in situations in which engineering controls will not succeed in reducing exposure levels below the TWA limit, it is still appropriate to require all feasible engineering controls to be installed, even though they would have to be supplemented by the use of respiratory protection. The engineering controls, by minimizing the exposure, without regard to the use of respirators, will have minimized the potential for over exposure resulting from poorly fitting respirators and will usually reduce the number of employees who need to wear respirators.

The final standard clarifies the language in the proposal by clearly placing the burden on the employer, for proving or disproving feasibility. The employer is in the best position to gather evidence on feasibility in a particular workplace. He is most familiar with his own production processes and engineering modifications which can be made. Further it is the policy of the OSHA Act that employers be required to take steps to investigate the feasibility of controls and install them as necessary.

(G) RESPIRATORY PROTECTION: PARAGRAPH (h)

The standard requires that respirators be used only during the time period necessary to install or implement feasible engineering and work practice controls, in operations where engineering controls are not appropriate such as some maintenance operations, in work operations in which such controls are not feasible or are not yet sufficient to reduce exposure to the permissible limit, or in emergencies. These restrictions on the use of respirators are consistent with the requirements of 29 CFR 1910.1000(e) and with good industrial hygiene practice.

Many comments (Exhibit 11, 19, 29G, 29H, 117, 118, 119) cited problems associated with respirators. Respirators are to be considered secondary to the objective of limiting emissions at the source (ATR 229). Proper facial fit is essential, but due to variations in individual facial dimensions, as well as facial hair, scars or growths, is difficult to maintain. Fatigue and reduced efficiency may occur more rapidly among workers wearing respirators due to increased breathing resistance, heat stress and reduced vision (ATR 228). Safety problems presented by respirators must be considered. Respirators can limit vision (ATR 228). This can be significant, in smelters, for example where physical hazards exist and the employee's ability to see is important (ATR 246, Ex. 29G). Speech is also limited. Voice transmission through a respirator can be difficult, annoying and fatiguing. Communication may make the difference between a safe efficient operation and a hazardous operation, especially in dangerous jobs. (ATR 245, Ex. 29G, p. 13). Entanglement of hoses of air respirators as well as limited mobility due to hose lengths (ATR 242) are problems in heavy industrial environments. Self-contained breathing apparatus have the problem of carrying around a heavy weight (ATR 242.)

It is clear that respirators cannot generally be considered as the primary means of employee health protection. OSHA has carefully considered all these problems and has nonetheless concluded that if the permissible exposure limit is exceeded then employees must use the respirators provided. Where engineering controls and work practices do not succeed in reducing exposure below the permissible exposure limit, it becomes necessary to utilize respirators to give sufficient health protection to employees.

In situations where a significant number of employees will be wearing respirators for more than a short period of time, the employer is required to institute a more elaborate respiratory protection program to maximize the effectiveness and minimize the discomfort of extended respirator use. Items to be considered for inclusion in such a program are making available a greater variety of respirators for employee use, having a technician fully trained in respirator use and selection, and organizing the work so that part of the day can be spent in clean rooms or areas where the TWA limit is not exceeded. The employer should also plan to provide respirators with microphones or other communication equipment where needed.

Respiratory protection also has a role during maintenance operations as well as during emergency situations. However the goal of the standard is the control of emissions at the source to minimize the need for respirators.

Since it is apparent that respirators may be necessary, an evaluation of respirators for inorganic arsenic use is necessary. The standard contains two respirator selection tables (Tables I and II) so the employer will provide the respirators which afford the proper degree of protection based on the airborne concentration of inorganic arsenic. These tables are principally based on the NIOSH recommendation made during the September 1976 hearings (Ex. 146B) and OSHA's experience in this and other rulemakings. However, a significant change has been made from the NIOSH recommendations. This principally involves permitting the use of air purifying respirators with half mask and high efficiency filter for protection against nonvolatile arsenicals including arsenic trioxide.

During the September 1976 hearings, NIOSH (Ex. 146A, 146B, STR 67) recommended that only chemical cartridge and gas mask respirators be used where workers are exposed to inorganic arsenic compounds based on theoretical considerations that some arsenic compounds may have high vapor pressures. Questions have been raised whether arsenic trioxide has significant vapor pressure at ambient temperatures (Ex. 129) and at elevated temperatures (Ex. 146, 157).

To see whether arsenic vapor might be eluding capture by high efficiency filters ASARCO conducted a respirator experiment (Ex. 160B No. 2). Respirator testing was performed by suspending the respirators from a metal bar supported by two ring stands. None of the test equipment was worn by a worker. To simulate a good fit against a worker's face, each respirator backing was covered with at least four thicknesses of plastic wrap. Two sampling trains were used. One employed a probe located inside the sealed respirator followed by a preweighed millipore filter. The millipore filter was backed up by impingers containing potassium permanganate or sodium hydroxide. A personal monitor (10 to 20 liters per minute flow rate) was used as the suction source. The second sampling train consisted of a probe, millipore filter, giant Greenburg-Smith impinger, dry gas meter and pump (10-20 liters per minute flow rate). Efficiencies of the high efficiency filters averaged better than 99 percent for protection against arsenic (Ex. 160B, No., 8, 9). Table 1 (Ex. 160B) contains the summary of ASARCO's results. It is noteworthy that the highest vapor and or sub/micron concentration was 0.66 $\mu g/m^3$ both inside and outside the respirator indicating that any vapor problem is minimal in comparison to the permissible exposure limit. Thus, air purifying respirators with high efficiency filters will be allowed in the final standard except for inorganic arsenic compounds with demonstrated significant vapor pressure.

Arsenic trioxide as well as some other arsenicals, are skin irritants and can cause skin irritation where the facepiece of the respirators comes in contact with the worker's face. Because they found no documented study indicating a threshold for eye irritation and because they judged there was an increased potential for skin irritation using half-masks, NIOSH recommended that full facepiece respirators be the minimal protection against particulate arsenic (STR 77-8). The record does not support these points. ASARCO has noted that complaints of eye irritation have been relatively few, mostly having arisen from gross accidental exposure to dust or to impaction of large particles on the eye (Ex. 164). Safety glasses which are now worn by smelter workers, have been noted to protect such smelter workers, except in rare occasions (Ex. 164). Finally, the use of a full facepiece would result in more skin contact with the rubber or plastic of the facepiece resulting in more discomfort and sweating. The increased contact and increased sweating has resulted in more skin irritation from arsenic trioxide dust. (Ex. 164). For the above reasons, OSHA will continue to allow the use of half-facepieces for protection against inorganic arsenic particulate.

In those situations where arsenic compounds do have high vapor pressures, the NIOSH recommendations for such a situation are followed. Table II of the standard specifies the respirators which must be worn to prevent excess exposure to arsenicals with high vapor pressures. Two chemicals which do have significant vapor pressure are arsenic trichloride and arsenic phosphide.

During the April 1975 hearing, Bruce Held (ATR 231-236) recommended changes to the proposed respirator selection table in paragraph (g)(2) of the proposal (Ex. 2A). Mr. Held stated that "constant flow" should be deleted from (g)(2)(i)(B), "pressure demand" changed to "demand" (g)(2)(iv)(A) and (g)(2)(v)(B) to "demand". We have adopted these recommendations using more recent terminology. The protection factors used in the table reflect the factors found in the August 2, 1976 joint OSHA/NIOSH Standard Completion Program Respirator Decision Logic (Ex. 146C).

There are numerous factors which affect the performance of air purifying respirators. These include the filter material and the fit of the facepiece on the wearer. Also important is wearer acceptance and training.

Proper fit of the respirator is critical. As a negative pressure is created within the facepiece when the wearer breathes, unfiltered air may enter the facepiece if gaps exist. Obtaining a proper fit on each employee may require the employer to provide two or three different mask styles.

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. 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. This contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

The employer must check to see that the employees' respirators fit properly and that leakage is at a minimum. A rapid simple fit test can be performed at the start of each shift by each employee wearing a negative pressure respirator. This test can be either a positive pressure test, in which the exhalation valve is closed and in which the wearer exhales into the facepiece to produce a positive pressure, or a negative pressure test, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Employees should be trained to perform this test.

The standard requires a qualitative fit test at the time of initial fitting and semiannually thereafter. If the particulate filters can be replaced with chemical cartridges, isoamyl acetate can be used to qualitatively test facepiece fit. If the employee can smell the isoamyl acetate while wearing the respirator it can be concluded that the particular respirator will not provide suitable protection.

The standard requires that employers with more than 20 employees wearing respirators provide a quantitative fit test at the time of initial fitting and semiannually thereafter. In a quantitative fit test the level of leakage and degree of protection is specifically measured by instrumentation. These tests are more accurate and provide greater assurance that the respirator is providing proper protection. One type of quantitative fit test involves using a simple hood, sodium chloride vapor, and automated instrumentation. At least one such device is commercially available at less than $10,000. These tests can be performed rapidly (10 to 20 minutes) and are relatively easy to perform. This requirement is limited to employers with more than 20 workers wearing respirators. At present, organizations are not available to provide these testing services. Therefore the requirement is limited to employers with greatest need for testing and for whom it is reasonable to acquire the equipment. However, OSHA recommends that all employers who have access to quantitative fit testing make use of such facilities for employees who regularly wear respirators. There was no specific requirement for quantitative fit tests in the proposal. But subsequent developments of equipment to make them relatively easy to carry out and the greater assurance of proper protection they provide, make it appropriate that they be required for employers with significant numbers of employees on respirators.

