



Testimony to DOL

STATEMENT OF
EDWARD J. BAIER, DEPUTY DIRECTOR
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CENTER FOR DISEASE CONTROL
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Department of Labor
Occupational Safety and Health Administration
Public Hearing on the Occupational Standard for Beryllium

August 19, 1977

I am Mr. Edward J. Baier, Deputy Director of the National Institute for Occupational Safety and Health (NIOSH) administered by the Center for Disease Control within the Department of Health, Education, and Welfare. With me today are: Dr. Joseph K. Wagoner, Dr. Peter F. Infante, Dr. Robert N. Ligo and Dr. Victor E. Archer, Division of Surveillance, Hazard Evaluations and Field Studies; Dr. David H. Groth, Division of Biomedical and Behavioral Sciences; Dr. Janet C. Haartz and Mr. John Sheehy, Division of Physical Sciences and Engineering; Dr. Douglas L. Smith, Division of Criteria Documentation and Standards Development, and Mr. Robert H. Schutz, Testing and Certification Branch.

We welcome this opportunity to appear here today to discuss the effects of occupational exposure to beryllium upon human health, including the results of recent studies conducted by NIOSH.

Since the early 1940s, evidence increasingly has demonstrated the presence of beryllium-induced non-neoplastic respiratory diseases (berylliosis) and their sequelae among workers employed in industries producing and using beryllium and its compounds¹. Cases of berylliosis also have been identified among individuals living near these industrial facilities¹. This accumulation of evidence led to a NIOSH recommendation, transmitted as a criteria document to OSHA in 1972, that occupational exposure to beryllium be limited to 2 micrograms of total airborne particulate beryllium per cubic meter of air (2 ug Be/m³) based on an 8-hour time weighted average (TWA)². In addition, NIOSH recommended at that time that no worker be exposed to peak concentrations of beryllium in excess of 25 ug Be/m³ based on thirty minutes sampling periods. That standard was recommended with the belief that it would "prevent the development of acute and chronic non-neoplastic respiratory disease in workers exposed to beryllium." That standard was not recommended with the stated belief that it would prevent beryllium-induced cancer, as the human studies available at that time were judged to be contradictory, and thus NIOSH concluded that the human evidence did not support animal studies demonstrating beryllium to be a carcinogen.

In 1975, OSHA requested NIOSH to re-evaluate the information available on the adverse health effects of occupational exposure to beryllium and to advise OSHA of the results of that re-evaluation. After a thorough review and evaluation of the most pertinent studies considered in the 1972 document and papers published during the three years since that document, NIOSH on December 10, 1975, transmitted its recommendations that beryllium posed a carcinogenic risk to man and that occupational exposures, therefore, should be reduced to a minimum².

Since 1975 additional data have been generated which further document the carcinogenicity of beryllium among humans. As a result of this collective evidence, NIOSH now recommends that occupational exposure to beryllium be controlled so that no worker will be exposed in excess of 0.5 ug Be/m³.

We believe that a review of the adverse non-neoplastic health effects of beryllium have been sufficiently presented by OSHA so that repetition at this point is unnecessary. We will address issues in this testimony which we believe to be important for consideration by OSHA for the permanent standard on beryllium.

Probably no compounds known to man give so consistent a carcinogenic response in so many animal species as do the compounds of beryllium. At least 20 different beryllium compounds, ranging from beryllium metal to beryllium-containing fluorescent phosphors, have been tested for their carcinogenic effects in animals. Almost without exception, these chemicals have induced metaplasia (pre-cancerous lesions) and/or cancer in the species tested, including the rat, rabbit and monkey^{3,4,5,6,7}. In addition, numerous studies have repeatedly shown beryllium to be carcinogenic by several routes of administration, i.e., inhalation; intravenous, intraperitoneal and subcutaneous injection; and intratracheal instillation. These tumors have metastasized and have been successfully transplanted, thus further substantiating the carcinogenicity of beryllium as well as indicating its high degree of malignancy^{5,7,8,9}.

