

federal register

TUESDAY, JANUARY 21, 1975

WASHINGTON, D.C.

Volume 40 ■ Number 14

PART III



DEPARTMENT OF LABOR

**Occupational Safety and
Health Administration**

■

INORGANIC ARSENIC

Proposed Exposure Standard

DEPARTMENT OF LABOR

Occupational Safety and Health
Administration

[29 CFR Part 1910]

[Docket No. OSH-37]

STANDARD FOR EXPOSURE TO
INORGANIC ARSENIC

Notice of Proposed Rulemaking

Pursuant to sections 6(b) and 8(c) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1599; 29 U.S.C. 655, 657), Secretary of Labor's Order No. 12-71 (36 FR 8754), and 29 CFR Part 1911, it is proposed to amend Part 1910 of Title 29, Code of Federal Regulations, by adding a new occupational safety and health standard for exposure to inorganic arsenic as § 1910.93r, and by deleting the present standards for arsenic and its compounds, calcium arsenate and lead arsenate, contained in Table G-1 of § 1910.93.

I. Introduction. The toxic effects of inorganic arsenic compounds on man, following oral ingestion, are well known. Some of the effects of acute inorganic arsenic poisoning are vomiting, nausea; diarrhea, irritation, inflammation and ulceration of the mucous membranes and skin; and kidney damage. Among the effects of chronic arsenic poisoning are increased pigmentation and keratinization of the skin, dermatitis, muscular paralysis, visual disturbances, and liver and kidney damage. Both acute and chronic poisoning by ingestion can lead to death.

Findings of excess cancer mortalities among worker populations exposed to airborne concentrations of various inorganic arsenic compounds have implicated inorganic arsenic as an occupational carcinogen. Results of a number of studies have shown sodium arsenite, arsenic trioxide, lead arsenate and calcium arsenate to be cancer-suspect agents (See Section III of this notice). Additionally, such effects as perforation of the nasal septum, conjunctivitis and dermatitis resulting from occupational exposure to airborne concentrations of inorganic arsenic compounds have been cited in the National Institute for Occupational Safety and Health (NIOSH) document, "Criteria for a Recommended Standard.—Occupational Exposure to Inorganic Arsenic."

In view of the observed effects and suspected carcinogenicity of these substances, the Occupational Safety and Health Administration (OSHA) has concluded that a comprehensive occupational health standard is needed to protect employees from the harmful effects of exposure to inorganic arsenic compounds.

In developing this proposed standard, OSHA has considered the NIOSH criteria document; written comments on the NIOSH document received in response to the OSHA advance notice of proposed rulemaking, published in the FEDERAL REGISTER on June 11, 1974 (39 FR 20494); recommended modifications of the criteria document, submitted by

NIOSH on November 8, 1974; and the complete record of the fact-finding hearing announced in the FEDERAL REGISTER on August 30, 1974 (39 FR 31644) and held on September 20, 1974, including all of the evidence presented at the hearing and all written comments received prior to the close of the hearing record on October 20, 1974.

II. Background. Inorganic arsenic, for the purpose of this standard, is defined as arsenic and all inorganic compounds containing arsenic, except arsine. Elemental arsenic (As), a gray metalloid, is primarily found in the ores of metals such as copper, lead, zinc, gold and silver. Arsenic is also widely distributed, in small amounts, throughout the soils and waters of the world. Traces are found in foods, particularly seafood, and in some meats and vegetables.

Arsenic trioxide, the compound used in the synthesis of many other arsenic compounds, is released and obtained primarily as a by-product of the smelting of sulfide ores of copper, zinc or lead. The U.S. consumption of arsenic trioxide has been estimated at 25,000-30,000 tons annually.

Arsenic compounds are manufactured and used as herbicides and pesticides due to their toxic effects on plants and insects. Calcium arsenate and lead arsenate are two of the arsenicals commonly used as insecticides. Calcium, sodium, and zinc arsenites are used as herbicides for the control of weed growth. Arsenic acid is used as a defoliant and desiccant, e.g., in the treatment of cotton prior to machine picking.

In addition to agricultural uses, arsenicals are used in the production of glass, wood preservatives and nonferrous alloys. Small quantities are used in cattle and sheep-dips, pyrotechnics, pigments, poultry feed additives, pharmaceuticals, leather tanning, and anti-fouling paints.

History of the Standard. In 1943, the American Standards Association (now the American National Standards Institute or ANSI) proposed a standard for arsenic of not more than 0.015 milligrams elemental arsenic per cubic meter of air (mg As/cu m). However, by 1945, this standard was increased by a factor of ten to 0.15 mg As/cu m.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommended a Maximum Airborne Concentration (MAC) of 0.1 mg As/cu m, in 1947. This was changed the following year to a Threshold Limit Value (TLV) of 0.5 mg As/cu m. It appears that this level was set to protect against the hazard of dermatitis from arsenic trioxide and without consideration for possible carcinogenicity.

The ACGIH has separate standards for lead arsenate and calcium arsenate. A limit for lead arsenate of 0.15 mg lead arsenate/cu m has remained in effect since 1957. (There are at least six forms of lead arsenate compounds, depending upon the molecular formula. The arsenic content (as As) can range from approximately 0.02 to 0.055 mg As/cu m.) Ac-

ording 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 0.1 mg/cu m, adopted by ACGIH in 1957, was later changed to the present 1.0 mg calcium arsenate/cu m (equivalent to 0.38 mg As/cu m).

The present OSHA standard for "arsenic and its compounds" in Table G-1, of § 1910.93 is 0.5 mg As/cu m, as determined on an eight-hour time-weighted average basis. The present OSHA standards for lead arsenate and calcium arsenate are 0.15 mg/cu m and 1.0 mg/cu m, respectively. These levels were based on the 1968 ACGIH list of Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment (TLV's).

III. Environmental and epidemiological studies. Historically, attention has focused upon issues concerning the specific toxicity of arsenic compounds, the overall toxic mode of respiratory versus skin effects, the lack of animal toxicity data and the question of carcinogenicity. These differences in emphasis are evidenced by the wide variation and numerous changes in the threshold limit values for inorganic arsenic compounds. NIOSH attempted to clarify these issues with an examination of the available studies on various inorganic, arsenic compounds (except lead arsenate and arsine) in the criteria document submitted to OSHA in January, 1974.

The first significant study involved a two-part investigation of the worker population of an English factory which manufactured a sodium arsenite sheep dip. The first part of the study, reported by Hill and Fanning, 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 Fanning reported 22 cancer deaths (29.3 percent) among 75 deceased factory workers as compared to 157 cancer deaths (12.9 percent) among 1,216 deceased workers from other occupations in the community. The excess 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 13.6 percent from skin cancer as compared to 1.3 percent for the general population.

The second part of the study, by Perry et al., 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.

Snegireff and Lombard (1951) 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

the control population (a plant 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.

However, NIOSH's evaluation of the Snegireff and Lombard data found the authors' conclusions to be of questionable validity. NIOSH's analysis revealed a large excess of lung cancer mortality in the worker populations for both plants, when the data were compared to the respiratory cancer death rates for the states in which the plants were located. NIOSH concluded that the authors should have placed more emphasis on the significance of the lung cancer data.

Further, NIOSH questioned the choice of control population. Since both plants were in the metallurgical industry and nearly identical, it may be assumed that both were metal smelters. Thus, based on the information available on the release of arsenic during the smelting of metal ores, there is a question as to whether the control population of employees was not, in fact, exposed to some arsenic trioxide. According to NIOSH, had a more suitable control population been chosen the excess of respiratory cancer might have been more readily apparent.

Pinto and McGill (1953) studied the effects of arsenic trioxide exposure in a copper smelter producing arsenic trioxide as a by-product. Without the use of air measurements, Pinto and McGill divided the workers into "exposed" and "nonexposed" groups. The authors measured the workers' urinary arsenic levels and noted that the urinary arsenic levels for those "nonexposed" averaged 0.13 milligrams of arsenic per liter (mg As/l) while those "exposed" averaged 0.82 mg As/l. As will be discussed below, the division of workers into the two exposure categories is questionable. The authors concluded that arsenic trioxide dust produced an irritant effect on body surfaces, but that systemic toxicity from inhalation was rare.

Milham and Strong, who measured urinary arsenic levels of residents downwind from the smelter studied by Pinto and McGill, found that the residents' urinary arsenic levels decreased with the distance from the smelter. Milham and Strong also collected samples of vacuum cleaner dust and reported that arsenic content of the dust declined from a high of 1300 parts per million parts of dust (ppm) at a distance of 0 to .4 mile from the smelter to 70 ppm at a distance of 2.0 to 2.4 miles. This would suggest that arsenic exposure was not confined to only one section of the smelter, but extended to the surrounding community. Thus, the "nonexposed" control group of smelter workers very likely also had a significant degree of arsenic exposure.

In 1963, Pinto and Bennett analyzed the causes of death for 229 plant workers and pensioners at the same smelter investigated by Pinto and McGill. On the basis of the average urinary arsenic levels found in the Pinto and McGill study, Pinto and Bennett divided the working population into "exposed" and

"nonexposed" groups. Pinto and Bennett concluded that arsenic exposures had no significant effect on the amount of cancer mortalities observed in the plant workers as compared to the cancer mortality rates for the state as a whole. However, these findings have since been challenged.

NIOSH's evaluation of the Pinto and Bennett study showed an increase in lung cancer mortality. As noted above, the "nonexposed" workers probably had, in fact, been subjected to significant occupational exposures. When the "exposed" and "nonexposed" worker populations were combined, 18 lung cancer deaths were found where only 8.6 would have been expected. Further, Dr. Milham stated at the OSHA fact-finding hearing that he had found an additional seven lung cancer deaths among Pinto and Bennett's study population (See fact-finding hearing transcript, hereinafter referred to as FTR, pages 111-116). Combining the 18 lung cancer deaths with the seven additional cases, increases the lung cancer deaths among the workers in the smelter to three times the number expected.

Further, the excess lung cancer mortalities found in the analysis of the Pinto and Bennett study were confirmed by the findings of a study by Milham and Strong, who examined death certificates of former smelter workers who had worked in the same smelter studied by Pinto and Bennett. For the years between 1950 and 1971, 40 lung cancer deaths were found among former smelter workers, where only 18 would have been expected (P less than .001).