The standard makes the wearing of respirators voluntary, at the option of the employee until December 31, 1979 except when employees are exposed in excess of 50 $\mu g/m^3$. While exposures in excess of the permissible exposure limit do constitute a hazard, OSHA believes that it is necessary to mitigate some of the problems associated with respirator use and to permit time for educating and training employees in the need for and use of respirators. During the voluntary period, control measures, such as installation of engineering controls and improved work practices can be implemented. These controls will result in an improved work environment which will substantially reduce the number of employees required to wear respirators. The voluntary nature of respirator use prior to December 31, 1979 does not reduce the employer's obligation to train employees in the proper use of the respirators and to make the appropriate respirators available. Indeed, since the employee is being granted a greater responsibility for his or her own protection, special attention must be given to the training program so the employee can make an informed choice.

The proposal required immediate use of respirators whenever employees were exposed in excess of the TWA limit. This would have essentially required the wearing of respirators by a large number of workers in some facilities on the effective date of the standard. The transition period provided by the final standard will alleviate this burden and permit more time for training and implementation of a respirator program. The employer is required to provide respirators for employees exposed between 10 and 50 $\mu g/m^3$ as soon as possible but with an outside limit of December 1, 1978 to allow time which may be needed to purchase and receive a sufficient number of respirators. There are fewer employees exposed between 50 $\mu g/m^3$ and 500 $\mu g/m^3$ and those employees face more severe risks. Therefore respirators must be supplied as soon as possible and no later than October 1, 1978 for those employees. Respiratory use is now required for employees exposed over 500 $\mu g/m^3$ and therefore respirators continue to be required from the effective date of this standard.

The standard requires that employees wearing air-purifying respirators be permitted to replace the respirator's filter whenever they detect a significant increase in breathing resistance. When the filter becomes loaded, the movement of air through the filter becomes restricted forcing the employee to breathe harder to overcome this resistance. The wearing of the respirator becomes increasingly more uncomfortable and it may not be used as a result. To aid in the minimizing of the discomfort of wearing a respirator and to keep the respirator working efficiently the employee must be allowed to change filters when the need arises.

The wearing of a respirator in an arsenical atmosphere can result in skin irritation as the dust may accumulate around the facepiece seal. To prevent this irritation and to minimize the discomfort of respirator use, employees must be allowed to periodically wash their faces and respirator facepieces in order to remove the accumulation of inorganic arsenic.

It will be necessary for some production employees in some smelters to wear respirators for a substantial percentage of the day for a number of years. Subsequent to the arsenic proposal and hearings, NIOSH has certified a lightweight Powered Air Purifying Respirator (PAPR). In addition, other types are under development. It is OSHA's experience that in many circumstances, PAPR's are more comfortable to wear and provide better protection. They are light, under positive pressure and do not require a tight facial fit thereby minimizing irritation and breathing resistance. Except in cold weather, the air stream provided makes them more comfortable. They have a higher protection factor than negative pressure respirators since face fit is not a crucial factor. While they are more expensive, they interfere with work far less than negative pressure respirators. Therefore, OSHA believes it appropriate that employees have the option of wearing PAPR's. Consequently, the standard gives the employee the option of wearing PAPR's in appropriate circumstances after December 1, 1978. The employer must also supply a combination dust filter with a gas sorbent where there will be exposure to gases (such as sulfur dioxide) over the relevant limit for that gas some of the time. This will be the case some of the time in smelters. If over-exposures to gases are relatively continuous, PAPR's would not provide suitable protection.

H. PROTECTIVE CLOTHING AND EQUIPMENT PARAGRAPH (j)

The standard requires the employer to provide and assure that employees use protective clothing and equipment where the employee is exposed above the permissible exposure limits to prevent contamination of street clothing, to prevent skin and eye irritation and to prevent skin absorption of arsenic trichloride. The employer is responsible for cleaning and replacing the clothing as necessary. Specifically, the employer is to provide coveralls or other full body clothing, gloves, and shoes. The employer must also provide eye protection and other equipment, when necessary to prevent skin or eye irritation.

The final standard makes a number of changes from the proposal to respond to the comments, to clarify the language and to utilize the experience developed in the Coke Oven Emissions proceeding. The clothing is to be supplied to employees exposed above the 10 $\mu g/m^3$ level. It is necessary that protective clothing and shoes be required to prevent contamination of the employees' street clothing and shoes, so that exposure is not extended beyond the work day. At exposures lower than the PEL, it is less likely that clothing will become significantly contaminated with inorganic arsenic.

Impervious protective clothing is required for those workers working with arsenic trichloride, because it can be *rapidly* absorbed through the skin.

The proposal required the employer provide and clean daily protective clothing. The final standard reduces the frequency to weekly, except where there is a significant probability of skin irritation because of exposures above 100 $\mu g/m^3$ such as in some locations in the ASARCO, Tacoma arsenic plant. The original requirement was designed to reduce skin irritation. However, at levels approaching 10 $\mu g/m^3$, skin irritation is unlikely. Accordingly, the cleaning requirement is changed to weekly to reduce the burden on the employer. At levels where skin irritation is likely, or at lower levels where skin irritation is occurring, the daily cleaning requirement is retained.

The final standard clarifies that the obligation is on the employer to provide protective equipment at no cost to the employee. In this way the employer is in the best position to provide the correct type of equipment and keep it in repair. Also, as the employer has permitted exposures to exceed the permissible exposure limits the obligation properly rests on the employer. The cost of necessary equipment has been included in the various economic analyses performed.

The standard provides that the employer ensure that all protective clothing is removed at the end of each work shift only in change rooms, and that the clothing that is to be laundered, cleaned, or disposed of be placed in a closable container in the change room. The purpose in requiring such a container is to prevent the contaminants on the clothing from coming into contact with an individual handling the container or being released in the change room. Since the container is to be located in the change room, it is appropriate to limit the removal of contaminated clothing to that area.

Finally, the standard requires the employer to inform those who handle the contaminated articles of the potentially harmful effects of exposure to inorganic arsenic. This provision is designed to make clear the need to use proper care in handling of the contaminated articles.

I. HYGIENE FACILITIES AND PRACTICES: PARAGRAPH (M)

The standard requires that the employer provide clean and suitable change room facilities, lavatories, showers, and lunchrooms for those employees working in regulated areas. One purpose of these requirements is to prevent exposure beyond the work day to the employee. Another purpose is to reduce the likelihood of skin irritation resulting from skin contact with inorganic arsenic. Both of these reasons have been discussed in more detail in the previous section on Protective Clothing and Equipment. A third purpose is to prevent the ingestion of inorganic arsenic.

Certain trivalent arsenicals (arsenic trioxide, sodium arsenite, potassium arsenite, copper acetoarsenite) have been implicated as systemic carcinogens. Some case reports based on long-term administration of medicinals containing potassium and sodium arsenite (Exhibits 180 and 101) and occupational exposure to sodium arsenite and copper acetoarsenite (Paris Green) (see sec. IV C of this preamble) have implicated ingestion of these chemicals as carcinogens. A high incidence of skin cancer has been reported in several populations exposed to high concentrations of arsenic in drinking water (Exhibit 180 pp. 299-301, Exhibit 58). In addition, OSHA believes as a general matter that efforts must be taken to minimize exposure to carcinogens by all exposure routes including ingestion.

The proposal did not include a requirement for lunchrooms with filtered air though it did prohibit eating in regulated areas. Union representatives recommended that such lunchrooms be provided (Exhibits 22, 30, 121). The suggestion has been adopted because such facilities are needed to provide a suitable place, relatively free from contamination to inorganic arsenic, for workers working in regulated areas to eat. In addition, suitable lunchroom facilities will provide an inducement for employees not to eat in regulated areas. As the risk of ingestion is highest in lunchrooms, somewhat more elaborate regulations for their design are included. Since the risk of ingestion is less below 10 $\mu g/m^3$, the standard requires those facilities only for employees exposed above that level rather than at the 2 $\mu g/m^3$ level of the proposal. This change will also reduce the burden on the employer.

Eye wash requirements contained in the proposal have been deleted. There appear to be few locations or arsenicals for which such facilities might be needed to prevent serious eye injury.

The standard requires employers to prevent employee skin or eye contact with liquid or particulate inorganic arsenic which is likely to cause skin or eye irritation. As discussed in the health effects section, some arsenicals cause skin irritation, and keratosis was a condition observed among workers exposed to substantial amounts of arsenic. These keratoses also seem to be related to various forms of cancer which subsequently developed.

Reducing the airborne exposure below the permissible exposure limit should eliminate skin irritation from exposure to arsenic. In areas where exposures are somewhat over the permissible exposure limit, supplying and using appropriate clean protective clothing and gloves as required by the standard should prevent skin irritation. In areas of higher exposure, such as arsenic kitchens, in addition to respirator use, suitable precautions need to be taken to avoid significant skin contact.

Arsenic trichloride is rapidly absorbed through the skin and creates a serious acute toxicity hazard. In consequence all skin and eye contact is prohibited. Where feasible arsenic trichloride should only be utilized in closed systems with suitable backup controls in case of system breakdowns. Where such a system is not feasible, the employer is required to provide impervious protective clothing and suitable respirators.

J. MEDICAL SURVEILLANCE: PARAGRAPH (N)

The standard requires each employer to institute a medical surveillance program for all employees who are exposed above the action level for at least 30 days per year and for employees who have been exposed to levels above the action level for more than 10 years who are no longer exposed above the action level. The record, including recommendations from NIOSH in its updated Criteria Document (Exhibit 99), clearly indicates that a medical surveillance program is appropriate in dealing with the problem of employee exposure to inorganic arsenic. Section 6(b)(7) of the Act provides that:

> * * * where appropriate, any such standard promulgated under subsection 6(b) shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such employment related hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure.

The proposed standard (Exhibit 2a, p. 3400), provided that medical examinations should be given to all employees exposed above the action level. The final standard also requires medical surveillance for all employees exposed above the action level (5 $\mu g/m^3$). Although the level of exposure which triggers medical surveillance has changed, the rationale remains the same.