Some beryllium compounds have been shown to cause lung cancer at doses lower than that for any other pulmonary carcinogen. Inhalation exposures to beryllium sulfate at 39 ug Be/m³ for six months⁵ and 2.8 ug Be/m³ for 18 months¹⁰ have produced pulmonary cancer in rats. A single injection of only 40 ug of beryllium as beryllium hydroxide induced lung cancer, and only 4 ug of beryllium produced metaplasia¹⁰. Based upon these observations, beryllium compounds are considered to be among the most potent carcinogens that have ever been tested in animals.

Hardy et al.¹¹ in a clinical review of the Beryllium Case Registry data reported that there was no Registry evidence as of 1967 that beryllium caused cancer in humans. Recognizing major deficiencies in the Registry for evaluating the carcinogenicity of beryllium, the authors urged a prospective study of workers employed in the beryllium industry. Bayliss and Lainhart in 1972¹² reported no significantly increased risk of respiratory tract cancer among workers employed at two beryllium production facilities. This study likewise was subject to multiple limitations. First, the study group consisted not only of workers directly engaged in the production of beryllium, but also individuals engaged in clerical, sales, and administrative activities at either of these two facilities. Second, the study group was defined using records submitted by industrial representatives with no independent scientific assessment of the plant employment files or other record systems to insure the exhaustive inclusion of all individuals having been employed at the facilities studied. Third, by definition, the study provided little opportunity to scientifically assess the potential carcinogenicity of beryllium at 20 or more years since onset of exposure, that time period previously shown in studies of other agents to be associated with the detection of a carcinogenic risk. Fourth, the study used rates from the entire U.S. white male population to generate expected deaths, with no consideration given to the fact that the majority of the study group were residents of Berks County, Pennsylvania, a geographic area having a lung cancer mortality rate significantly lower than that of the U.S.

In 1969, Mancuso and El-Attar¹³ reported that individuals employed in two beryllium production plants during 1937-1948 and followed through 1965 experienced an increased risk of lung cancer when contrasted with rubber workers followed over the same period of time. More recently, rubber workers themselves have been shown to be at an increased risk of cancer, including bronchogenic cancer, thus the previously reported excessive risk of lung

cancer among beryllium production workers was an underestimate of the true risk^{14,15,16,17}. In 1970, Mancuso¹⁸ further reported on the role of beryllium-induced bronchitis and pneumonitis in the etiology of lung cancer among beryllium production workers. In this study, among 142 cases of beryllium-related bronchitis and pneumonitis identified during 1940-1948, six deaths due to lung cancer subsequently occurred, for an age-adjusted lung cancer mortality rate of 284.3 per 100,000 population. This rate when contrasted with 77.7 for all white males employed in the same beryllium production facility during 1937-1948, led the author to conclude "prior" chemical respiratory illness influences the subsequent development of lung cancer among beryllium workers. More recently, Hasan and Kazemi¹⁹ reported an increased risk of death due to lung cancer among 53 males who, since 1965, were entered into the Beryllium Case Registry because of berylliosis. Within the past month, Bayliss and Wagoner²⁰ reported a statistically significant increased risk of death due to bronchogenic cancer, non-neoplastic respiratory disease and heart disease among white males occupationally employed in a beryllium extraction, processing and fabrication facility during 1942 through 1967 and followed through 1976. The excess of bronchogenic cancer was most marked after 25 years since onset of beryllium exposure and occurred irrespective of the duration of employment. This increased risk of bronchogenic cancer could not be attributed to cigarette smoking and was an underestimate of the true risk experience by beryllium production workers due to the choice of the control population and the statistical treatment of individuals lost to follow-up.

Additional analyses²¹ demonstrated that the increased risk of bronchogenic cancer among workers occupationally exposed to beryllium persisted for those individuals initially employed in 1950 or later, that time period during which the Atomic Energy Commission limit of 2 ug Be/m³ was in effect. More recently, Mancuso²² using records derived from the Social Security Administration, demonstrated an increased risk of bronchogenic cancer among workers at each of two beryllium production facilities, one in Ohio and one in Pennsylvania. This increased risk of bronchogenic cancer at each facility was most marked after 15 years since onset of beryllium exposure.