In 1969, Lee and Fraumeni, in an effort to clarify the role of arsenic in human carcinogenesis, studied and compared the mortality data of 8,047 white male smelter workers exposed to both arsenic trioxide and sulfur dioxide during 1938-1963, with that of a similar population in the same states. As of December 1963, of the 8,047 workers, 5,397 were known to be alive; 1,877 deceased; and 773 had status unknown. Hence, there were 1,877 observed deaths compared to 1,634 expected deaths (P less than 0.01). The authors divided the deceased workers by duration and degree of exposure to arsenic trioxide and sulfur dioxide. Excesses of lung cancer deaths were found to increase with increasing lengths of exposure to arsenic trioxide. These increases ranged from 2.03 to 4.7 times expected. These groups were further subdivided into "heavy," "medium," and "light" exposures to arsenic trioxide. Lung cancer mortalities for each group were found to increase with increasing degrees of exposure to arsenic trioxide.

Similarly, workers were grouped according to duration and degree of exposure to sulfur dioxide. Again, excess lung cancer mortality was found with increasing exposure to sulfur dioxide. The greatest excesses of lung cancer were found among workers exposed to 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."

Animal Studies. In its 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 studies were designed to observe lung cancer.

The first of these was an inhalation study, by Rozenstein, on albino rats exposed to arsenic trioxide for 24 hours per day, for three months. The study was designed to observe the effects of atmospheric pollution. The second study, by Bencko and Symon, involved an evaluation of hairless mice exposed to fly ash containing .1% arsenic trioxide. The authors observed an accumulation of arsenic in the animals' livers and kidneys from exposures to the fly ash.

At the OSHA fact-finding hearing, Dr. Kraybill, of the National Cancer Institute, discussed the overall lack of carcinogenic animal data, and the important elements to be considered in evaluating animal studies. Of significance, Kraybill said, is the dose given the animal, the adequacy of the numbers of animals within the test and control groups to permit statistical evaluation of the data, and the time frame of the study.

Dr. Kraybill discussed the findings of 20 animal studies included in a review published by the International Agency for Research on Cancer. These studies were primarily concerned with routes of entry other than inhalation. Dr. Kraybill referred to two preliminary reports suggesting possible carcinogenic effects in mice exposed to sodium arsenate, potassium arsenate, and arsenic trioxide. However, Kraybill said that these studies were difficult to interpret and must await further confirmation. Kraybill commented, "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 36-40)

IV. Recent studies and comments. On July 8, 1974, in response to the Notice of Proposed Rulemaking, the Dow Chemical Company submitted a retrospective mortality study, by Ott et al., of the relationship between respiratory cancer and occupational exposure to dry arsenicals (FTR Exhibit #3). Arsenic trioxide was the compound used for the synthesis of the other dry arsenicals. Therefore, OSHA concludes that there may have been some worker exposure to arsenic trioxide as well as to the following dry arsenicals, listed by extent of production, over the 37-year period of the study: lead arsenate (59 percent), calcium arsenate (34 percent), copper acetoarsenate (5 percent), and magnesium arsenate (2 percent).

The Dow study compared the proportionate mortality experience among the

arsenic-exposed employees with the experience among nonexposed employees, for the period from 1919 to 1956. The exposed employee population included only those who had spent one or more days in the arsenical production area. The control group had never worked in the arsenic exposure area. Noteworthy was the fact that of the 173 deaths among exposed employees, 138 of these had worked in the exposure areas for a period of less than one year. Of these 138, 16 died of lung cancer. An increased percentage of cancer deaths was observed among the exposed (32.9 percent) versus the nonexposed (20.7 percent). The authors' analysis of the data indicated an approximate threefold increase in lung cancer for the exposed (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 than expected.

In addition, Ott performed a cohort analysis to supplement the results of the above study by examining mortality data for 603 men who had worked for at least one month in the exposure area. Death rates of this group were compared to those of the U.S. white male population. There were 35 cancer deaths observed among the exposed group versus 19.4 expected. Of the total cancer deaths, 20 lung cancer deaths were observed where 5.8 would have been expected. Additionally, there were 5 deaths attributable to lymphatic cancer, where 1.3 were expected. Hence, the results of the cohort analysis confirmed the findings of the earlier mortality study.

The Allied Chemical Corporation submitted a mortality study to OSHA and NIOSH with findings similar to the Dow study for respiratory and lymphatic cancer deaths (FTR Exhibit #24). The Allied facility had also been engaged in the manufacturing of dry arsenicals for pesticides. 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 retirees with that of the general population of Baltimore, Maryland, the location of the pesticide facility. The study 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, based on figures adjusted for the combined age, race and sex-specific relative frequencies in the general population of Baltimore, were 5.6, 1.5 and 0.18, respectively.

When an analysis was carried out on death rates among male retirees from this plant, Baetjer found even greater differences between observed and expected deaths from all 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 with .05 expected.

Kennecott Copper Corporation (KCC) submitted a survey of mortalities from respiratory diseases observed among its active and retired employees. The study, performed by Drs. T. H. Milby and C. H. Hine, compared the ratios of observed employee deaths to the expected ratios. Additionally, the authors compared 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 the State of Utah. They found that the proportion of respiratory cancer deaths among KCC employees was not very different from the U.S. respiratory cancer death rate or that of Utah State.

Milby and Hine also compared results of their study with three earlier studies of copper smelter workers (Snegireff and Lombard, Pinto and Bennett, and Lee and Fraumeni). Their results of lung cancer deaths were well below those found by the other groups of investigators.

NIOSH's evaluation of the KCC study showed it to be inadequate in several ways. For example, although the study showed no excess lung cancer, it utilized a relatively insensitive technique (analysis by proportionate mortality ratios); it excluded some of the exposed population (workers who left KCC before retirement); and it apparently included many workers who did not have significant exposure to arsenic (e.g. miners).

A study by Kuratsune et al., reported a high frequency of respiratory cancer mortality among workers at a Japanese copper smelter. Kuratsune stated that the results of his study were reported to both the Ministry of Labor and to the employer. On the basis of Kuratsune's findings, the Ministry 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 confirms the findings of excess mortalities in some American smelters.

In 1973, W. C. Nelson et al., of the Environmental Protection Agency (EPA) published a follow-up mortality study for a cohort of 1,231 individuals in Wenatchee, Washington, who had participated in a 1938 mortality survey of the effects of exposures 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 consist-

ently from the amount of exposure to lead arsenate spray. In fact, the orchardists, the most highly exposed group, had the lowest SMR of the three groups analyzed.

Especially noteworthy, however, is the authors' discussion of their 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 as to whom the most exposed individuals were, and that the dosage levels were especially a problem for the intermediate group, who had the most heterogeneous exposure. He also admitted difficulty with interpretation of 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. Moreover, many of the volunteers in the 1938 study "are still too young to have reached high risk mortality age." (FTR Exhibit #28)

Because the results of the Nelson study were at a variance with previous evidence on the long-term effects of arsenic exposure, NIOSH queried EPA regarding possible explanations for the differences, and reviewed data from other sources which might confirm the findings. Upon review of the life table procedure used by Nelson, NIOSH suggested that the unexpected differences noted might have resulted from use of an incorrect statistical technique for computing the expected numbers of deaths. While EPA reported to NIOSH that the statistical method used was entirely appropriate, EPA confirmed the authors' conclusions that the paper had unfortunate methodologic limitations.

Using two types of data sources, NIOSH attempted to independently evaluate the Nelson study findings. The first data source reviewed was occupational mortality data for adult white males in the State of Washington for the period 1950-1971 (FTR Exhibit #34). Dr. Samuel Millham of the Washington Department of Social and Health Services compared disease frequencies of approximately 400 distinct occupational groups and found that deaths due to respiratory cancer were 19 percent higher than expected for the decedents classified as "orchardists". Further, during the most recent 11 years (1961-1971) an increase of 27 percent was observed for lung cancer among orchardists.

The second data source reviewed was age-adjusted mortality rates for specific types of cancers for the three-county area from which the Nelson orchardist sample was drawn. The mortality rates for the three counties during the period 1950 to 1969 were compared to the rates for the state as a whole to identify unusual cancer patterns. NIOSH found that the rates were highest for Chelan County, the county in which the majority of the persons in the Nelson study resided. The mortality data on orchardists and men residing in Chelan

County indicate a significant excess of lung cancer.

Because the two independent sources of information contradicted, rather than confirmed, the Nelson study, NIOSH questioned the negative results found by Nelson. While no explanation for the contradictory results could be determined it appears that the Nelson study did not correctly depict the cancer experience of the persons exposed to lead arsenate in the Wenatchee Valley.

V. *Conclusions.* From an analysis of available studies and consistent with the findings of the National Institute for Occupational Safety and Health and the National Cancer Institute, OSHA considers exposure to airborne concentrations of inorganic arsenic compounds to be strongly implicated as a cause in occupational carcinogenesis.

In six epidemiological studies, excess lung cancer mortalities were observed among worker populations having had exposure to inorganic arsenic compounds. The authors of four other epidemiological studies concluded that there was no significant excess of cancer mortalities among inorganic arsenic workers. However, in the analysis of three of these studies, both NIOSH and OSHA confirmed that excess lung cancer mortalities were involved, but were not observed due to inadequate study designs. No definitive conclusions could be ascribed to the fourth study. Further, it is recognized that the retrospective epidemiological mortality studies are deficient in providing accurate occupational exposure data. However, most of the available studies, including the data submitted by Dow and Allied, do show significant excesses of lung cancer mortalities for workers exposed to a variety of inorganic arsenic compounds.

In the epidemiological studies to date, both the trivalent compounds (such as arsenic trioxide) and pentavalent compounds (such as lead and calcium arsenate) have been observed to be carcinogenic, eliciting lung cancer, lymphatic cancer and skin cancer. While little is known about relative carcinogenic activity of the two valence states of arsenic in the various inorganic compounds, there is no evidence supporting a distinction between the various inorganic arsenic compounds.

The evidence to date, including both environmental and epidemiological studies, shows that exposure to airborne concentrations of inorganic arsenic presents the most significant occupational health hazard. The proposed standard is directed primarily to protect employees from the hazard of airborne concentrations of inorganic arsenic. We have found only limited evidence to date implicating the ingestion of inorganic arsenic and no evidence implicating the ingestion of organic arsenic as a cause of cancer. The proposed standard, however, does protect employees from poisoning due to ingestion of inorganic arsenic. OSHA has no evidence that inhalation of organic arsenic compounds causes cancer and therefore, organic arsenic

compounds are not included in this standard.

With respect to the permissible exposure limits, the proposal sets a limit of .004 mg As/cu m with an action level of .002 mg As/cu m. NIOSH originally recommended, in the criteria document, that the standard for controlling inorganic arsenic exposure, except for lead arsenate and arsine, be set at .05 mg As/cu m. This limit resulted from their evaluation of the then available data, from which they concluded that respiratory cancer was associated with occupational exposure to inorganic arsenic.