Some employees may be assigned to work areas where they may be exposed to inorganic arsenic above the action level on a temporary or short term basis, e.g. during vaction periods or certain types of repair work. Therefore a cut-off point for the required medical surveillance program is needed since it would not be appropriate to provide medical surveillance for every employee regardless of duration of exposure. It is important that the time period selected be sufficiently inclusive without being administratively impracticable. The arsenic record did not specifically address this point. Consistent with OSHA's experience gained in the coke oven emissions proceedings where the matter was considered at length, OSHA has determined that 30 days is an appropriate cut-off point for inclusion in medical examinations.

The final standard includes a requirement that all employees who may have been exposed above the action level for 10 or more years must be provided with medical examinations although they are no longer exposed above the action level. The language in the proposal was unclear on this point. Medical examinations are mandated for this group because they represent a potentially higher risk group. Arsenic exposures have been reduced since the 1950's in most smelters and chemical manufacturers.

Long-term employees who have exposures now or in the near future below the action level, but have had exposure above the action level now or in the recent past, are quite likely to have had substantially greater exposures in the more distant past. Dr. Brooks testified on this point (STR 45-52) and the epidemiological studies indicate that risk increases with both *degree* and *duration* of exposure.

The medical examination required is principally based on the known utility of x-ray and sputum cytology as screening tests for respiratory cancer.

Two portions of the proposed medical surveillance protocol have been deleted. These are palpation of superficial lymph nodes and, a complete blood count. As noted previously, lymphatic and hematopoietic cancer excesses have only been observed in worker populations in the Ott and Baetjer studies (in which workers were exposed to sodium arsenite, potassium arsenite, and copper acetoarsenite). As OSHA is not aware of groups of workers in this category at the present time, it is not appropriate to require these tests generally. These tests may be given at the discretion of the examining physician and would be advisable if an employee has been exposed to those chemicals.

Neither the proposal nor the final standard requires that urinary arsenic determinations be a mandatory part of the medical surveillance protocal. The correlation of urinary arsenic levels and airborne arsenic exposure is fairly weak (r=0.528). Urinary arsenic levels vary considerably from individual to individual and time to time. Accordingly, we feel that the use of urinary arsenic determination to supplement monitoring of airborne levels of arsenic should be left to the discretion of the individual company or physician.

All examinations and procedures are required to be performed by or under the supervision of a licensed physician and provided without cost to the employee. Clearly, a licensed physician is the appropriate person to be supervising and evaluating a medical examination. However, certain parts of the required exam do not necessarily require the physician's expertise and may be conducted by another person under the supervision of the physician.

The proposed standard included a requirement that all medical examinations be given during the employees' normal working hours. The final standard does not include the requirement because it may be impractical for shift workers or less convenient for employee or employer. However the employer is obligated to pay for the time spent taking the medical examination if it is taken outside normal working hours and the exam must be given at a reasonable time and place. It is necessary that exams be convenient and without loss to the employee to assure that they are taken.

The standard provides that a work history, medical history and medical examination be performed at the time of initial assignment to areas where exposure exceeds the action level or by December 1, 1978, for employees exposed above the action level at the effective date of the standard. The purposes of this requirement are to make an initial assessment of the health of each employee and to establish a baseline health condition against which changes in an employee's health may be compared. The proposed standard (Exhibit 2a, 40 FR 3401), and Criteria Document (Exhibit 99, p. I-2) all contained requirements for an initial or preplacement exam. The history has been expanded slightly from the proposal to include information on smoking because of its relevance to increased respiratory cancer risk.

The various tests that comprise the medical exam are designed to be used in an initial assessment of an employee's health and to detect changes in health which may occur. The value of each of the specified examinations is described below.

A 14 in. by 17 in. X-ray is a screening test of proven value in the detection of lung cancer. The International Labour Office UICC/Cincinnati (ILO U/C) rating is useful in obtaining uniform quality in the reading of X-rays.

Sputum cytology is required in certain circumstances by the final standard though it was only recommended in the proposal. (See Appendix C to the proposal). The proposal did not mandate sputum cytology on the basis that it should be optional depending on the opinion of the examining physician. Subsequent information received during the coke ovens proceeding indicated that sputum cytology would be of value. The issue was raised more fully in the FEDERAL REGISTER notice of July 16, 1976 (41 FR 29425) which specifically requested comments on this issue and included it as one issue to be considered in the September 1976 hearing.

Comments received from Dr. Dahlgren (Exhibit 137-12) and Health Research Group (Exhibit 137-8), and testimony by Dr. Brooks, a noted expert in the field (STR 45-52), as well as by NIOSH (Exhibit 146) were in favor of requiring sputum cytology. Comments from the Motor Vehicle Manufacturers' Association (Exhibit 137-9) and Dr. Clark Cooper (Exhibit 137-7) were opposed. Anaconda submitted preliminary results of a study of sputum cytology among its workers (Exhibit 165B Appendix E, STR 600-601) which cast doubt on its usefulness. ASARCO recommended that sputum cytology be included on a trial basis (Exhibit 111-3).

Based on the information received, OSHA believes it appropriate to include sputum cytology in the medical surveillance protocol. With the development of the fiberoptic bronchoscope, sputum cytology has become an effective tool for early detection of respiratory cancer among a higher risk population such as workers exposed to inorganic arsenic. (Exhibit 140, 141A). Used in conjunction with X-rays, OSHA is hopeful that such early detection will result in prolonged life for those discovered to have respiratory cancer. X-rays and sputum cytology appear to be complementary, one being more a powerful tool for detection in the peripheral airways while the other is for the central airways. (Exhibit 140, 141A, STR 45-52).

A nasal examination is required because employees with significant exposures to inorganic arsenic are subject to perforation of the nasal septum. A skin examination is also required. Such an examination will detect gross overexposures to arsenic. Such exposure is rare now. However, the examination can be quickly and simply performed and therefore has been included.

The standard provides for semiannual examinations for employees exposed over the action level who are 45 years of age or older, and for employees who have been exposed for 10 or more years above 5 $\mu g/m^3$. All other employees working in regulated areas are to be provided with medical examinations on an annual basis and their examination need not include sputum cytology except for the initial examination. ASARCO recommended a less frequent examination. The frequency in the final standard is consistent with the proposal, Dr. Brook's testimony (ATR 45-52) and OSHA's experience during the coke oven emissions proceeding. The more frequent and more extensive examinations are specified for the higher risk population as discussed above.

Employers are required to make a medical examination available to an employee who has not had one within six months of termination of employment. This was not included in the proposal. It is believed necessary to inform the employee to the extent possible if the condition of his health has been affected during the period of employment.

The employer is required to provide the physician with certain information. The employer is also required to obtain a written opinion from the examining physician containing: the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of health from exposure to inorganic arsenic; the results of the medical examination; any recommended limitations upon the employee's exposure to inorganic arsenic and upon the use of protective clothing and equipment such as respirators; and a statement that the employee has been informed by the physician of any medical conditions which require further examination or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure, and a copy of the opinion must be provided to the affected employee.

The purpose in requiring the examining physician to supply the employer with a written opinion containing the above mentioned analyses is to provide the employer with a medical basis to aid in the determination of initial placement and ability to use protective clothing and equipment of employees. Requiring that opinion be in written form will serve as an objective check that employers have actually had the benefit of this information in making these determinations. Likewise, the requirement that the employee be provided with a copy of the physician's written opinion will insure that the employee is informed of the results of the medical exam and may take any appropriate action. The purpose in requiring that specific findings or diagnoses unrelated to occupational exposure not be included in the written opinion is to encourage employees to submit to medical examination by removing the fear that employers may find out information about their physical condition that has no relation to occupational exposures.

The proposal included a provision that the physician state whether exposure to inorganic arsenic would directly or indirectly aggravate any medical condition. This provision has been deleted from the standard for two reasons: It is vague, in that it is unclear what "aggravate" means. Secondly, it adds nothing to the requirement to determine whether an employee has any detected medical conditions which place the employee at increased risk of material impairment of health from exposure to inorganic arsenic.

The proposed standard included a provision prohibiting the exposure of an employee to inorganic arsenic if the employee would be placed at increased risk of material impairment to his or her health from such exposure (Exhibit 2A, 40 FR 3402). The proposal did not include any provision requiring the transfer of that employee to another job, or requiring that the employee be guaranteed his earlier rate of pay.

In this proceeding, representatives of unions indicated their great concern regarding any requirement for the mandatory removal of employees because of increased risk, in the absence of a medical removal protection or rate retention, right for employees so removed (Exhibit 22, 103). The major argument presented was that in the absence of a medical removal protection provision, such a requirement would constitute a major disincentive to employees to submit to physical examinations because they would fear that an adverse medical opinion could result in loss of employment. As a result, the purpose of the medical surveillance requirements would be undetermined and early detection of illness would, too often, not occur. It was also suggested that the absence of a medical removal protection provision creates a dilemma antithetical to the purposes of the Act—namely, the employee's need to choose between continuing to work but risking his life by continuing to do so, and protecting his health, but losing his job.

The Agency agrees that the approach taken in the proposed standard confronts the employee with a difficult choice and we are sympathetic to the concerns reflected in the unions' position on this issue. However, we believe that the present record does not contain sufficient evidence on the propriety, scope and implications of mandatory transfer and rate retention requirement so as to constitute an adequate basis for the incorporation of such a provision in the standard.

While we are not providing for medical removal protection in the standard, we are convinced that further exploration of this issue is necessary in order to deal in considerably more depth with the numerous issues raised by such a provision. OSHA has held a hearing specifically in regard to medical removal protection for employees exposed to lead. OSHA is now considering the record developed in that hearing. Based on the experience gained in that proceeding OSHA will consider whether medical removal protection should be proposed for employees exposed to other substances.