Infante et al.²³ demonstrated no increased risk of bronchogenic cancer among 418 white males enrolled alive in the Beryllium Case Registry (BCR) during January 1, 1952, through December 31, 1975. The inability to demonstrate an increased risk of bronchogenic cancer among individuals diagnosed with beryllium disease was largely a function of the high case fatality due to non-neoplastic respiratory disease. This was demonstrated by an 18-fold excessive risk of non-neoplastic respiratory disease deaths, the large majority of which occurred within 15 years since enrollment into the BCR.

The reports of Bayliss and Wagoner and of Mancuso are confirmatory of earlier animal bioassay and human epidemiological studies showing beryllium to be a carcinogen.

In view of the cumulative evidence presented, NIOSH recommends that beryllium be classified as a carcinogen. Since no safe level has yet been demonstrated for a carcinogen, NIOSH further recommends that beryllium be controlled as low as possible in the industrial setting so as to materially reduce the risk of cancer.

In the subsequent portion of this testimony, NIOSH will address issues for the OSHA permanent standard on beryllium. OSHA has not recommended a specific method of measurement for assessing compliance with permissible units of airborne concentrations or employee exposure to beryllium. A slight modification in the sampling and analytical method recommended in the NIOSH criteria document is indicated. NIOSH recommends that the method of measurement of employee exposure be collection of personal samples on cellulose ester membrane filters followed by flameless atomic absorption determination of the total beryllium in the sample. This method has been evaluated by NIOSH over the range of 2.68-11.84 ug Be/m³ using a 40-liter air sample. The precision and accuracy of the method were determined to be within +25% of the "true" value at the 95% confidence level²⁴. The data indicate that this method would be satisfactory for the measurement of air concentrations of 0.5 ug Be/m³, providing that a 220 liter (130 minutes at 1.7 liter per minute) air sample was collected.

Numerous published reports document environmental concentrations of beryllium in beryllium processing and manufacturing facilities. Schulte²⁵ reported environmental concentrations of beryllium in a beryllium machine shop which included lathes, a mill and a surface grinder. Of 1,271 air samples collected from 1952 through 1960, 98% contained less than 1.0 ug Be/m³, and 91% contained less than 0.2 ug Be/m³. During the last two years of this study (1959-1960), beryllium concentrations were even lower, with 96% of the samples containing less than 0.2 ug Be/m³. More recently, NIOSH found no detectable concentrations of beryllium in a survey of a plant machining precision metal parts, including beryllium²⁶.

In a NIOSH survey²⁷, personal gross air samples of 39 workers at a beryllium production plant showed average beryllium concentrations greater than 2 ug Be/m³ for 28 of the workers. In a second plant that produces beryllium metal and fabricates it, personal gross air samples of 17 workers were taken²⁷. Of these 17, all but one showed a beryllium concentration greater than 2.0 ug/m³. In a third plant which produces beryllium copper, the beryllium concentrations by the gross personal sample method averaged greater than 2.0 ug/m³ for five of the 12 workers²⁷. A more recent study²⁸ of one of the above beryllium production facilities showed that the average beryllium concentration in four of five areas evaluated exceeded 2 ug/m³ with one area averaging 13 ug/m³.

These environmental data clearly show that the three existing beryllium production facilities in the United States not only have exceeded the NIOSH proposal of 0.5 ug Be/m³ but also during the recent past have exceeded the current OSHA standard of 2 ug Be/m³ promulgated in 1971. As such, NIOSH does not consider environmental data from these beryllium production facilities appropriate to evaluate feasibility of engineering control. NIOSH believes that in these several beryllium production facilities, application of existing engineering control technology would contribute to significant reduction of beryllium concentrations. In contrast, beryllium machining operations already having applied existing engineering control technology are currently at or below both the existing OSHA standard and the NIOSH proposed standard of 0.5 ug Be/m³.

In proposing a standard NIOSH recognizes that in each beryllium operation the amount of beryllium emitted to the workplace air during the course of a day or week or year is variable. For example, in one area of a beryllium production facility the average beryllium concentration on 105 samples taken

over a 12 month period was 5.2 ug/m³ while the standard deviation was 10.73 ug/m³²⁸. This variability inherent in beryllium operations means that engineering and work practice controls should be designed to meet a concentration well below the proposed standard to ensure that the standard is not exceeded.