However, based on the presently available evidence, which strongly indicates that inorganic arsenic causes cancer, NIOSH now recommends that the standard be set at a "non-detectable" level for all inorganic compounds, except arsine. NIOSH defines non-detectable as "the limit of analytical sensitivity when general workplace air samples are collected for 15 minutes at a flow rate of 10 liters a minute." Application of NIOSH's factors of analytical sensitivity, flow rate, and sampling time, results in an air concentration of .002 mg As/cu m.

OSHA feels that the evidence clearly establishes the need to limit occupational exposures to inorganic arsenic in order to prevent harmful health effects on workers. Since inorganic arsenic is considered to be a carcinogen, and since there is no evidence of a safe level of exposure, it is felt that the exposure levels must be reduced as low as feasible. For the purposes of controlling worker exposures to inorganic arsenic, OSHA believes that a range of .002 to .004 mg As/cu m will significantly reduce, if not prevent arsenic-induced cancer. At the same time, it is felt that such a range will facilitate employer surveillance of exposure conditions, the implementation and maintenance of control measures, and compliance enforcement.

For the implementation of this range, OSHA proposes that employer measurement of inorganic arsenic levels begin at an action level of .002 mg As/cu m, as determined on an eight-hour time-weighted average basis. This level of exposure would also trigger the requirements concerning medical surveillance, regulated areas, and protective clothing.

A ceiling limit of .01 mg As/cu m over any 15 minute period during the work shift is proposed to prohibit significant excursions above the permissible exposure limit.

STUDIES CITED ABOVE

- A. Baetjer, M. Levin, A. Lillienfeld—"Analysis of Mortality Experience of Allied Chemical Plant" unpublished.
- V. Bencko and K. Symon—"The Cumulative, Dynamics in Some Tissue of Hairless Mice Inhaling Arsenic." *Atmos. Environ.* 4 157-61 (1970).
- A. B. Hill, E. L. Fanling—"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).
- M. Kuratsune, S. Tukodome, T. Shirakusa, M. Yoshida, Y. Tokumitsu, T. Hayano, Mr. Seita—"Occupational Lung Cancer Among

Copper Smelters" *Int. J. Cancer* 13 552-8 (1974).

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- M. Ott, B. Holder, H. Gordon—"Respiratory Cancer and Occupational Exposure to Arsenicals" to be published in *Archives of Environmental Health*.
- K. Perry, R. G. Bowler, H. M. Buckell, H. A. Druett, R. S. F. Schilling—"Studies in the Incidence of Cancer in a Factory Handling Inorganic Compounds of Arsenic—II Chemical and Environmental Investigations" *Br. J. Ind. Med.* 5 6-15 (1948).
- S. S. Pinto, B. M. Bennett—"Effect of Arsenic Trioxide Exposure on Mortality" *Arch. Environmental Health* 7 583-91 (1963).
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- L. S. Snegireff and O. M. Lombard—"Arsenic and Cancer—Observations in the Metallurgical Industry" *Arch. Ind. Hyg. Occup. Med.* 4 199-205 (1951).
- World Health Organization, International Agency for Research on Cancer, IARC Monographs on the Evaluation of Carcinogenic Risk to Man: Some Inorganic and Organometallic Compounds, Vol. II, IARC Publishers, Lyon, France 1973.

VI. *The proposed standard.* The proposed standard would include the following major points:

(1) *Scope and application.* The proposed standard would apply to all employers having establishments where inorganic arsenic and its compounds are produced, reacted, released, packaged, repackaged, stored, handled or used, except that this section will not apply to working conditions with respect to which the Mining Enforcement and Safety Administration, Department of the Interior, or the Environmental Protection Agency have exercised statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health. Further, the proposal would apply to transportation of the substances except that this section will not apply to working conditions with respect to which the Department of Transportation has exercised statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health. Although the proposal's scope is broad, including nearly every use of inorganic arsenic, the specific provisions of the proposed standard that would apply to any particular employer, depend upon the amount of the substance actually released in the workplace.

The proposal would apply to all inorganic compounds containing arsenic, with the exception of arsine. In its criteria document, NIOSH excluded lead arsenate and arsine. NIOSH felt that

lead arsenate poses a double threat of chronic lead poisoning as well as acute arsenic intoxication, and should be considered separately. However, following their analysis of new studies by Dow, Allied and EPA, NIOSH concluded and we agree that lead arsenate should be included in this proposed rulemaking.

Since arsine has different toxicological properties than other inorganic arsenic compounds, NIOSH felt and we agree that it should be excluded from this standard.

(2) *Permissible exposure limit.* The proposed standard sets a maximum limit for employee exposure of .004 milligrams of arsenic (As) per cubic meter of air averaged over an eight-hour period. Additionally, a ceiling limit of .01 mg As/cu m is proposed for any 15 minute time period during the work shift. These limits set levels above which no employee exposure is permitted.

Further, the proposal prohibits all skin contact with liquid arsenic trichloride, and repeated skin contact with other liquid or solid forms of inorganic arsenic compounds which are likely to cause skin irritation. The strict requirement for arsenic trichloride is due to the particularly hazardous nature of this compound. It has an extremely high vapor pressure at room temperature, and can be absorbed directly through the skin. Repeated contact with other inorganic arsenic compounds may result in skin irritation.

(3) *Action level.* The proposed standard sets an "action level" of .002 mg As/cu m averaged over an eight hour period. The purpose of the action level is to set a level at which airborne inorganic arsenic can be practicably detected by the employer, and above which precautionary measures such as medical surveillance and monitoring are warranted. Regulated areas would be established for all areas in which levels of inorganic arsenic exceed the action level. Where it has been determined that operations involving inorganic arsenic do not exceed the action level, provisions of this standard such as requirements for medical surveillance and regulated areas do not apply.

In OSHA's judgment, exposures below the action level do not present a sufficient hazard to warrant application of the entire standard to places of employment which have such exposures.

It should be noted, however, that certain provisions of the proposed standard, such as employee training and information, apply wherever inorganic arsenic is released as a result of operations, without regard to the airborne concentrations.

(4) *Monitoring.* Under the provisions of this proposed standard, the employer would be required to make an initial determination of employee exposure to airborne concentrations of inorganic arsenic. This initial determination may be an observation based on the amount of inorganic arsenic present, type of operations being performed, the amount and type of ventilation, and the proximity of employees to the sources of emission. Ini-

tially, the employer is not required to sample or measure airborne concentrations. However, the employer must be certain that the determination accurately reflects employee exposure conditions over the working day. If the employer chooses to perform any measurements at this time, these must be considered in the determination.

If the results of the initial determination are negative, that is, if the employer determines that no employee is exposed above the action level, a written record of this determination must be made. This record must include any information or observations that indicate an employee may be exposed in excess of the action level, such as employee complaints of signs or symptoms that may be attributed to overexposure. Further, the determination record must include any measurements of inorganic arsenic exposures taken, and the names and social security numbers of the employees considered under this determination.

In establishments having more than one work operation involving the use of inorganic arsenic, an initial determination must be made for each operation. Also, the determination must be repeated each time there is a change in production, process or control measures which could result in new or additional exposures, or whenever the employer has any other reason to suspect that a change in exposure conditions has occurred.

If the results of the initial determination are positive, indicating that an employee is exposed to concentrations in excess of the action level, the employer would be required to implement a program to measure the exposures of affected employees. Because the determination has indicated exposure in excess of the action level, thus triggering the monitoring program, no written record of the determination need be made.

The results of the exposure measurement program would determine further action to be taken by the employer: (1) If measurements show that an employee is exposed to concentrations above the action level, but below the permissible exposure limit, measurements of that employee's exposure must be made at least every two months. (2) If measurements show that an employee is exposed to concentrations above the permissible limit, the employer would be required to measure that employee's exposure at least monthly. Such exposures also trigger other actions on the part of the employer, such as notifying the employee of his overexposure and institution of engineering and work practice controls to reduce the exposure to within permissible limits. (3) If the results of two consecutive measurements, taken at least five working days apart, show that an employee is not exposed above the action level, the measurement program may be terminated for that employee.

The monitoring provisions are designed so that employers having work places in which use of inorganic arsenic is controlled, without regard to the use of respirators, to the extent that ex-

posures are below the action level, would not be required to make any measurements. The intent of this procedure is to provide adequate protection for employees while minimizing unnecessary burdens on employers.

The frequency of measurement would depend on the degree of employee exposure. Bimonthly measurement for employees whose exposures are in the range between the action level and permissible level would be required to provide sufficient warning when exposures are approaching the permissible limit. A minimum bimonthly sampling frequency would be required because the data from fewer samples would not provide statistical information of an accuracy necessary to assure protection of employees.

For work places in which exposures are above the permissible limit, monthly measurements would be required because OSHA believes that exposure above the permissible level presents a hazard to the employee. Monthly measurements would be required even when employees routinely wear respirators, because the type of respirator to be worn is determined by the concentrations of inorganic arsenic present in the work place air.

The proposal provides for the termination of exposure measurement when two samples indicate levels below the action level. Two samples, rather than one, are required in order to allow for the normal variability of individual exposure measurements, which may produce unrepresentative samples. A requirement for a period of five working days between samples has been included to ensure that any recorded decrease in exposure levels is not merely a short-term reduction. It should be noted that the termination of measurement would be effective only as long as there is no change in production, process or control which could result in new or additional exposure. If such a change occurs, the procedure, beginning with the initial determination, must be repeated.

(5) *Methods of measurement.* The proposal would require that exposure measurements reflect the actual exposure conditions for each employee. No specification is made for the location of the samples taken. Thus, the employer is free to choose to perform either personal breathing zone samples or general air samples, provided that the method chosen gives accurate indication of the employees' exposures. Further, any appropriate combination of long-term or short-term samples would be acceptable, although the proposal would require that all exposures be calculated on an eight-hour time-weighted average basis.

The provisions state that the accuracy of the sampling method must have a confidence level of 95 percent. The term accuracy refers to the difference between the measured value and the true concentration. It allows for both the random variation of the method (its precision) and the difference between the average result from the method and the true value (bias of the method). The re-

guled accuracy for concentrations above the action level is 25 percent at a 95 percent confidence level. This means that out of a long series of measurements, 95 percent must be within 25 percent of the true value. The required accuracy values allow the use of relatively inexpensive collection and analytical equipment.