In the meantime, OSHA has decided to delete the mandatory removal provision. In our view, the issue of mandatory removal is closely related to the issue of rate retention and neither should be addressed in the present standard. The Agency's further study of rate retention will also involve consideration of the mandatory removal question.

(K) EMPLOYEE INFORMATION AND TRAINING: PARAGRAPH (o)

The final standard requires the employer to provide a training program for employees exposed above the action level or for whom there is a possibility of skin or eye irritation from contact with inorganic arsenic.

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 the Criteria Document (Ex. 99, p. 7) and the proposed standard.

The proposal required training in all locations where any inorganic arsenic was released or handled. However, inorganic arsenic is naturally present at very low levels in some substances where there is little possibility of its release. The benefit in requiring training in these circumstances did not seem significant and the scope of the training provision has been narrowed accordingly.

The training program is required to be completed by October 1, 1978, for employees initially covered by the standard and at the time of initial assignment to areas where there is possibility of exposure over the action level or skin irritation otherwise. OSHA believes that it is important to train employees as soon as possible, consistent with developing suitable materials, 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 except that it must be provided quarterly for those employees who have optional use of respirators until December 31, 1979. OSHA believes that an annual training program is both necessary and sufficient to remind the employee of the hazard. Quarterly training is required for employees who have optional use of respirators so that those employees will be in a position to make informed choices regarding the use of respiratory protection.

The content of the training program is intended to apprise the employees of (1) the hazards to which they are exposed; (2) the necessary steps to protect themselves, including minimizing exposure, respiratory protection and medical surveillance; (3) their role in reducing emissions; and (4) their rights under this standard.

The employer is required to make a copy of the standard and its appendixes available to affected employees. This requirement, in combination with the review provided for as part of the training program, is intended to ensure that employees understand their rights and duties under this standard.

The employer is also required to provide, upon request, all materials relating to the training program to the Assistant Secretary and the Director. This is intended to provide an objective check of compliance with the content requirements of the standard. It should be noted that the recordkeeping requirement regarding the training program which had been included in the proposal has not been retained in the standard to reduce the recordkeeping burden. This places greater reliance on access to training materials as a check to ensure that employees are being properly trained.

L. SIGNS AND LABELS: PARAGRAPH (p)

The final standard requires that regulated areas be sign posted stating: "Danger, Inorganic Arsenic Present, Cancer Hazard, Authorized Personnel Only, No Smoking or Eating, Respirator Required". It also requires labeling of containers of inorganic arsenicals, except when the arsenic is bound in such a manner as to make unlikely the possibility of exposure to inorganic arsenic. The labels must state, "Caution, Contains Inorganic Arsenic, Cancer Hazard, Harmful if Inhaled or Swallowed, Use only with Adequate Ventilation or Respiratory Protection".

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 inorganic arsenic, OSHA believes that sign posting is needed as well as periodic training to adequately inform employees of the cancer hazard. The appearance of the phrase "Cancer Hazard" on the warning sign will serve as an objective check on whether employees are actually being informed of this hazard. It is a reasonable precaution to discourage unnecessary entry of occasional visitors to regulated areas. Also, the warning signs will inform all employees entering regulated areas of the need to utilize respirators and other protective equipment which the employer is to provide.

A number of comments were made that such signs would cause unnecessary alarm (Exs. 3E, 3T, 27). Given the evidence of the carcinogenicity of inorganic arsenic, a strong warning is necessary and the word "Hazard" has in consequence been substituted for the ambiguous term, "Suspect Agent." Additionally, the phrases "Authorized Personnel Only" and "No Smoking or Eating" and "Respirator Required" relate directly to requirements in the standard which limit access and activities within regulated areas. (See discussions of Regulated Area and of Hygiene Facilities and Practices.)

All shipping and storage containers of inorganic arsenic compounds and products containing it are required to be labeled with a warning of the cancer hazard and the precautions to be taken. This is so employees handling the materials will treat them with care and take suitable precautions to avoid inhalation. It is necessary to warn employees to take precautions in case of spills or broken containers.

The proposal did not include any exception to this provision. Comments were received stating that the inorganic arsenic present in certain products was bound in such a manner as to make unlikely the possibility of exposure to inorganic arsenic. An example of this is the light emitting diode (Exhibit 137-4). In such circumstances, a warning label is inappropriate because the hazard does not exist. Therefore, the final standard excludes from the labeling requirements, those containers or products in which arsenic is bound in such a manner to make unlikely airborne exposure.

Exposures are not unlikely if dropping, breaking or ordinarily negligent handling will likely result in overexposure.

M. RECORDKEEPING: PARAGRAPH (q)

Section 8(c)(3) of the Act (29 U.S.C. 657) mandates the inclusion of provisions requiring employers to maintain accurate 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 exposures 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. These include names of employees, the physician's written opinion, and copy of the results of the examination. In addition, the initial x-ray and cytology slide, the most recent 5 years of x-rays and 10 years of sputum cytology slides, and all x-ray and cytology slides indicating atypia, or subsequent to atypia must be retained. These records must be kept for 40 years or for at least 20 years after termination of employment, whichever is longer.

The participants at the hearing generally agreed with the necessity for keeping such records, but objected to the length of the record retention period. It is necessary to keep these records for such extended periods of time because of the long latency periods commonly observed for carcinogens. Cancer is often not detected until 20 or more years after onset of exposure. The extended retention period is therefore needed for two purposes. Diagnosis of disease in employees is assisted by having exposure data as well as the results of the medical exams even many years in the past. The original x-ray and cytology slide and those in the recent past are required to provide a baseline as well as a guide to the progression of symptoms. It is necessary to retain monitoring and medical surveillance data for the same period because the data has to be considered together. The second purpose for retaining records for 40 years is so that it will be possible at some future date to review the adequacy of the standard.

The final standard makes a number of changes from the proposal. Some of these reduce the recordkeeping burden. The respirator recordkeeping has been simplified and the retention period made the same length as for exposure measurements so that exposure levels can be assessed. Provisions in the proposal requiring records of employee training and regulated area rosters have not been retained in the final standard. These two records were deleted because there appeared to be little benefit in their retention. Training materials can be inspected when necessary to determine compliance. The roster duplicated data required to be retained for the medical surveillance and exposure records. Records of ventilation testing have been reduced to a notation of the last test and is included as part of the housekeeping paragraph. The initial inspection provisions have been replaced by specific measurement requirements and the recordkeeping requirements have been changed accordingly. The recordkeeping requirements have been substantially reduced as a result of the changes discussed above. The reduction in the monitoring frequency and change in the definitions of persons subject to medical surveillance will also reduce the volume of the records which must be retained.

The final standard, in uniformity with the proposal and other OSHA standards, requires that such records be made available to the Director and Assistant Secretary, that exposure records be available to employees and their representatives, and medical records to an employee or physician 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. The employees or their representatives need access to exposure records because they help the employees determine the effectiveness of the employers' exposure abatement program. The physician needs access to medical records for diagnostic purposes. The transfer provisions are unchanged except that NIOSH is to be notified at the expiration of the retention period so it can determine if the records are still needed for research purposes.

N. EMERGENCIES

The final standard, unlike the proposal, includes no specific paragraph covering emergency situations. OSHA generally includes specific provisions on emergencies for chemicals produced in high pressure processes, where there is the possibility of explosions or other massive release of the substance, or where there are acute toxicity dangers.

In non-ferrous metal smelters these dangers appear unlikely. Arsenic is not generally subject to explosion. Further the arsenic is usually present as only a small percentage in the material stream, making unlikely acute toxicity episodes as a result of equipment breakdown.

Therefore, OSHA has decided to include no specific regulatory paragraph on emergencies. However, it should be noted that the employer is required by the respirator section to have available and provide respirators when a breakdown of equipment or accident leads to high exposures. Further, as a matter of proper industrial practice, OSHA expects employers handling or producing arsenical chemicals where the possibility of acute toxicity exists, to have procedures for safely handling spills, breakage of drums, and equipment breakdowns.

O. OBSERVATION OF MONITORING: PARAGRAPH (r)

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 ensure 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 (s)

The effective date is August 1, 1978.

Q. STARTUP DATES: PARAGRAPH (u)

Startup dates included have been extended from the proposal. This is based on OSHA's experience as to the time required to set up employee training programs and medical surveillance, to order and receive protective equipment and respirators, and to plan, order, receive, and install engineering controls. The approximately 3-month period between the publication of this standard and its effective date provides time to arrange to make available protective clothing and to commence monitoring on the effective date of the standard (or earlier if the employer wishes). It gives additional time to arrange for the implementation of this standard and to order necessary equipment. All startup dates are listed at the beginning of the preamble. It should be noted that some starting dates are set forth in the paragraphs to which they directly pertain. If there is no specific startup date set forth in the standard, then the startup date is the effective date of the standard. The immediate installation of change houses, etc., is not required if installation of engineering controls would only make their use necessary for a few months. 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 section 6(b)(6)(A) of the Act.

R. APPENDIXES: PARAGRAPH (t)

The three appendixes included with the regulation are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligation.

S. ORGANIC ARSENIC AND SPECIFIC ARSENIC COMPOUNDS

The existing entry in Table Z-1 of 1910.1000 reads "Arsenic and its compounds (as As), 0.5 mg/m³," and accordingly covers both inorganic and organic arsenic. The new section 1910.1018 covers just inorganic arsenic. Accordingly the Table Z-1 entry is amended to indicate that just organic arsenic is covered by the 0.5 mg/m³ limit.