The use of engineering control is the primary method for keeping exposure at or below the environmental standard. Such control may include new process systems; redesign of processes to remove the worker from the process; enclosure of process equipment; local exhaust ventilation with a balanced make-up air supply; and low volume-high velocity vacuum pickup points.

In addition to the use of engineering control, work practices for reducing beryllium exposures in the workplace at or below the proposed standard should be instituted. Work practice control may include: vacuum cleaners or water spray cleanup methods; separate locker-rooms for street clothes and work clothes; adequate showering facilities; provisions for a decontamination chamber for beryllium contaminated equipment requiring maintenance; tight-fitting beryllium transfer operations; moving beryllium contaminated equipment about in enclosures; and designing containers for beryllium with adapters so that a tight seal can be formed during beryllium transfer steps. To be effective, work practices must be clearly explained and carefully supervised.

Where engineering and work practice controls do not reduce beryllium exposures to or below the environmental standard, respirators must be worn. The use of respiratory equipment should be permitted only until engineering and work practice controls can be implemented which reduce the beryllium exposure in the workplace at or below the environmental standard and should be mandated during maintenance of operations. The employer should not rely on the use of respirators as a control, since these will not reduce the beryllium concentrations in the workplace. A list of the recommended respirator requirements for the permanent beryllium standard is submitted for the record²⁹. In addition NIOSH recommends that the Medical Surveillance Section of the OSHA proposed standard be revised. A recommended revision is submitted for the record³⁰. In keeping with the principles of medical surveillance, NIOSH further recommends that OSHA require all known and suspected cases of beryllium-related respiratory diseases be reported to the Beryllium Case Registry.

Finally, because beryllium is a carcinogen, NIOSH recommends that this danger be prominently displayed on all warning signs, placards and labels. Training programs should also be initiated to fully inform employees of the hazards related to beryllium exposure.

Reports and other items referenced in this NIOSH testimony have been submitted for the hearing record.

We are now ready to answer questions.

REFERENCES

1. NIOSH Recommended Standard - Occupational Exposure to Beryllium. U.S. Department of Health, Education, and Welfare, NIOSH Publication No. HSM 72-10268, 1972.
2. Letter to Assistant Secretary for Occupational Safety and Health, Department of Labor, "Update of NIOSH Criteria Document on Beryllium." From Director, National Institute for Occupational Safety and Health, December 10, 1975.
3. Stokinger, H.E. Experimental Toxicology. In The Toxicology of Beryllium, by I.R. Tabershaw, pp 17-32. U.S. Department of Health, Education and Welfare, NIOSH Publication No. HSM 73-11008, 1972
4. Gardner, L.U. and Heslington, H.F. Osteosarcoma from Intravenous Beryllium Compounds in Rabbits. Fed. Proc. 5:221, 1946.
5. Schepers, G.W.H., Duncan, T.M., Delephant, A.B., et al. The Biological Action of Inhaled Beryllium Sulfate. Arch. Industrial Health 15:32-58, 1957.
6. Wagner, W.D., Groth, D.H., et al. Comparative Chronic Inhalation Toxicity of Beryllium Ores, Bertrandite and Beryl with Production of Pulmonary Tumors by Beryl. Toxicol. and Appl. Pharmacol. 15:10-29, 1969.
7. Vorwald, A.J. Biologic Manifestations of Toxic Inhalants in Monkeys. In Use of Nonhuman Primates in Drug Evaluation, ed., H. Vagtberg, pp. 222-228, University of Texas Press, Austin.
8. Groth, D.H., Scheel, L.D. and Mackay, B.A. Comparative Pulmonary Effects of Beryllium and Arsenic Compounds in Rats. Unpublished presentation at the Annual Meeting of the International Academy of Pathology, Cincinnati, Ohio, March 15, 1972.
9. Dutra, F.R., Largent, E.J., et al. Osteogenic Sarcoma after Inhalation of Beryllium Oxide. A.M.A. Arch. Pathol. 51:473-479, 1951.
10. Vorwald, A.J., Reeves, A.L., et al. Experimental Beryllium Toxicology. In Beryllium Its Industrial Hygiene Aspects, ed., H.E. Stokinger, pp. 201-234, Academic Press, 1966.
11. Hardy, H.L., Rabe, E.W. and Lorch, S. United States Beryllium Case Registry (1952-1966): Review of Its Methods and Utility. J. Occup. Med. 9:271-276, 1967.
12. Bayliss, D.L. and Lainhart, W.S. Mortality Patterns in Beryllium Production Workers. Paper presented at the American Industrial Hygiene Association, Cincinnati, Ohio, May 18, 1972.
13. Mancuso, T.F. and El-Attar, A.A. Epidemiological Study of the Beryllium Industry. J. Occup. Med. 11(8):423-434, 1969.
14. Mancuso, T.F. Relation of Duration of Employment and Prior Respiratory Illness to Respiratory Cancer Among Beryllium Workers. Env. Res. 3:251-275, 1970.