(6) *Regulated area.* The proposal requires that regulated areas be established, that access be limited to authorized persons and that a roster of persons authorized to enter be made daily and maintained for at least 40 years. One purpose of establishing regulated areas is to limit the exposures above the action level to as few people as possible. The 40 year record retention requirement is based on the observed latency period for inorganic arsenic-induced cancer. The burden on the employer is considered to be minimal because the provisions require the employer merely to identify and control such areas.

(7) *Methods of compliance.* The proposed standard requires that employers immediately institute feasible engineering controls to reduce employee exposures to inorganic arsenic to at or below .004 mg As/cu m. In establishments where controls that can be instituted immediately will not reduce exposure to the permissible level, they must nonetheless be implemented to reduce exposures to the lowest practicable level, and be supplemented by the use of work practice controls or respirators to provide the necessary protection.

Engineering controls for inorganic arsenic may include mechanical ventilation and closed processing systems. When mechanical ventilation is used for engineering control, checks of air system efficiency, such as air velocity, static pressure, or air volume, must be made at least every three months. Engineering controls, which reduce levels of exposure in the work place environment by removing airborne contaminants, are the preferred means of compliance because of the problems generally associated with the use of respirators and work practice controls.

As part of its modified criteria document, NIOSH has included recommendations for the use of "standby rooms" under positive air pressure, with a filtered air supply for controlling exposure to inorganic arsenic. OSHA believes that this may be a useful method, particularly in the smelting industry, although we question the uniform application of standby rooms for all types of industry. The proposed standard does not specifically require the use of standby rooms.

Administrative or work practice controls which distribute exposures over a large number of workers are less desirable than engineering controls since this increases the population of employees at risk from exposure to potentially harmful levels of inorganic arsenic.

Respirators are capable of providing very good protection if they are properly selected, properly fitted, and if they are worn by the employee. The proposal

would require proper selection and fitting, and that the employer ensure their proper use. However, because of the difficulties inherent in the use of respirators, they are less favored than engineering controls.

Where compliance with this standard cannot be achieved immediately through the institution of engineering controls, they must nevertheless be used to control exposures to the lowest practicable level. In addition, a program must be established and implemented to reduce exposures to the permissible exposure limit, or to the greatest extent feasible, solely by means of engineering controls. Written plans for this program must be developed and be furnished upon request for examination and copying to representatives of the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or his designee and the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or his designee. These plans must be reviewed and updated to reflect the current status of exposure control. The revisions must be made at least every six months.

(8) *Respiratory protection.* When engineering controls and work practices are not feasible or are inadequate, respirators would be required. Additionally, the proposed standard provides for the use of respirators in other specific situations, including during installation of engineering controls, in hazardous operations, and in emergencies.

The proposal requires the employer to select respirators that have been approved by the Mining Enforcement and Safety Administration or NIOSH. Further, the employer must select the type of respirator to be used from the table provided in the proposed standard. This table lists the type of respirator to be used based on the concentrations of inorganic arsenic in the workplace. For situations in which the airborne concentrations are unknown, respirators which afford the maximum protection, as stated in the table, are required.

NIOSH recommended that only two types of respirators be permitted, based on their recommendation of a nondetectable level of exposure. These respirators are capable of providing protection for conditions of unknown or massive concentrations of inorganic arsenic. However, OSHA feels that other respirators provide adequate employee protection as long as their use is limited to specific ranges of concentrations. For this reason, OSHA has provided an expanded respirator table in the standard, which requires that particular types of respirators be used for specific concentrations.

(9) *Hazardous operations.* Certain operations are inherently hazardous due to the working conditions, amount of toxic material used, or the toxic properties of the materials. Examples of such hazardous operations are the cleaning of electrostatic precipitators or dust collection systems; maintenance operations on smelter furnaces; arsenic kitchen operations; loading and unloading of bulk

quantities of inorganic arsenic compounds; other maintenance operations; and operations involving arsenic trichloride.

The proposed standard requires that employees wear respirators when engaged in hazardous operations because it might be expected that these operations will result in the release of inorganic arsenic in excess of the permissible limit. Appropriate protective clothing is required during hazardous operations to prevent employees from having any skin contact with arsenic trichloride.

(10) *Emergency situations.* The proposed standard would require employers to prepare a written plan of action to be followed in the event of occurrences which result in massive releases of inorganic arsenic. Examples of such emergencies are ruptures of containers and control or operating equipment failures. Emergency plans are necessary to inform employees of actions required for personal protection and for reduction of hazards in the event of an emergency. Employees not engaged in correcting the emergency situations must be restricted from the area and normal operations halted until the emergency is abated.

(11) *Protective clothing.* The proposal requires the employer to provide, and ensure that employees wear, clean protective clothing, such as but not limited to coveralls, smocks, aprons, face shields, gloves, shoes, hats and dust proof goggles, where exposures are in excess of the action level. This requirement is intended to prevent the accumulation of inorganic arsenic dust on the body or street clothes of the employee.

The proposed standard requires the employer to ensure that all protective clothing is removed in special change rooms and that contaminated protective clothing is removed from these rooms only in closed, impermeable containers. The employer is also required to ensure that no employee removes contaminated protective clothing from the change rooms, except those employees authorized by the employer to do so for the purpose of disposal, maintenance or laundering. The employer is responsible for disposal, maintenance and laundering of protective clothing and equipment. The employer must ensure that the person who is charged with laundering contaminated protective clothing is apprised of the harmful effects of exposure to inorganic arsenic.

(12) *Housekeeping.* Removal and prevention of accumulations of inorganic arsenic dust deposits on all surfaces in the work environment are an important aspect in dust control. Thus, for the purpose of ensuring that inorganic arsenic dust and particles are not reintroduced into the workplace air, the proposal prohibits dry sweeping or the use of compressed air for cleaning of floors and other surfaces. Vacuuming and water spray methods of dust removal are both safe and adequate, provided the practices outlined in the standard are followed.

(13) *Hygiene facilities and practices.* The proposal prohibits smoking, non-food chewing products, application of cosmetics, or consumption of food in areas where exposures to airborne concentrations of inorganic arsenic are above the action level or in areas where skin contact with inorganic arsenic may occur. Storage of such items is also prohibited in these areas. Further, all employees must be required to wash hands, forearms, face and neck before eating or smoking or at the end of the work shift. Workers exposed above the action level, must shower at the end of the work shift, prior to changing into street clothes. Employers must also provide eye wash facilities wherever eye contact with inorganic arsenic could occur, and both eye wash facilities and emergency showers where arsenic trichloride is handled.

This section of the proposed standard requires the employer to provide for the number and placement of facilities such as change rooms, toilets, lavatories and showers in accordance with 29 CFR 1910.141.

(14) *Medical surveillance.* Medical surveillance provisions have been included in this proposal to provide for early diagnosis of health effects of inorganic arsenic exposure. The employer must make medical examinations and tests available to all employees who are exposed or will be exposed to inorganic arsenic in excess of the action level. All medical examinations and procedures must be performed by, or under the supervision of a physician, and provided during the employee's normal working hours, without cost to the employee. Examinations must be repeated every 6 months for employees who have had 10 years or more of occupational exposure to inorganic arsenic, and annually for all other employees exposed above the action level.

OSHA has placed special emphasis on medical surveillance of employees exposed for 10 years or more by requiring a medical examination every 6 months. More frequent examinations of these employees are required because their past exposure may have been at high levels, and these examinations may help in early diagnoses of any harmful effects resulting from their past exposures.

The medical examination includes such items as a medical and work history; 14 x 17 posterior-anterior chest X-ray; a complete blood count; palpation of the superficial lymph nodes; and examination of body surfaces for hyperpigmentation, keratoses or other skin lesions. NIOSH suggested the use of periodic sputum cytologic examination for early detection of lung cancer. OSHA recognizes that this particular examination may be useful in a medical surveillance program, but feels that the necessity for a sputum cytological analysis is more appropriately determined by the examining physician. Therefore, a recommendation for this type of test is mentioned in the Medical Surveillance Guidelines (Appendix C), but not required by the proposed standard.

Additionally, periodic urine analysis for arsenic content has been suggested as a useful indication of arsenic exposure. However, because of the ubiquitous nature of arsenic (it is found in food, water, etc.) it is difficult to relate occupational exposure to the amount excreted in the urine. A urine sample program might benefit the medical surveillance program provided background levels for each employee are established. Since such background levels are difficult to establish, the proposal does not require arsenic urine analysis.

The employer must provide the examining physician with a copy of the standard for inorganic arsenic, including appendices; a description of the employee's duties; a description of any personal protective equipment used by the employee; and information concerning actual and estimated exposures to which the employee has been or may be exposed. The employer must also provide any available employee medical history information requested by the physician.

Following the medical examination, the employer must obtain a written opinion from the examining physician stating whether the employee has any medical condition that would place him at increased risk to his health, or that would be aggravated by exposure to inorganic arsenic. Additionally, the physician's opinion must state any recommended limitations upon the employee's exposure or upon the use of protective equipment and respirators. Also, the opinion must state that the employee has been informed of any medical conditions which require further examination or treatment; however, the written opinion shall not contain specific findings or diagnoses unrelated to the employee's exposure to inorganic arsenic. The employer must provide a copy of the physician's opinion to each employee.

If, based on the physician's opinion, the employer determines that exposure of an employee to inorganic arsenic would materially impair the employee's health, it is the responsibility of the employer to remove that employee from exposure.

(15) *Employee information and training.* The proposal would require the employer to provide an annual training program for all employees assigned to the workplace areas within the scope of the standard. The program must be provided at the time of initial assignment to such work areas, and at least annually thereafter.

The program must, at a minimum, present the information contained in Appendices A and B; inform the employee of the quantity, location, and manner of use, release or storage of inorganic arsenic; inform the employee of necessary protective steps; inform the employee of the purpose for, proper use of, and limitations of respiratory protection devices; explain the purpose for, and a description of the medical surveillance program; and explain emergency procedures to be followed. Additionally, the

training program must include a review of this standard. A copy of the standard and its appendices must be readily available to employees.

Training and information are essential factors in the protection of employees. An employee can do a great deal to protect himself from harmful exposures to inorganic arsenic; but only if he is aware of the nature of the hazard and what actions are needed for prevention of overexposure.

(16) *Signs and labels.* Due to the hazardous nature of inorganic arsenic, OSHA feels that emphasis should be placed on warning employees and other persons about the dangers of exposure. For this reason, the proposed standard includes a section on signs and labels for regulated areas, areas in which hazardous operations exist, or where exposures exceed the permissible limit, and for containers of inorganic arsenic.