Calcium arsenate and lead arsenate are inorganic arsenicals. Accordingly the existing entries in Table Z-1 of § 1910.1000 setting exposure limits for them are deleted. Calcium arsenate and lead arsenate will now be regulated under the new standard on inorganic arsenic in § 1910.1018.

IX. 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 6(b) and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1599; 29 U.S.C. 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 arsenic at § 1910.1018 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, and in Parts 1915, 1916, 1917, 1918, and 1926 of Title 29, Code of Federal Regulations. Therefore, these corresponding standards are superseded by § 1910.1018. This determination, and the application of the new standard to the maritime and construction industries are implemented by adding a new paragraph (e) to § 1910.19.

Signed at Washington, D.C., this 26th day of April, 1978. These amendments are effective on August 1, 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended as follows:

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

§ 1910.19 Special provisions for air contaminants.

* * * * *

(e) Section 1910.1018 shall apply to the exposure of every employee to inorganic arsenic in every employment covered by §§ 1910.12, 1910.13, 1910.14, 1910.15, or 1910.16, in lieu of any different standard on exposure to inorganic arsenic which would otherwise be applicable by virtue of any of those sections.

§ 1910.1000 [Amended]

2. Table Z-1 of § 1910.1000 is amended by deleting the following entries:

"Calcium Arsenate .... 1"
"Lead Arsenate .... 0.15"

and by amending the entry which now reads:

"Arsenic and its compounds (as As)... 0.5 mg/m³."

to read:

"Organic Arsenic compounds (as As)... 0.5 mg/m³."

3. A new § 1910.1018 and appendices A, B and C are added to read as follows:

§ 1910.1018 Inorganic arsenic.

(a) *Scope and application.* This section applies to all occupational exposures to inorganic arsenic except that this section does not apply to employee exposures in agriculture or resulting from pesticide application, the treatment of wood with preservatives or the utilization of arsenically preserved wood.

(b) *Definitions.* "Action level" means a concentration of inorganic arsenic of 5 micrograms per cubic meter of air (5 $\mu g/m^3$) averaged over any eight (8) hour period.

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

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (e) of this section.

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

"Inorganic arsenic" means copper aceto- arsenite and all inorganic compounds containing arsenic except arsine, measured as arsenic (As).

(c) *Permissible exposure limit.* The employer shall assure that no employee is exposed to inorganic arsenic at concentrations greater than 10 micrograms per cubic meter of air (10 $\mu g/m^3$), averaged over any 8-hour period.

(d) *Notification of use.* (1) By October 1, 1978 or within 60 days after the introduction of inorganic arsenic into the workplace, every employer who is required to establish a regulated area in his workplaces shall report in writing to the OSHA area office for each such workplace:

(i) The address of each such workplace;

(ii) The approximate number of employees who will be working in regulated areas; and

(iii) A brief summary of the operations creating the exposure and the actions which the employer intends to take to reduce exposures.

(2) Whenever there has been a significant change in the information re-

quired by paragraph (d)(1) of this section the employer shall report the changes in writing within 60 days to the OSHA area office.

(e) *Exposure monitoring.*—(1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to inorganic arsenic over an eight (8) hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(iii) 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.

(2) *Initial monitoring.* Each employer who has a workplace or work operation covered by this standard shall monitor each such workplace and work operation to accurately determine the airborne concentration of inorganic arsenic to which employees may be exposed.

(3) *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 (e)(4) of this section.

(ii) If the initial monitoring, required by this section, or subsequent monitoring reveals employer exposure to be above the permissible exposure limit, the employer shall repeat monitoring at least quarterly.

(iii) If the initial monitoring, required by this section, or subsequent monitoring reveals employee exposure to be above the action level and below the permissible exposure limit the employee shall repeat monitoring at least every six months.

(iv) The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least seven (7) days apart, are below the action level at which time the employer may discontinue monitoring for that employee until such time as any of the events in paragraph (e)(4) of this section occur.

(4) *Additional monitoring.* Whenever there has been a production, process, control or personal change which may result in new or additional exposure to inorganic arsenic, or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to inorganic arsenic, additional monitoring which complies with paragraph (e) of this section shall be conducted.

(5) *Employee notification.* (i) Within five (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 exposures.

(ii) Whenever the results indicate that the representative employee exposure 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 to reduce exposure to or below the permissible exposure limit.

(6) *Accuracy of measurement.* (i) The employer shall use a method of monitoring and measurement which has an accuracy (with a confidence level of 95 percent) of not less than plus or minus 25 percent for concentrations of inorganic arsenic greater than or equal to 10 $\mu g/m^3$.

(ii) The employer shall use a method of monitoring and measurement which has an accuracy (with confidence level of 95 percent) of not less than plus or minus 35 percent for concentrations of inorganic arsenic greater than 5 $\mu g/m^3$ but less than 10 $\mu g/m^3$.

(f) *Regulated area.*—(1) *Establishment.* The employer shall establish regulated areas where worker exposures to inorganic arsenic, without regard to the use of respirators, are in excess of the permissible limit.

(2) *Demarcation.* Regulated areas shall be demarcated and segregated from the rest of the workplace in any manner that minimizes the number of persons who will be exposed to inorganic arsenic.

(3) *Access.* Access to regulated areas shall be limited to authorized persons or to persons otherwise authorized by the Act or regulations issued pursuant thereto to enter such areas.

(4) *Provision of respirators.* All persons entering a regulated area shall be supplied with a respirator, selected in accordance with paragraph (h)(2) of this section.

(5) *Prohibited activities.* The employer shall assure that in regulated areas, food or beverages are not consumed, smoking products, chewing tobacco and gum are not used and cosmetics are not applied, except that these activities may be conducted in the lunchrooms, change rooms and showers required under paragraph (m) of this section. Drinking water may be consumed in the regulated area.

(g) *Methods of compliance.*—(1) *Controls.* (i) The employer shall institute at the earliest possible time but not later than December 31, 1979, engineering and work practice controls to reduce exposures to or below the permissible exposure limit, except to the extent that the employer can establish that such controls are not feasible.

(ii) Where engineering and work practice controls are not sufficient to reduce exposures to or below the permissible exposure limit, they shall nonetheless be used to reduce exposures to the lowest levels achievable by these controls and shall be supplemented by the use of respirators in accordance with paragraph (h) of this section and other necessary personal protective equipment. Employee rotation is not required as a control strategy before respiratory protection is instituted.

(2) *Compliance Program.* (i) The employer shall establish and implement a written program to reduce exposures to or below the permissible exposure limit by means of engineering and work practice controls.

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

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

(B) Engineering plans and studies used to determine methods selected for controlling exposure to inorganic arsenic;

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

(D) Monitoring data;

(E) A detailed schedule for implementation of the engineering controls and work practices that cannot be implemented immediately and for the adaption and implementation of any additional engineering and work practices necessary to meet the permissible exposure limit;

(F) Whenever the employer will not achieve the permissible exposure limit with engineering controls and work practices by December 31, 1979, the employer shall include in the compliance plan an analysis of the effectiveness of the various controls, shall install engineering controls and institute work practices on the quickest schedule feasible, and shall include in the compliance plan and implement a program to minimize the discomfort and maximize the effectiveness of respirator use; and

(G) Other relevant information.

(iii) Written plans for such a program 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) The plans required by this paragraph shall be revised and updated at least every 6 months to reflect the current status of the program.

(h) *Respiratory protection.*—(1) *General.* The employer shall assure that respirators are used where required under this section to reduce employee exposures to below the permissible exposure limit and in emergencies. Respirators shall be used in the following circumstances:

(i) During the time period necessary to install or implement feasible engineering or work practice controls;

(ii) In work operations such as maintenance and repair activities in which the employer establishes that engineering and work practice controls are not feasible;

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

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required under this section the employer shall select, provide at no cost to the employee and assure the use of the appropriate respirator or combination of respirators from Table I below for inorganic arsenic compounds without significant vapor pressure, or Table II below for inorganic arsenic compounds which have significant vapor pressure.

(ii) Where employee exposures exceed the permissible exposure limit for inorganic arsenic and also exceed the relevant limit for particular gasses such as sulfur dioxide, any air purifying respirator supplied to the employee as permitted by this standard must have a combination high efficiency filter with an appropriate gas sorbent. (See footnote in Table 1)

TABLE I.—*Respiratory protection for inorganic arsenic particulate except for those with significant vapor pressure*

Concentration of inorganic arsenic (as As) or condition of use	Required respirator
(i) Unknown or greater or lesser than 20,000 $\mu g/m^3$ (20 mg/m^3) or firefighting.	(A) Any full facepiece self-contained breathing apparatus operated in positive pressure mode.
(ii) Not greater than 20,000 $\mu g/m^3$ (20 mg/m^3)	(A) Supplied air respirator with full facepiece, hood, or helmet or suit and operated in positive pressure mode.
(iii) Not greater than 10,000 $\mu g/m^3$ (10 mg/m^3)	(A) Powered air-purifying respirators in all inlet face coverings with high efficiency filters.[1] (B) Half-mask supplied air respirators operated in positive pressure mode.
(iv) Not greater than 500 $\mu g/m^3$	(A) Full facepiece air-purifying respirator equipped with high-efficiency filter.[1] (B) Any full facepiece supplied air respirator. (C) Any full facepiece self-contained breathing apparatus.
(v) Not greater than 100 $\mu g/m^3$	(A) Half-mask air-purifying respirator equipped with high-efficiency filter.[1] (B) Any half-mask supplied air respirator.

[1]High-efficiency filter—99.97 pct efficiency against 0.3 micrometer monodisperse diethyl-hexyl phthalate (DOP) particles.