The signs to be posted at regulated areas inform employees of the suspected carcinogenicity of inorganic arsenic and alert them to the fact that only persons authorized by the employer should enter the area. Signs posted for hazardous operations or where exposure exceeds the permissible limit, where personal protective equipment is mandated by the standard, reiterate the warning of carcinogenicity, and advise that respiratory equipment is necessary for entry and that such entry is limited to authorized personnel.

Containers of inorganic arsenic are required to be labeled with a more detailed description of the hazard and practices to be followed in use of the substance. These labels may be applied in addition to or in combination with labels required by other statutes, regulations or ordinances. In addition, no sign or instruction may contradict or detract from the effect of the warnings, information, or instructions required for labels in this section.

(17) *Records.* The proposed standard would require employers to make written records of the following: negative initial determinations; measurements of employee exposures; tests of mechanical ventilation systems (where such systems are used for engineering control); respirator usage; annual training and information sessions; rosters of persons authorized to enter regulated areas; and records required under medical surveillance provisions. Records of exposure determinations and respirator usage have to be retained five years. Exposure measurements and regulated area rosters would be required to be maintained for 40 years. Medical surveillance records would have to be maintained for 40 years, or for the duration of employment plus 20 years, whichever is longer. The other records required would only have to be retained for two years.

Additionally, this portion of the proposal would provide for access to records of exposure measurements by employees, former employees or their representatives, and access to medical records by

physicians designated by employees or former employees.

Further, the proposed standard would require that in the event the employer ceases to do business, the successor shall retain all records for the required length of time. If there is no successor to receive and maintain his records, the employer shall send the records to the Director, by registered mail, and individually notify each employee of the transfer.

(18) *Observation of monitoring.* The proposed standard would require employers to assure that affected employees or their representatives are given an opportunity to observe any measuring of employee exposure to inorganic arsenic conducted pursuant to this standard. The proposal requires the observers to use whatever personal protective devices are required, and to comply with all other applicable safety procedures.

Observers would be entitled to receive an explanation of the measurement procedure, observe all the steps related to the measurement procedure that are performed at the place of exposure, and to record the results obtained.

(19) *Reports.* The proposal would require the employer to notify the OSHA Area Director within one month of establishment of a regulated area. This report would include the address and location of each establishment having one or more regulated areas and the approximate number of employees authorized to enter such areas during normal operations. Further, this portion of the proposal would require the employer to report all emergencies, and the facts obtainable at the time, to the Area Director within 24 hours of their occurrence.

VII. *Public Participation.* Interested persons are invited to comment on the proposed standard on or before March 3, 1975. Written data, views, and arguments must be submitted in quadruplicate to Ms. N. Hucke, OSHA Committee Management Office, Docket OSH 37, 1726 M Street, NW, Room 200, U.S. Department of Labor, Washington, D.C. 20210 (Phone: 202/961-2248 or 2487). Written submissions must clearly identify the provision of the proposal addressed and the position taken with respect to each such provision. The data, views, and arguments will be available for public inspection and copying at the above address. All written submissions received will be made a part of the record of this proceeding.

In order to expedite this rulemaking proceeding and in anticipation of requests for a hearing, we are scheduling an informal public hearing, pursuant to section 6(b) of the Act and 29 CFR Part 1911, to begin on April 8, 1975, in the Departmental Auditorium, U.S. Department of Labor, Constitution Avenue between 12th and 14th Streets, NW., Washington, D.C. All aspects of the proposed standard, including environmental impact, will be at issue in the hearing. Beginning at 9:30 a.m. e.d.t. on April 8, 1975, the presiding Administrative Law Judge will hold a pre-hearing conference in order to settle any matters relating to the proceedings. All

persons intending to make presentations should attend the pre-hearing conference which is open to the public. The hearing will be conducted, and the decisions made, in accordance with 29 CFR Part 1911.

Persons desiring to appear at the hearing must file a notice of intention to appear on or before March 17, 1975, with Ms. N. Hucke, OSHA Committee Management Office, Docket OSH-37, 1726 M Street, NW., Room 200, U.S. Department of Labor, Washington, D.C. 20210 (Phone: 202/961-2248 or 2487). The notice must contain the following information:

- (1) The name and address of the person to appear;
- (2) The capacity in which he will appear;
- (3) The approximate amount of time required for the presentation;
- (4) The specific provisions of the proposal that will be addressed;
- (5) A brief statement of the position that will be taken with respect to each provision addressed; and
- (6) A summary of the evidence with respect to each such provision proposed to be adduced at the hearing.

The oral proceedings will be reported verbatim. All statements and documents that are intended to be submitted for the record of the hearing must be submitted in quadruplicate. The use of prepared statements by witnesses is encouraged.

The Administrative Law Judge shall have all the powers necessary or appropriate to conduct a fair and full informal hearing, including the powers:

- (a) To regulate the course of the proceedings;
- (b) To dispose of procedural requests, objections, and comparable matters;
- (c) To confine the presentations to matters pertinent to the proposed standard;
- (d) To regulate the conduct of those present at the hearing by appropriate means;
- (e) In his discretion, to question and permit questioning of any witnesses; and
- (f) In his discretion, to keep the record open for a reasonable, stated time to receive written information from any person who has participated in the oral proceeding.

Following the close of the hearing, the presiding Administrative Law Judge shall certify the record thereof to the Assistant Secretary of Labor for Occupational Safety and Health.

The proposed standard will be reviewed after consideration of all relevant oral and written information, data, views, or arguments and will be modified appropriately if the submissions so warrant.

Accordingly, pursuant to sections 6(b) and 8(c) of the William-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1599; 29 U.S.C. 655, 657), Secretary of Labor's Order No. 12-71 (36 FR 8754), and 29 CFR Part 1911, it is hereby proposed to amend Part 1910 of Title 29 of the Code of Federal Regulations as set forth below:

§ 1910.93 [Amended]

1. In § 1910.93, Table G-1 would be amended by deleting the following substances:

Arsenic and compounds (as As) ..	0.5
Calcium arsenate.....	.15

Calcium arsenate.....	1
Lead arsenate.....	.15

2. A new § 1910.93r would be added to Part 1910 of Title 29 of the Code of Federal Regulations to read as follows:

§ 1910.93r Inorganic arsenic.

(a) *Scope and application.* (1) This section includes requirements for the control of employee exposure to inorganic arsenic.

(2) This section applies to the production, reaction, synthesis, release, packaging, repackaging, storage, handling or use of inorganic arsenic except that this section will not apply to working conditions with respect to which the Mining Enforcement and Safety Administration, Department of the Interior, or the Environmental Protection Agency have exercised statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

(3) This section applies to the transportation of inorganic arsenic except that this section will not apply to working conditions with respect to which the Department of Transportation has exercised statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

(b) *Definitions.* (1) "Inorganic arsenic" means arsenic and all inorganic compounds containing arsenic except arsine.

(2) "Action level" means a concentration of inorganic arsenic of 0.002 milligrams arsenic per cubic meter of air (mg As/cu m) as determined on an eight-hour, time-weighted average basis.

(3) "Emergency" means any occurrence such as, but not limited to equipment failure, rupture of containers, or failure of control equipment which is likely to, or does, result in the massive release of inorganic arsenic.

(4) "Hazardous operation" means any operation, procedure or activity where a release of inorganic arsenic might be expected as a consequence of the operation or because of an accident in the operation which would result in an employee exposure in excess of the permissible exposure limit. All operations involving the release of, or direct skin contact with arsenic trichloride shall be considered hazardous.

(5) "Authorized person" means any person specifically authorized by the employer whose duties require him to enter a regulated area or any person entering such an area as a designated representative of employees for the purpose of exercising an opportunity to observe monitoring and measuring procedures.

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

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

(8) "OSHA Area Director" means the Director of the Occupational Safety and Health Administration Area Office having jurisdiction over the geographic

area in which the employer's establishment is located.

(c) *Permissible exposure limit.* (1) No employee may be exposed to airborne concentrations of inorganic arsenic greater than 0.004 mg As/cu m as determined on an eight-hour, time-weighted average basis; or a ceiling limit greater than .01 mg As/cu m averaged over any 15 minute period during the working day.

(2) No employee may be exposed to any skin contact with liquid arsenic trichloride, or to repeated skin contact with liquid or solid inorganic arsenic likely to cause skin irritation.

(d) *Determination and monitoring of exposure.* (1) Each employer who has a place of employment in which inorganic arsenic is produced, reacted, synthesized, released, packaged, repackaged, stored, handled or used shall inspect each work place and work operation to accurately determine if any employee may be exposed, without regard to the use of respirators, to inorganic arsenic above the action level.

(2) Such a determination shall be based on the following, along with any other relevant considerations:

(i) Any information, observations, or calculations which would indicate employee exposure to inorganic arsenic; and

(ii) Any measurements of inorganic arsenic; and

(iii) Any employee complaints of symptoms which may be attributable to exposure to inorganic arsenic.

(3) When a determination is made that no employee is exposed, without regard to the use of respirators, in excess of the action level, the employer shall make a record of such determination which shall include at least the information specified in paragraph (d) (2) and shall also include the date of determination, work being performed at the time, location within work site, name and social security number of employees considered.

(4) Where a determination conducted under paragraphs (d) (1) and (d) (2) of this section shows the possibility of any employee exposure in excess of the action level, without regard to the use of respirators, the employer shall immediately make measurements to accurately determine the actual exposure for each such employee.

(i) Such measurements shall be repeated at least monthly for any employee who is exposed, without regard to the use of respirators, in excess of the permissible exposure limit.

(ii) Such measurements shall be repeated at least bimonthly for any employee who is exposed, without regard to the use of respirators, in excess of the action level.

(iii) Such measurements may be discontinued for any employee only when at least two consecutive measurements, made not less than five working days apart, show exposures for the employee are at or below the action level.

(5) Whenever there has been a production, process or control change which may result in new or additional exposures or whenever the employer has any

other reason to suspect a change in exposure conditions, a new determination under this paragraph shall be made.

(6) A record of measurements of employee exposure to airborne concentrations of inorganic arsenic shall be made and shall include at least the information required in paragraph (q) (2) of this section.

(7) The employer shall individually notify in writing, within 10 working days after the occurrence, every employee who is found to be exposed to inorganic arsenic above the permissible exposure limit. Such notification need not be given more frequently than once a month. The employee shall also be notified of the corrective action being taken to reduce exposure to or below the permissible exposure limit.

(8) The method of monitoring and measurement shall have 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 .002 mg As/cu m. (Some methods meeting the accuracy requirements are available in the "NIOSH Manual of Analytical Methods.")

(e) *Regulated area.* (1) A regulated area shall be established where inorganic arsenic concentrations are in excess of the action level.

(2) Access to regulated areas shall be limited to authorized persons.

(3) A daily roster shall be made of authorized persons who enter a regulated area.

(f) *Methods of compliance.* Employee exposures to inorganic arsenic shall be controlled to or below the permissible exposure limit provided in paragraph (c) of this section by engineering controls, work practices, and personal protection controls as follows:

(1) Engineering controls shall be instituted immediately to reduce exposures to or below the permissible exposure limit, except to the extent that such controls are not feasible.

(2) Wherever feasible engineering controls which can be instituted immediately are not sufficient to reduce expo-

sure to the permissible exposure limit, they shall nonetheless be used to reduce exposures to the lowest practicable level, and shall be supplemented by work practice controls and by respiratory protection in accordance with paragraph (g) of this section. A program shall be established and implemented to reduce exposures to or below the permissible exposure limit, or to the greatest extent feasible, solely by means of engineering controls, as soon as practicable.

(3) Written plans for such a program shall be developed and furnished upon request for examination and copying to the Assistant Secretary and the Director. Such plans shall be reviewed and revised as necessary, at least every six months, to reflect the current status of such a program.

(4) When mechanical ventilation is used to control exposure, measurements which demonstrate the effectiveness of the system to control such exposure, such as air velocity, static pressure or air volume, shall be made at least every three months. Measurements of the system's effectiveness to control exposure shall also be made within five days of any change in production, process or control which might result in an increase in airborne concentrations of inorganic arsenic.

(g) *Respiratory protection.* (1) Where respiratory protection is required under this section, compliance with the permissible exposure limit may not be achieved by the use of respirators except:

(i) During the time period necessary to install engineering controls; or

(ii) In work operations in which engineering controls are not feasible; or

(iii) In work situations in which engineering controls are insufficient to reduce exposure to or below the permissible exposure limit; or

(iv) In emergencies.

(2) Where respiratory protection is required under this section, the employer shall select and provide the appropriate respirator from the Table below and shall ensure that the employee uses the respirator provided.

RESPIRATORY PROTECTION FOR INORGANIC ARSENIC

Concentration of inorganic arsenic	Required respirator
(i) Unknown or greater than 4.0 mg As/m ³ .	(A) Self-contained breathing apparatus, pressure-demand type (positive pressure), with full facepiece; or (B) Combination constant flow or pressure demand full facepiece, supplied-air respirator type with auxiliary self-contained air supply.
(ii) Not greater than 4.0 mg As/m ³ .	(A) Supplied air respirator (positive pressure), continuous flow, with full facepiece, hood, helmet, or suit; or (B) Supplied air respirator, pressure demand, with full facepiece.
(iii) Not greater than 0.8 mg As/m ³ .	(A) Powered air purifying respirator, with high efficiency filter ¹ and full facepiece, hood, or helmet.
(iv) Not greater than 0.40 mg As/m ³ .	(A) Supplied air respirator, pressure-demand type, with full facepiece; or (B) Air purifying respirator, with high efficiency filter, ¹ with full facepiece.
(v) Not greater than 0.04 mg As/m ³ .	(A) Air purifying respirator, with high efficiency filter, ¹ with half mask; or (B) Supplied air respirator, pressure demand, with half mask.

¹ High efficiency filter—99.97 percent efficient against 0.3-micron size particles.

(3) Respirators shall be selected from those approved by the Mining Enforcement and Safety Administration (formerly called the Bureau of Mines) or by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

(4) The employer shall institute a respiratory protection program in accordance with § 1910.134.

(5) Respirators prescribed for higher concentration may be used for any lower concentration.

(6) Employees who wear respirators shall be allowed to leave work areas to wash the face and respiratory facepiece to prevent potential skin irritation associated with respirator use.

(h) **Hazardous operations.** (1) Employees engaged in hazardous operations, as defined in paragraph (b) (4), such as, but not limited to, cleaning of electrostatic precipitators or dust collection systems, maintenance of smelter furnaces, arsenic kitchen operations, loading and unloading operations, or other maintenance operations or exposed to the release of or direct skin contact with arsenic trichloride shall be provided with and required to wear and use:

(i) Respiratory protection in accordance with paragraph (g) of this section; and

(ii) Appropriate protective clothing, in accordance with paragraph (j) of this section, to prevent skin irritation due to contact with inorganic arsenic and any skin and eye contact with arsenic trichloride. The protective clothing shall be selected for the operation and its possible exposure conditions.

(2) In addition to the requirements of paragraph (h) (1) of this section, all operations involving arsenic trichloride shall be performed under well ventilated conditions.

(i) **Emergency situations.** (A) A written plan for emergency situations shall be developed for each facility involved in an inorganic arsenic operation in which there is a possibility of an emergency as defined in paragraph (b) (3) of this section. Appropriate portions of the plan shall be implemented in the event of an emergency.

(B) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped as required in paragraphs (g) and (j) of this section until the emergency is abated.

(C) Employees not engaged in correcting the emergency shall be restricted from the area and normal operations in the affected area(s) shall not be resumed until the emergency is abated.

(j) **Protective equipment.** (1) Where exposures are in excess of the action level, the employer shall provide and ensure that the employees wear appropriate clean protective equipment such as, but not limited to, coveralls, smocks, aprons, face shields, gloves, shoes, hats, or dust proof goggles to prevent contamination of the employee's street clothing and to prevent skin contact.

(2) Clean and dry protective equipment shall be provided at least daily to each affected employee.

(3) The employer shall ensure that all protective equipment is removed only in change rooms as prescribed in paragraph (m) (3) of this section and shall ensure that used protective equipment is removed from the facility only in accordance with paragraph (k) of this section.

(4) Where required by this section, the employer shall provide and ensure that the employee wears eye and face protection in accordance with § 1910.133(a) (2) through (a) (6).

(k) **Laundrying.** (1) The employer shall launder, maintain, and dispose of protective equipment used in inorganic arsenic operations.

(2) The employer shall ensure that employees remove contaminated protective equipment only in change rooms as required in paragraph (m) (3) of this section.

(3) The employer shall ensure that no employee removes contaminated protective equipment from the change room except for those employees authorized to do so for the purpose of laundering, maintenance, and disposal.

(4) Inorganic arsenic contaminated protective equipment shall be placed in impermeable closed containers.

(5) Containers of contaminated protective equipment which are to be removed from change rooms or from the work place for laundering or disposal, or for any other reason, shall bear labels in accordance with paragraph (p) (3) of this section.

(6) Dust removal may not be done by blowing or shaking of clothing.

(7) The employer shall inform any person who launders or cleans inorganic arsenic protective equipment of the potentially harmful effects of exposure to inorganic arsenic.

(l) **Housekeeping.** (1) All external surfaces shall be maintained free of accumulation of inorganic arsenic if, with their dispersion, there would be an excessive air concentration.

(2) Floors and other surfaces may not be cleaned by dry sweeping or the use of compressed air.

(3) Where vacuuming methods are selected, either portable units or permanent systems shall be used. (i) If a portable unit is selected, the exhaust shall be attached to the exhaust of the work place ventilation system or collected with the vacuum unit so that inorganic arsenic is not reintroduced into the work place air; and

(ii) Portable vacuum units used to collect inorganic arsenic may not be used for other cleaning purposes and shall be labeled as prescribed in paragraph (p) (3) of this section.

(4) Cleaning of floors and other contaminated surfaces may not be performed by washing down with a hose, unless a fine spray has first been laid down.

(m) **Hygiene facilities and practices.**

(1) The presence or consumption of food or beverages, the presence or use of smoking or non-food chewing products, and the presence or application of cosmetics are prohibited in areas where airborne concentrations of inorganic arsenic are in excess of the action level and

in areas where skin contact with inorganic arsenic may occur.

(2) Employees shall be required to wash hands, forearms, face, and neck before leaving work areas specified in paragraph (m) (1) of this section, for the purpose of drinking, eating, or smoking and at the end of each work shift.

(3) Where employees wear protective clothing and equipment, clean change rooms shall be provided, in accordance with § 1910.141(e).

(4) Where toilets are in regulated areas, such toilets shall be in a separate room.

(5) Where employees are required by this section to wash, washing facilities shall be provided, in accordance with § 1910.141(d) (1) and (2) (ii) through (vii).

(6) The employer shall provide eye wash facilities that are suitable for quick drenching or flushing of the eyes for immediate emergency use in locations where eye contact with inorganic arsenic may occur.

(7) The employer shall provide eye wash facilities and emergency showers that are suitable for quick drenching or flushing of the eyes and body for immediate emergency use where arsenic trichloride is handled.

(8) Workers exposed above the action level, without regard to the use of respirators, shall be required to shower prior to changing into street clothes.

(9) Where employees are required by this section to shower, shower facilities shall be provided in accordance with § 1910.141(d) (3).

(n) **Medical surveillance.** (1) Each employer who has a place of employment in which employees are, or have been exposed, without regard to the use of respirators, to inorganic arsenic in excess of the action level shall institute a medical surveillance program.

(2) (i) The program shall provide each employee exposed or who will be exposed above the action level, without regard to the use of respirators, with medical examinations and tests in accordance with this paragraph.

(ii) If any employee refuses any required medical examination, the employer shall inform the employee of the possible health consequences of such refusal and shall obtain a signed statement from the employee indicating that the employee understands the risk involved in the refusal to be examined.

(3) All medical examinations and procedures shall be performed by or under the supervision of a licensed physician, and shall be provided during the employee's normal working hours without cost to the employee.

(4) At the time of initial assignment, or upon institution of medical surveillance, the following shall be performed by the physician:

(i) A medical and work history;
(ii) A medical examination which must include as a minimum the following:

(A) A 14 x 17 posterior-anterior chest X-ray giving particular attention to parenchymal and hilar changes;

PROPOSED RULES

(B) A complete blood count to include differential;

(C) Palpation of the superficial lymph nodes for indication of neoplastic changes;

(D) Careful examination of the skin for the presence of hyperpigmentation, keratoses or other skin lesions.

(5) Examinations provided in accordance with this paragraph shall be performed at least:

(i) Every 6 months for each employee who has been employed in operations involving inorganic arsenic for 10 years or more, except that chest X-rays shall be given annually only; and

(ii) Annually for all other employees as specified in paragraph (n) (2) (i).

(6) Each employee exposed to an emergency shall be given appropriate medical surveillance.