TABLE II.—*Respiratory protection for inorganic arsenicals (such as arsenic trichloride[2] arsenic phosphide) with significant vapor pressure*

Concentration of inorganic arsenic (as As) or condition of use	Required respirator
(i) Unknown or greater or lesser than 20,000 $\mu g/m^3$ (20mg/m^3) or firefighting.	(A) Any full facepiece self-contained breathing apparatus operated in positive pressure mode.
(ii) Not greater than 20,000 $\mu g/m^3$ (20 mg/m^3)	(A) Supplied air respirator with full facepiece hood, or helmet or suit and operated in positive pressure mode.
(iii) Not greater than 10,000 $\mu g/m^3$ (10mg/m^3)	(A) Half-mask[2] supplied air respirator operated in positive pressure mode.
(iv) Not greater than 500 $\mu g/m^3$	(A) Front or back mounted gas mask equipped with high-efficiency filter [1] and acid gas canister. (B) Any full facepiece supplied air respirator. (C) Any full facepiece self-contained breathing apparatus.
(v) Not greater than 100 $\mu g/m^3$	(A) Half-mask [2] air-purifying respirator equipped with high- efficiency filter [1] and acid gas cartridge. (B) Any half-mask supplied air respirator.

[1]High efficiency filter—99.97 pct efficiency against 0.3 micrometer monodisperse diethyl-hexyl phthalate (DOP) particles.

[2]Half-mask respirators shall not be used for protection against arsenic trichloride, as it is rapidly absorbed through the skin.

(iii) The employer shall select respirators from among those approved for protection against dust, fume, and mist by 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) The employer shall perform qualitative fit tests at the time of initial fitting and at least semi-annually thereafter for each employee wearing respirators, where quantitative fit tests are not required.

(iii) Employers with more than 20 employees wearing respirators shall perform quantitative face fit test at the time of initial fitting and least semi-annually 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 I or II.

(iv) If an employee has demonstrated difficulty in breathing during the fitting test or during use, he or she shall be examined by a physician trained in pulmonary medicine to determine whether the employee can wear a respirator while performing the required duty.

(4) *Respirator program.* (i) The employer shall institute a repiratory 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 to prevent skin irritation associated with respirator use.

(5) *Commencement of respirator use.* (i) The employer's obligation to provide respirators commences on August 1, 1978 for employees exposed over 500 $\mu g/m^3$ of inorganic arsenic, as soon as possible but not later than October 1, 1978 for employees exposed to over 50 $\mu g/m^3$ of inorganic arsenic, and as soon as possible but no later than December 1, 1978 for employees exposed between 10 and 50 $\mu g/m^3$ of inorganic arsenic.

(ii) Employees with exposures below 50 $\mu g/m^3$ of inorganic arsenic may choose not to wear respirators until December 31, 1979.

(iii) After December 1, 1978 any employee required to wear respirators may choose, and if so chosen the employer must provide, if it will give proper protection, a powered air purifying respirator and in addition if necessary a combination dust and acid gas respirator for times where exposures to gases are over the relevant exposure limits.

(j) *Protective work clothing and equipment*—(1) *Provision and use.* Where the possibility of skin or eye irritation form inorganic arsenic exists, and for all workers working in regulated areas, the employer shall provide at no cost to the employee and assure that employees use appropriate and clean protective work clothing and equipment such as, but not limited to:

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

(ii) Gloves, and shoes or coverlets;

(iii) Face shields or vented goggles when necessary to prevent eye irritation, which comply with the requirements of § 1910.133(a)(2)(a)(6); and

(iv) Impervious clothing for employees subject to exposure to arsenic trichloride.

(2) *Cleaning and replacement.* (i) The employer shall provide the protective clothing required in paragraph (j) (1) of this section in a freshly laundered and dry condition at least weekly, and daily if the employee works in areas where exposure are over 100 $\mu g/m^3$ of inorganic arsenic or in areas where more frequent washing is needed to prevent skin irritation.

(ii) The employer shall clean, launder, or dispose of protective clothing required by paragraph (j) (1) of this section.

(iii) The employer shall repair or replace the 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 prescribed in paragraph (m) (1) 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 inorganic arsenic outside the container.

(vi) The employer shall inform in writing any person who cleans or launders clothing required by this section, of the potentially harmful affects including the carcinogenic effects of exposure to inorganic arsenic.

(vii) The employer shall assure that the containers of contaminated protective clothing and equipment in the workplace or which are to be removed from the workplace are labelled as follows:

CAUTION: Clothing contaminated with inorganic arsenic; do not remove dust by blowing or shaking: Dispose of inorganic arsenic contaminated wash water in accordance with applicable local, State, or Federal regulations.

(viii) The employer shall prohibit the removal of inorganic arsenic from protective clothing or equipment by blowing or shaking.

(k) *Housekeeping*—(1) *Surfaces.* All surfaces shall be maintained as free as practicable of accumulations of inorganic arsenic.

(2) *Cleaning floors.* Floors and other accessible surfaces contaminated with inorganic arsenic may not be cleaned by the use of compressed air, and shoveling and brushing may be used only where vacuuming or other relevant methods have been tried and found not to be effective.

(3) *Vacuuming.* Where vacuuming methods are selected, the vacuums shall be used and emptied in a manner to minimize the reentry of inorganic arsenic into the workplace.

(4) *Housekeeping plan.* A written housekeeping and maintenance plan shall be kept which shall list appropriate frequencies for carrying out housekeeping operations, and for cleaning and maintaining dust collection equipment. The plan shall be available for inspection by the Assistant Secretary.

(5) *Maintenance of equipment.* Periodic cleaning of dust collection and ventilation equipment and checks of their effectiveness shall be carried out to maintain the effectiveness of the system and a notation kept of the last check of effectiveness and cleaning or maintenance.

(l) [Reserved.]

(m) *Hygiene facilities and practices*—(1) *Change rooms.* The employer shall provide for employees working in regulated areas or subject to the possibility of skin or eye irritation from inorganic arsenic, clean change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing and equipment in accordance with 29 CFR 1910.141(e).

(2) *Showers.* (i) The employer shall assure that employees working in regulated areas or subject to the possibility of skin or eye irritation from inorganic arsenic shower at the end of the work shift.

(ii) The employer shall provide shower facilities in accordance with § 1910.141(d)(3).

(3) *Lunchrooms.* (i) The employer shall provide for employees working in regulated areas, lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees working in regulated areas.

(ii) The employer shall assure that employees working in the regulated area or subject to the possibility of skin or eye irritation from exposure to inorganic arsenic wash their hands and face prior to eating.

(4) *Lavatories.* The employer shall provide lavatory facilities which comply with § 1910.141(d) (1) and (2).

(5) *Vacuuming clothes.* The employer shall provide facilities for employees working in areas where exposure, without regard to the use of respirators, exceeds 100 $\mu g/m^3$ to vacuum their protective clothing and clean or change shoes worn in such areas before entering change rooms, lunchrooms or shower rooms required by paragraph (j) of this section and shall assure that such employees use such facilities.

(6) *Avoidance of skin irritation.* The employer shall assure that no employee is exposed to skin or eye contact with arsenic trichloride, or to skin or eye contact with liquid or particulate inorganic arsenic which is likely to cause skin or eye irritation.

(n) *Medical surveillance*—(1) *General*—(i) *Employees covered.* The employer shall institute a medical surveillance program for the following employees:

(A) All employees who are or will be exposed above the action level, without regard to the use of respirators, at least 30 days per year; and

(B) All employees who have been exposed above the action level, without regard to respirator use, for 30 days or more per year for a total of 10 years or more of combined employment with the employer or predecessor employers prior to or after the effective date of this standard. The determination of exposures prior to the effective date of this standard shall be based upon prior exposure records, comparison with the first measurements taken after the effective date of this standard, or comparison with records of exposures in areas with similar processes, extent of engineering controls utilized and materials used by that employer.

(ii) *Examination by physician.* The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

(2) *Initial examinations.* By December 1, 1978, for employees initially covered by the medical provisions of this section, or thereafter at the time of initial assignment to an area where the employee is likely to be exposed over the action level at least 30 days per year, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history and a medical history which shall include a smoking history and the presence and degree of respiratory symptoms such as breathlessness, cough, sputum production and wheezing.

(ii) A medical examination which shall include at least the following:

(A) A 14" by 17" posterior-anterior chest X-ray and International Labor Office UICC/Cincinnati (ILO U/C) rating;

(B) A nasal and skin examination;

(C) A sputum cytology examination; and

(D) Other examinations which the physician believes appropriate because of the employees exposure to inorganic arsenic or because of required respirator use.

(3) *Periodic examinations.* (i) The employer shall provide the examinations specified in paragraphs (n)(2)(i) and (n)(2)(ii) (A), (B), and (D) at least annually for covered employees who are under 45 years of age with fewer than 10 years of exposure over the

action level without regard to respirator use.

(ii) The employer shall provide the examinations specified in paragraphs (n)(2)(i) and (n)(2)(ii) of this section at least semi-annually for other covered employees.

(iii) Whenever a covered employee has not taken the examinations specified in paragraphs (n)(2)(i) and (n)(2)(ii) of this section within six (6) months preceding the termination of employment, the employer shall provide such examinations to the employee upon termination of employment.

(4) *Additional examinations.* If the employee for any reason develops signs or symptoms commonly associated with exposure to inorganic arsenic the employer shall provide an appropriate examination and emergency medical treatment.

(5) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its Appendices;

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

(iii) The employee's representative exposure level or anticipated exposure level;

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

(v) Information from previous medical examinations of the affected employee which is not readily available to the examining physician.

(6) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical examination and tests performed;

(B) The physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of the employee's health from exposure to inorganic arsenic;

(C) Any recommended limitations upon the employee's exposure to inorganic arsenic or upon the use of protective clothing or equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further explanation or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure.