(7) The employer shall provide to the examining physician the following information: (i) A copy of this regulation for inorganic arsenic including all the appendices;

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

(iii) A description of any personal protective equipment used;

(iv) The results of the employee's exposure measurement, if available;

(v) The employee's anticipated exposure level; and

(vi) Upon request of the physician, information from previous medical examinations of the affected employee.

(8) (i) The employer shall obtain a written opinion from the examining physician containing the following:

(A) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at increased risk of material impairment of the employee's health from exposure to inorganic arsenic or would directly or indirectly aggravate any detected medical condition;

(B) Any recommended limitations upon the employee's exposure to inorganic arsenic and upon the use of protective equipment and respirators;

(C) A statement that the employee has been informed by the physician of any medical conditions which require further examination or treatment;

(ii) The written opinion shall not reveal specific findings or diagnoses unrelated to exposure to inorganic arsenic.

(iii) A copy of the physician's written opinion shall be provided to each employee.

(9) If the employer determines, on the basis of the physician's written opinion, that any employee's health would be materially impaired by continued exposure to inorganic arsenic, such employee shall be withdrawn from possible exposure to inorganic arsenic.

(o) *Employee information and training.* (1) The employer shall provide a training program for employees assigned to workplace areas where any inorganic arsenic is produced, reacted, synthesized, released, packaged, repackaged, stored, handled, or used. The training program shall be provided at the time of initial

assignment, and at least annually thereafter, and shall include informing each employee of:

(i) The information contained in the substance data sheets for inorganic arsenic, which are contained in Appendix A and B; and

(ii) The quantity, location, manner of use, release or storage of inorganic arsenic and the specific nature of operations which could result in exposure to inorganic arsenic in excess of the action level as well as any necessary protective steps; and

(iii) The purpose for, proper use, and limitations of respiratory devices as specified in § 1910.134; and

(iv) The purpose for, and a description of, the medical surveillance program as required by paragraph (n) of this section and the information contained in Appendix C; and

(v) Emergency procedures as required by paragraph (o) (1) (i) of this section; and

(vi) A review of the standard.

(2) A copy of this standard and its appendices shall be made readily available to all employees exposed to inorganic arsenic.

(3) All materials relating to the employee information and training program shall be provided upon request to the Assistant Secretary and the Director.

(p) *Signs and labels.* (1) Entrances or access ways to regulated areas shall be posted with legible signs bearing the legend:

CANCER-SUSPECT AGENT IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(2) Areas containing hazardous operations or where exposures exceed the permissible exposure limit shall be posted with legible signs bearing the legend:

CANCER-SUSPECT AGENT IN THIS AREA
RESPIRATORY EQUIPMENT REQUIRED
AUTHORIZED PERSONNEL ONLY

(3) Containers of inorganic arsenic shall bear the following label, in addition to or in combination with labels required by other statutes, regulations, or ordinances:

Name of Compound
Danger! Contains Arsenic
Cancer-Suspect Agent
Harmful if Inhaled or Swallowed
Avoid Contact with Skin and Eyes
Use only with adequate ventilation

(4) No statement shall appear on or near any required sign, label or instruction which contradicts or detracts from the effect of any required warning, information, or instruction.

(q) *Recordkeeping.* (1) *Exposure determination.* The employer shall keep an accurate record of all determinations as prescribed in paragraphs (d) (1), (d) (2), and (d) (3) of this section.

(i) This record shall include the written determination and any supporting documentation required in paragraph (d) (3) of this section.

(ii) This record shall be maintained for at least five years and shall include at least the most recent determination.

(2) *Measurement.* The employer shall keep an accurate record of all measurements taken to determine employee exposure to inorganic arsenic.

(i) This record shall include:

(A) The date of measurements;

(B) The operation involving exposure to inorganic arsenic which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Name and social security number and exposure of the employee monitored.

(ii) This record shall be maintained for at least 40 years.

(3) *Mechanical ventilation measurements.* When mechanical ventilation is used as an engineering control, the employer shall maintain a record of the measurements, required by paragraph (f) (4) of this section, demonstrating the effectiveness of such ventilation.

(i) This record shall include:

(A) Date of measurement;

(B) Type of measurement taken;

(C) Result of measurement;

(ii) This record shall be maintained for at least two years.

(4) *Respirator usage.* The employer shall keep and maintain an accurate record of all respirator usage pursuant to paragraph (g) of this section.

(i) The record shall include:

(A) Type of respirator used;

(B) The nature, duration, and names and social security numbers of employees in each operation; and

(C) Airborne concentrations of inorganic arsenic if known.

(ii) This record shall be maintained for at least five years.

(5) *Employee information and training.* The employer shall keep an accurate record of all employee training required by paragraph (o) of this section.

(i) The record shall include:

(A) Date of training;

(B) Name and social security number of employee trained;

(C) Content or scope of training provided.

(ii) This record shall be maintained for at least two years.

(6) *Medical surveillance.* The employer shall keep an accurate medical record for each employee subject to medical surveillance required by paragraph (n) of this section.

(i) The record shall include:

(A) Physician's written opinion required in paragraph (n) (8) (i);

(B) Any employee medical complaints related to exposures to inorganic arsenic;

(C) A signed statement of any refusal to be examined;

(D) A copy of the information provided to the physician pursuant to paragraph (n) (7) of this section.

(ii) This record shall be maintained for at least 40 years, or for the duration of employment plus 20 years, whichever is longer.

(7) *Rosters.* Authorized personnel rosters required in paragraph (e) (3) of this

section shall be maintained for at least 40 years.

(8) *Availability.* (i) All records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Written determinations and employee exposure measurements required by paragraphs (d) (3) and (d) (6) of this section shall be made available for examination and copying to employees, former employees, and their designated representatives.

(iii) Employee medical records required to be maintained by this section shall be made available upon request for examination and copying to a physician designated by the employee or former employee.

(9) *Transfer of records.* (i) In the event the employer ceases to do business, the successor shall receive and retain all records required to be maintained by this section.

(ii) In the event the employer ceases to do business and there is no successor to receive and retain his records for the prescribed period, these records shall be transmitted by registered mail to the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, Washington, D.C. 20852.

(r) *Observation of monitoring.* (1) The employer shall give affected employees or their representatives an opportunity to observe any measuring of employee exposure to inorganic arsenic which is conducted pursuant to this section.

(2) When observation of the monitoring of employee exposure to inorganic arsenic requires entry into an area where the use of personal protective devices is required, the observer shall be provided with and required to use such equipment and shall comply with all other applicable safety procedures.

(3) Without interfering with the measurement, observers shall be entitled to:

(i) Receive an explanation of the measurement procedure;

(ii) Observe all steps related to the measurement of airborne concentration of inorganic arsenic performed at the place of exposure; and

(iii) Record the results obtained.

(s) *Reports.* (1) Not later than one month after the establishment of a regulated area, the following information shall be reported to the OSHA Area Director:

(i) The address and location of each establishment which has one or more regulated areas; and

(ii) The approximate number of employees authorized to enter each regulated area including during maintenance operations; and

(iii) Any changes in such information shall be reported within 15 days.

(2) Emergencies, and the facts obtainable at that time, shall be reported within 24 hours to the OSHA Area Director. Upon request of the Area Direc-

tor, the employer shall submit all additional information in writing relevant to the nature and extent of employee exposures and corrective measures taken to prevent similar emergencies.

(t) *Effective date.* This standard shall become effective January 21, 1975.

(u) *Startup dates.* (1) Determinations and measurements prescribed in paragraph (d) of this section shall be instituted within three months of the promulgation of the final standard, except that for new production areas or operations such determinations and measurements shall be instituted within 30 days of startup of operation.

(ii) Medical surveillance prescribed in paragraph (n) of this section shall be instituted within three months of the promulgation of the final standard.

APPENDIX A

SUBSTANCE SAFETY DATA SHEET

Inorganic Arsenic

I. SUBSTANCE IDENTIFICATION

A. *Substance:* Inorganic Arsenic.

B. *Permissible Exposure:* 0.004 milligrams of arsenic per cubic meter of air (mg As/cu m) as determined on an eight hour time weighted average or a ceiling limit of .01 mg As/cu m averaged over any 15 minute period. No employee may be exposed to any skin contact with arsenic trichloride, or to repeated skin contact with inorganic arsenic which is likely to cause skin irritation.

C. *Appearance:* Inorganic arsenic is usually a white powder. Metallic arsenic is a gray powder. Arsenic trichloride is a clear, almost colorless to pale yellow corrosive oily liquid.

II. HEALTH HAZARD DATA

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

B. *Ways in which the chemical affects your body:* Inorganic arsenic can affect your body if you inhale it, or if it comes in contact with your skin. Inorganic arsenic may also affect your body if swallowed. Arsenic trichloride is especially dangerous because it can be absorbed through the skin. Because inorganic arsenic is a poison, you could be poisoned if you eat or smoke without thoroughly washing your hands after working in an inorganic arsenic work area.

C. *Effects of Overexposure:* If you are exposed to high concentration of inorganic arsenic you may be affected in various ways. You may feel nauseous, weak, and have a loss of appetite. Gradually your skin may harden and darken which may be followed by a feeling of "pins and needles." Excessive inhalation of inorganic arsenic compounds may cause cancer.

III. EMERGENCY AND FIRST AID PROCEDURES

A. *Eye and face exposure:* If arsenic trichloride is splashed in your eyes, wash it out immediately with large amounts of water. Remove contact lenses if worn. Call a doctor as soon as possible.

B. *Skin exposure:* If arsenic trichloride is spilled on your clothing or your skin, wash the exposed skin and clothes under an emergency shower with large amounts of water. You are required to wear protective clothing to prevent repeated skin contact with inorganic arsenic which is likely to cause skin irritation. All inorganic arsenic protective clothing shall be provided by and washed by the employer or any launderer he designates before you wear it again. You may not take your protective clothing home.

C. *Swallowing (Ingestion):* Upon ingestion of any inorganic arsenic compounds, seek immediate medical attention.

IV. PROTECTIVE CLOTHING AND EQUIPMENT

A. *Respirators:* Respirators can only be required for routine use if your employer is in the process of installing engineering controls or where engineering controls are not feasible or insufficient. You must wear respirators for nonroutine activities (e.g., maintenance operations) where you are likely to be exposed to levels of inorganic arsenic above the permissible exposure limit. You must wear respirators in emergencies. Where respirators are worn, they must have a label of approval from the Mining Enforcement and Safety Administration or the National Institute for Occupational Safety and Health. (Older respirators may have a Bureau of Mines approval label). If you experience difficulty in breathing while wearing a respirator, tell your employer.