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) *Employee information and training.*—(1) *Training program.* (i) The employer shall institute a training program for all employees who are subject to exposure to inorganic arsenic above the action level without regard to respirator use, or for whom there is the possibility of skin or eye irritation from inorganic arsenic. The employer shall assure that those employees participate in the training program.

(ii) The training program shall be provided by October 1, 1978, for employees covered by this provision, at the time of initial assignment for those subsequently covered by this provision, and shall be repeated at least quarterly for employees who have optional use of respirators and at least annually for other covered employees thereafter; and the employer shall assure that each employee is informed of the following:

(A) The information contained in appendix A;

(B) The quantity, location, manner of use, storage, sources of exposure, and the specific nature of operations which could result in exposure to inorganic arsenic as well as any necessary protective steps;

(C) The purpose, proper use, and limitation of respirators;

(D) The purpose and a description of the medical surveillance program as required by paragraph (n) of this section;

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

(F) A review of this standard.

(2) *Access to training materials.* (i) The employer shall make readily available to all affected employees a copy of this standard and its appendixes.

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

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

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

(2) *Signs.* (i) The employer shall post signs demarcating regulated areas bearing the legend;

DANGER

INORGANIC ARSENIC

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

NO SMOKING OR EATING

RESPIRATOR REQUIRED

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

(3) *Labels.* The employer shall apply precautionary labels to all shipping and storage containers of inorganic arsenic, and to all products containing inorganic arsenic except when the inorganic arsenic in the product is bound in such a manner so as to make unlikely the possibility of airborne esposure to inorganic arsenic. (Possible examples of products not requiring labels are semiconductors, light emitting diodes and glass). The label shall bear the following legend:

DANGER

CONTAINS INORGANIC ARSENIC

CANCER HAZARD

HARMFUL IF INHALED OR SWALLOWED

USE ONLY WITH ADEQUATE VENITLATION

OR RESPIRATORY PROTECTION

(q) *Recordkeeping.*—(1) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring require in paragraph (e) 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 employees 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 the employees exposure.

(ii) 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 (n) of this section.

(ii) This record shall include:

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

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

(C) Results of any 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 inorganic arsenic.

(iii) The employer shall in addition 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 (n) 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) The initial X-ray;

(D) The X-rays for the most recent 5 years;

(E) Any X-rays with a demonstrated abnormality and all subsequent X-rays;

(F) The initial cytologic examination slide and written description;

(G) The cytologic examination slide and written description for the most recent 5 years; and

(H) Any cytologic examination slides with demonstrated atypia, if such atypia persists for 3 years, and all subsequent slides and written descriptions.

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

(ii) The employer shall make available upon request records of employee exposure monitoring required by paragraph (q)(1) of this section for inspection and copying to affected employees, former employees and their designated representatives.

(iii) The employer shall make available upon request an employee's medical records and exposure records representative of that employee's exposure required to be maintained by paragraph (q) of this section to the affected employee or former employee or to a physician designated by the affected employee or former employee.

(4) *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 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 he requests them within that period.

(r) *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 inorganic arsenic conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) Whenever observation of the monitoring of employee exposure to inorganic arsenic 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 inorganic arsenic performed at the place of exposure; and

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

(s) *Effective date.* This standard shall become effective August 1, 1978.

(t) *Appendixes.* The information contained in the appendixes 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.

(u) *Startup dates.*—(1) *General.* The startup dates of requirements of this standard shall be the effective date of this standard unless another startup date is provided for either in other paragraphs of this section or in this paragraph.

(2) *Monitoring.* Initial monitoring shall be commenced on August 1, 1978, and shall be completed by September 15, 1978.

(3) *Regulated areas.* Regulated areas required to be established as a result of initial monitoring shall be set up as soon as possible after the results of that monitoring is known and no later than October 1, 1978.

(4) *Compliance program.* The written program required by paragraph (g)(4) as a result of initial monitoring shall be made available for inspection and copying as soon as possible and no later than December 1, 1978.

(5) *Hygiene and lunchroom facilities.* Construction plans for changerooms, showers, lavatories, and lunchroom facilities shall be completed no later than December 1, 1978, and these facilities shall be constructed and in use no later than July 1, 1979. However, if as part of the compliance plan it is predicted by an independent engineering firm that engineering controls and work practices will reduce exposures below the permissible exposure limit by December 31, 1979, for affected employees, then such facilities need not be completed until 1 year after the engineering controls are completed or December 31, 1980, whichever is earlier, if such controls have not in fact succeeded in reducing exposure to below the permissible exposure limit.

(6) *Summary of startup dates set forth elsewhere in this standard.*

STARTUP DATES

August 1, 1978—Respirator use over 500 $\mu g/m^3$.

AS SOON AS POSSIBLE BUT NO LATER THAN

September 15, 1978—Completion of initial monitoring.

October 1, 1978—Complete establishment of regulated areas. Respirator use for employees exposed above 50 $\mu g/m^3$. Completion of initial training. Notification of use.

December 1, 1978—Respirator use over 10 $\mu g/m^3$. Completion of initial medical. Completion of compliance plan.

July 1, 1979—Completion of lunch rooms and hygiene facilities.

December 31, 1979—Completion of engineering controls.

All other requirements of the standard have as their startup date August 1, 1978.

APPENDIX A—INORGANIC ARSENIC SUBSTANCE INFORMATION SHEET

I. SUBSTANCE IDENTIFICATION

A. *Substance.* Inorganic Arsenic.

B. *Definition.* Copper acetoarsenite, arsenic and all inorganic compounds containing arsenic except arsine, measured as arsenic (As).

C. *Permissible Exposure Limit.* 10 micrograms per cubic meter of air as determined as an average over an 8-hour period. No employee may be exposed to any skin or eye contact with arsenic trichloride or to skin or eye contact likely to cause skin or eye irritation.

D. *Regulated Areas.* Only employees authorized by your employer should enter a regulated area.

II. HEALTH HAZARD DATA

A. *Comments.* The health hazard of inorganic arsenic is high.

B. *Ways in which the chemical affects your body.* Exposure to airborne concentrations of inorganic arsenic may cause lung cancer, and can be a skin irritant. Inorganic arsenic may also affect your body if swallowed. One compound in particular, arsenic trichloride, is especially dangerous because it can be absorbed readily through the skin. Because inorganic arsenic is a poison, you should wash your hands thoroughly prior to eating or smoking.

III. PROTECTIVE CLOTHING AND EQUIPMENT

A. *Respirators.* Respirators will be provided by your employer at no cost to you for routine use if your employer is in the process of implementing engineering and work practice controls or where engineering and work practice controls are not feasible or insufficient. You must wear respirators for non-routine activities or in emergency situations where you are likely to be exposed to levels of inorganic arsenic in excess of the permissible exposure limit. Since how well your respirator fits your face is very important, your employer is required to conduct fit tests to make sure the respirator seals properly when you wear it. These tests are simple and rapid and will be explained to you during training sessions.

B. *Protective clothing.* If you work in a regulated area, your employer is required to provide at no cost to you, and you must wear, appropriate, clean, protective clothing and equipment. The purpose of this equipment is to prevent you from bringing to your home arsenic-contaminated dust and to protect your body from repeated skin contact with inorganic arsenic likely to cause skin irritation. This clothing should include such items as coveralls or similar full-body clothing, gloves, shoes or coverlets, and aprons. Protective equipment should include face shields or vented goggles, where eye irritation may occur.

IV. HYGIENE FACILITIES AND PRACTICES

You must not eat, drink, smoke, chew gum or tobacco, or apply cosmetics in the regulated area, except that drinking water is permitted. If you work in a regulated area your employer is required to provide lunchrooms and other areas for these purposes.

If you work in a regulated area, your employer is required to provide showers, washing facilities, and change rooms. You must wash your face, and hands before eating and must shower at the end of the work shift. Do not take used protective clothing out of change rooms without your employer's permission. Your employer is required to provide for laundering or cleaning of your protective clothing.

V. SIGNS AND LABELS

Your employer is required to post warning signs and labels for your protection. Signs must be posted in regulated areas. The signs must warn that a cancer hazard is present, that only authorized employees may enter the area, and that no smoking or eating is allowed, and that respirators must be worn.

VI. MEDICAL EXAMINATIONS

If your exposure to arsenic is over the Action Level (5 $\mu g/m^3$)—(including all persons working in regulated areas) at least 30 days per year, or you have been exposed to arsenic for more than 10 years over the Action Level, your employer is required to provide you with a medical examination. The examination shall be every 6 months for employees over 45 years old or with more than 10 years exposure over the Action Level and annually for other covered employees. The medical examination must include a medical history; a chest x-ray; skin examination; nasal examination and sputum cytology exam for the early detection of lung cancer. The cytology exams are only included in the initial exam and examinations given after you are either 45 years or older or have 10 or more years employment over the Action Level. The examining physician will provide a written opinion to your employer containing the results of the medical exams. You should also receive a copy of this opinion. The physician must not tell your employer any conditions he detects unrelated to occupational exposure to arsenic but must tell you those conditions.

VII. OBSERVATION OF MONITORING

Your employer is required to monitor your exposure to arsenic and you or your representatives are entitled to observe the monitoring procedure. You are entitled to receive an explanation of the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you must also be provided with and must wear the protective clothing and equipment.

VIII. ACCESS TO RECORDS

You or your representative are entitled to records of your exposure to inorganic arsenic upon request to your employer. Your medical examination records can be furnished to your physician if you request your employer to provide them.

IX. TRAINING AND NOTIFICATION

Additional information on all of these items plus training as to hazards of exposure to inorganic arsenic and the engineering and work practice controls associated with your job will also be provided by your employer. If you are exposed over the permissible exposure limit, your employer must inform you of that fact and the actions he is taking to reduce your exposures.