B. *Protective clothing:* Your employer is required to provide and you must wear appropriate impervious protective clothing (such as boots, gloves, aprons, etc.) over any parts of your body that could be exposed to arsenic trichloride. Your employer is required to provide appropriate protective clothing where repeated skin contact with inorganic arsenic is likely to cause skin irritation.

C. *Eye and face protection.* Your employer is required to provide and you must wear eye and face protection where you may be splashed by arsenic trichloride, or in cases where handling any other inorganic arsenic compounds which may cause eye or face irritation.

V. PRECAUTIONS FOR SAFE USE, HANDLING, AND STORAGE

Cleanup crews shall wear respirators. Because inorganic arsenic is a poison, you must wash your hands thoroughly before eating and smoking. You shall not eat or smoke in a work area where there is skin contact with inorganic arsenic. You shall not wear your work clothes home. You shall shower, when required by this standard, at the end of each workday before going home. Ask your supervisor where inorganic arsenic is used in your work area and for any additional plant rules.

APPENDIX B

SUBSTANCE TECHNICAL GUIDELINES

Arsenic, Arsenic Trioxide, and Arsenic Trichloride

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 (H₂O=1): 5.73.

5. Solubility in Water: Insoluble.

B. Arsenic Trioxide.

1. Formula: As₂O₃.

2. Appearance: White powder.

3. Melting Point: 315C.

4. Specific Gravity (H₂O=1): 3.74.

5. Solubility in Water: 3.7 grams in 100 cc of water at 20°C.

C. Arsenic Trichloride (liquid).

1. Formula: AsCl₃.

2. Appearance: Colorless or pale yellow liquid.

3. Melting Point: -85C.

4. Boiling Point: 130.2C.

5. Specific Gravity (H₂O=1): 2.16 at 20C.

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

7. Solubility in Water: Decomposes in water.

PROPOSED RULES

II. FIRE, EXPLOSION AND REACTIVITY
HAZARD 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. SPILL OR LEAK PROCEDURES

Steps to be taken if substance is released or spilled: No one should enter areas where massive amounts of arsenic (or inorganic arsenic) have been released into the air without appropriate protective equipment until a determination is made that the hazard is abated. Respirators as prescribed in the table of paragraph (g) of this section shall be used during emergencies, cleanup, and repair work. Because of its high vapor pressure and because it can be directly absorbed through the skin, operations involving arsenic trichloride require appropriate protective equipment and shall be handled only under well ventilated conditions.

IV. MONITORING AND MEASUREMENTS
PROCEDURES

Measurements taken for the purpose of determining employee exposure under this section shall be taken in a manner such that the average eight-hour exposure can be determined. Air samples shall accurately reflect the exposure conditions of each employee. The method of sampling and analysis of inorganic arsenic shall have an accuracy of not less than 25% (with a confidence limit of 95%) for concentrations of inorganic arsenic at or above .002 milligrams arsenic per cubic meter (mg As/cu m).

V. MISCELLANEOUS PRECAUTIONS

A. The employer shall provide and ensure that the employee wear clean protective clothing each day. The employer shall not allow any employee to take protective clothing home. The employer must inform the launderer of inorganic arsenic protective clothing of the hazardous properties of inorganic arsenic. Eating and smoking are prohibited in regulated areas or anywhere where skin contact with inorganic arsenic may occur.

B. Employers must advise employees of all plant areas and operations where exposure to inorganic arsenic can occur. Inorganic arsenic is primarily produced in the smelting of ores of copper, zinc, and lead and is most commonly used in pesticide production, glass manufacture, paint anti-fouling, sludge control in lubricating oils, and as an alloying agent.

APPENDIX C

MEDICAL SURVEILLANCE GUIDELINES

*Arsenic and Its Inorganic Compounds
Excluding Arsine*

Physical and Chemical Properties.—Arsenic is a gray lustrous metal which is stable at room temperature. Arsenic trioxide is a white powder released as a by-product of the roasting of copper, zinc, and lead ores in the smelting industry and is the starting material for the synthesis of most other arsenicals such as arsenic acid, lead arsenate, calcium arsenate, and sodium arsenite. Arsenic trichloride is a clear, almost colorless to pale yellow corrosive oily liquid which has a very high vapor pressure and is particularly hazardous because it can be absorbed through the skin. Some of the most serious exposures to inorganic arsenic may occur in the smelting of copper, zinc, lead, and iron ores and in the manufacture and use of insecticides.

Route of Entry.—Inhalation, skin absorption (arsenic trichloride) and ingestion.

Toxicology.—The health hazard is high. Inorganic arsenic is principally absorbed via the lungs and is a skin irritant. Inorganic arsenic has been implicated as a cause of dermatitis, lung cancer, skin cancer, and lymphatic cancer. Dermatitis can be a problem where the rubber of respirators is in direct contact with the skin.

Symptoms and signs.—Acute—Irritation of eyes and mucous membranes of upper respiratory tract. Excessive skin contact may produce a dermatitis. Chronic—Excess skin contact may produce hyperpigmentation and keratoses.

Surveillance and Preventive Examinations.
General.—Inorganic arsenic is considered to be of high toxicity and extensive experience indicates it is a high health hazard.

Medical and Work History Preplacement.—Routine medical histories and physical ex-

aminations are required for each employee subject to exposures in excess of the action level. In addition to the medical history, a complete physical examination shall be given that shall include a minimum of the following:

a. 14 x 17 posterior-anterior chest X-ray giving particular attention to parenchymal and hilar changes; and

b. A complete blood count to include differential; and

c. Palpation of superficial lymph nodes for indication of neoplastic changes; and

d. Careful examination of the skin for the presence of hyperpigmentation, keratoses, or other skin lesions.

Periodic Examinations.—The above examinations are to be given to each employee subject to exposure above the action level. These examinations are to be repeated every 6 months for each employee who has been employed in operations involving inorganic arsenic for 10 years or more, with the exception of X-rays shall be given only annually; for all other employees exposed above the action level.

It is highly recommended that the physician become familiar with the conditions under which inorganic arsenic is used.

Recommended Supplementary Procedures.—Sputum cytological analysis is a recommended procedure for early detection of lung cancer.

2. Patty, Frank A.: *Industrial Hygiene and Toxicology* (Second Edition) John Wiley and Sons, 1962.

(Secs. 6, 8, 84 Stat. 1593, 1599 (29 U.S.C. 655, 657) Secretary of Labor's Order No. 12-71, 36 FR 8754, and 29 CFR Part 1911)

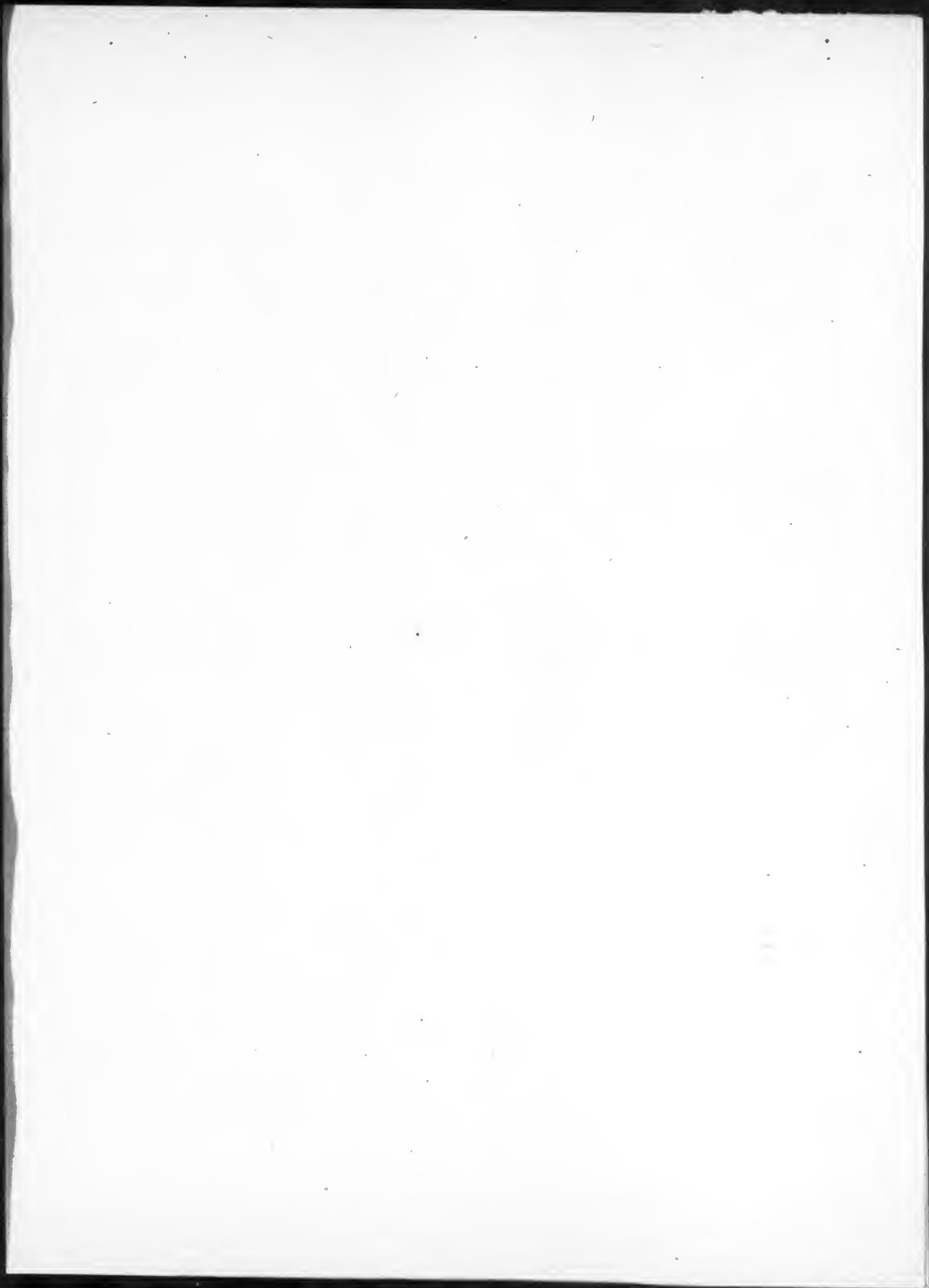
Signed at Washington, D.C. this 10th day of January, 1975.

JOHN STENDER,
Assistant Secretary of Labor.

[FR Doc.75-1727 Filed 1-20-75; 8:45 am]

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1. Hunter, Donald: *The Diseases of Occupations* (Fourth Edition) English University Press, 1969, pp. 333-55.



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