APPENDIX B—SUBSTANCE TECHNICAL GUIDELINES

ARSENIC, ARSENIC TRIOXIDE, ARSENIC TRICHLORIDE (THREE EXAMPLES)

I. Physical and chemical properties

A. Arsenic (metal).

1. Formula: As.

2. Appearance: Gray metal.

3. Melting point: Sublimes without melting at 613C.

4. Specific Gravity: (H20=1):5.73.

5. Solubility in water: Insoluble.

B. Arsenic Trioxide.

1. Formula: As203, (As406).

2. Appearance: White powder.

3. Melting point: 315C.

4. Specific Gravity (H20=1):3.74.

5. Solubility in water: 3.7 grams in 100cc of water at 20c.

C. Arsenic Trichloride (liquid).

1. Formula: AsC13.

2. Appearance: Colorless or pale yellow liquid.

3. Melting point: −8.5C.

4. Boiling point: 130.2C.

5. Specific Gravity (H20=1):2.16 at 20C.

6. Vapor Pressure: 10mm Hg at 23.5C.

7. Solubility in Water: Decomposes in water.

II. Fire, explosion and reactivity data.

A. Fire: Arsenic, arsenic Trioxide and Arsenic Trichloride are nonflammable.

B. Reactivity:

1. Conditions Contributing to instability: Heat.

2. Incompatibility: Hydrogen gas can react with inorganic arsenic to form the highly toxic gas arsine.

III. Monitoring and Measurement Procedures

Samples collected should be full shift (at least 7-hour) samples. Sampling should be done using a personal sampling pump at a flow rate of 2 liters per minute. Samples should be collected on 0.8 micrometer pore size membrane filter (37mm diameter). Volatile arsenicals such as arsenic trichloride can be most easily collected in a midget bubbler filled with 15 ml. of 0.1 N NaOH.

The method of sampling and analysis should have an accuracy of not less than ±25 percent (with a confidence limit of 95 percent) for 10 micrograms per cubic meter of air (10 $\mu g/m^3$) and ±35 percent (with a confidence limit of 95 percent) for concentrations of inorganic arsenic between 5 and 10 $\mu g/m^3$.

APPENDIX C—MEDICAL SURVEILLANCE GUIDELINES

I. GENERAL

Medical examinations are to be provided for all employees exposed to levels of inorganic arsenic above the action level (5 $\mu g/m^3$) for at least 30 days per year (which would include among others, all employees, who work in regulated areas). Examinations are also to be provided to all employees who have had 10 years or more exposure above the action level for more than 30 days per year while working for the present or predecessor employer though they may no longer be exposed above the level.

An initial medical examination is to be provided to all such employees by December 1, 1978. In addition, an initial medical examination is to be provided to all employees who are first assigned to areas in which worker exposure will probably exceed 5 $\mu g/m^3$ (after the effective date of this standard) at the time of initial assignment. In addition to its immediate diagnostic usefulness, the initial examination will provide a baseline for comparing future test results. The initial examination must include as a minimum the following elements:

(1) A work and medical history, including a smoking history, and presence and degree of respiratory symptoms such as breathlessness, cough, sputum production, and wheezing;

(2) A 14" by 17" posterior-anterior chest X-ray and an International Labor Office UICC/Cincinnati (ILO U/C) rating;

(3) A nasal and skin examination;

(4) A Sputum Cytology examination; and

(5) Other examinations which the physician believes appropriate because of the employee's exposure to inorganic arsenic or because of required respirator use.

Periodic examinations are also to be provided to the employees listed above. The periodic examinations shall be given annually for those covered employees 45 years of age or less with fewer than 10 years employment in areas where employee exposure exceeds the action level (5 $\mu g/m^3$). Periodic examinations need not include sputum cytology and only an updated medical history is required.

Periodic examinations for other covered employees, shall be provided every six (6) months. These examinations shall include all tests required in the initial examination, except that the medical history need only be updated.

The examination contents are minimum requirements. Additional tests such as lateral and oblique X-rays or pulmonary function tests may be useful. For workers exposed to three arsenicals which are associated with lymphatic cancer, copper acetoarsenite, potassium arsenite, or sodium arsenite the examination should also include palpation of superficial lymph nodes and complete blood count.

II. NONCARCINOGENIC EFFECTS

The OSHA standard is based on minimizing risk of exposed workers dying of lung cancer from exposure to inorganic arsenic. It will also minimize skin cancer from such exposures.

The following three sections quoted from "Occupational Diseases: A Guide to Their Recognition", Revised Edition, June 1977, National Institute for Occupational Safety and Health is included to provide information on the nonneoplastic effects of exposure to inorganic arsenic. Such effects should not occur if the OSHA standards are followed.

A. *Local*—Trivalent arsenic compounds are corrosive to the skin. Brief contact has no effect but prolonged contact results in a local hyperemia and later vesicular or pustular eruption. The moist mucous membranes are most sensitive to the irritant action. Conjunctiva, moist and macerated areas of skin, the eyelids, the angles of the ears, nose, mouth, and respiratory mucosa are also vulnerable to the irritant effects. The wrists are common sites of dermatitis, as are the genitalia if personal hygiene is poor. Perforations of the nasal septum may occur. Arsenic trioxide and pentoxide are capable of producing skin sensitization and contact dermatitis. Arsenic is also capable of producing keratoses, especially of the palms and soles.

B. *Systemic*—The acute toxic effects of arsenic are generally seen following ingestion of inorganic arsenical compounds. This rarely occurs in an industrial setting. Symptoms develop within ½ to 4 hours following ingestion and are usually characterized by construction of the throat followed by dysphagia, epigastric pain, vomiting, and watery diarrhea. Blood may appear in vomitus and stools. If the amount ingested is sufficiently high, shock may develop due to severe fluid loss, and death may ensue in 24 hours. If the acute effects are survived, exfoliative dermatitis and peripheral neuritis may develop.

Cases of acute arsenical poisoning due to inhalation are exceedingly rare in industry. When it does occur, respiratory tract symptoms—cough, chest pain, dyspnea—giddiness, headache, and extreme general weakness precede gastrointestinal symptoms. The acute toxic symptoms of trivalent arsenical poisoning are due to severe inflammation of the mucous membranes and greatly increased permeability of the blood capillaries.

Chronic arsenical poisoning due to ingestion is rare and generally confined to patients taking prescribed medications. However, it can be a concomitant of inhaled inorganic arsenic from swallowed sputum and improper eating habits. Symptoms are weight loss, nausea and diarrhea alternating with constipation, pigmentation and eruption of the skin, loss of hair, and peripheral neuritis. Chronic hepatitis and cirrhosis have been described. Polyneuritis may be the salient feature, but more frequently there are numbness and parasthenias of "glove and stocking" distribution. The skin lesions are usually melanotic and keratotic and may occasionally take the form of an intradermal cancer of the squamous cell type, but without infiltrative properties. Horizontal white lines (striations) on the fingernails and toenails are commonly seen in chronic arsenical poisoning and are considered to be a diagnostic accompaniment of arsenical polyneuritis.

Inhalation of inorganic arsenic compounds is the most common cause of chronic poisoning in the industrial situation. This condition is divided into three phases based on signs and symptoms.

First Phase: The worker complains of weakness, loss of appetite, some nausea, occasional vomiting, a sense of heaviness in the stomach, and some diarrhea.

Second Phase: The worker complains of conjunctivitis, a catarrhal state of the mucous membranes of the nose, larynx, and respiratory passage. Coryza, hoarseness, and mild tracheobronchitis may occur. Perforation of the nasal septum is common, and is probably the most typical lesion of the upper respiratory tract in occupational exposure to arsenical dust. Skin lesions, eczematoid and allergic in type, are common.

Third Phase: The worker complains of symptoms of peripheral neuritis, initially of hands and feet, which is essentially sensory. In more severe cases, motor paralyses occur; the first muscles affected are usually the toe extensors and the peronei. In only the most severe cases will paralysis of flexor muscles of the feet or of the extensor muscles of hands occur.

Liver damage from chronic arsenical poisoning is still debated, and as yet the question is unanswered. In cases of chronic and acute arsenical poisoning, toxic effects to the myocardium have been reported based on EKG changes. These findings, however, are now largely discounted and the EKG changes are ascribed to electrolyte disturbances concomitant with arsenicalism. Inhalation of arsenic trioxide and other inorganic arsenical dusts does not give rise to radiological evidence or pneumoconiosis. Arsenic does have a depressant effect upon the bone marrow, with disturbances of both erythropoiesis and myelopoiesis.

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III. SPUTUM CYTOLOGY

Sputum can be collected by aerosol inhalation during the medical exam or by spontaneous early morning cough at home. Sputum is induced by transoral inhalation of an aerosolized solution of eight per cent (8 percent) sodium chloride in water. After inhaling as few as three to five breaths the subject usually yields an adequate sputum. All sputum should be collected directly into sixty percent (60 percent) alcohol.

Scientific evidence suggests that chest X-rays and sputum cytology should be used together as screening tests for lung tests for lung cancer in high risk populations such as workers exposed to inorganic arsenic. The tests are to be performed every six months on workers who are 45 years of age or older or have worked in the regulated area for 10 or more years. Since the tests seem to be complementary, it may be advantageous to alternate the test procedures. For instance, chest X-rays could be obtained in June and December and sputum cytologies could be obtained in March and September. Facilities for providing necessary diagnostic investigation should be readily available as well as chest physicians, surgeons, radiologists, pathologists and immunotherapists to provide any necessary treatment services.

(Pub. L. 91-596; Secs. 4, 6, 8, 84 Stat. 1592, 1593, 1599 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 8-76 (41 FR 25059); 29 CFR Part 1911).

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