15. Andjelkovic, D., Taulbee, J. and Symons, M. Mortality Experience of a Cohort of Rubber Workers, 1964-1973. *J. Occup. Med.* 18(6):387-394, 1976.
16. Monson, R.R. and Nankano, K.K. Mortality Among Rubber Workers: I. White Male Union Employees in Akron, Ohio. *American J. Epid.* 103:284-296, 1976.
17. Fox, A.J. and Collier, P.F. A Survey of Occupational Cancer in the Rubber and Cabelmaking Industries - Analysis of Deaths Occurring in 1972-1974. *Brit. J. Ind. Med.* 33(4):249-264, November 1976.
18. Mancuso, T.F., Ciocco, A., El-Attar, A.A. An Epidemiologic Approach to the Rubber Industry. *J. Occup. Med.* 10:213-232, 1968.
19. Hosan, F.M. and Kazami, H. Chronic Beryllium Disease: A Continuing Epidemiologic Hazard. *Chest* 65:289-293, 1974.
20. Bayliss, D.L. and Wagoner, J.K. Bronchogenic Cancer and Cardio-Respiratory Disease Mortality Among White Males Employed in a Beryllium Production Facility. Unpublished report of the National Institute for Occupational Safety and Health, Cincinnati, Ohio, 1977.
21. Bayliss, D.L. and Wagoner, J.K. Brochogenic Cancer Risk Among White Males Employed in a Beryllium Production Facility According to Initial Employment. Unpublished report of the National Institute for Occupational Safety and Health, Cincinnati, Ohio, prior to and subsequent to issuance of the AEC Beryllium Guidance of 2 mg/m³.
22. Mancuso, T.F. Personal communication to Director, National Institute for Occupational Safety and Health, Rockville, Maryland, July 1977.
23. Infante, P.F., Sprince, N.L. and Wagoner, J.K. Clinical Diagnosis and Mortality Patterns Among Subjects in the Beryllium Case Registry. Unpublished report of the National Institute for Occupational Safety and Health, Cincinnati, Ohio, 1977.
24. NIOSH Method No. S339, Beryllium and Beryllium Compounds. National Institute for Occupational Safety and Health Contract No. CDC-99-74-45, Cincinnati, Ohio.
25. Schulte, H.F. and Hyatt. Beryllium Machining: Hazard Control and Costs. Workshop on Beryllium, Kettering Laboratory, University of Cincinnati, Cincinnati, Ohio, pp. 19-33, 1961.
26. NIOSH Health Hazard Evaluation Determination Report No. 76-103-349. National Institute for Occupational Safety and Health, Cincinnati, Ohio, December 1976.
27. Donaldson, H.M. Industry-Wide Study of Beryllium Production Facilities. National Institute for Occupational Safety and Health, Cincinnati, Ohio, July 1973.

28. Donaldson, H.M. and Stringer, W.T. Beryllium Sampling Methods. National Institute for Occupational Safety and Health, Cincinnati, Ohio, July 1976.

29. Respirator Section Guide for Beryllium Applicable under Proposed Standard of 0.5 ug/m³. National Institute for Occupational Safety and Health submits a list of recommended respirator requirements for the permanent beryllium standard during these hearings.

30. Medical Surveillance for Beryllium. National Institute for Occupational Safety and Health submits a recommended revision for the Medical Surveillance Section of the OSHA proposed standard during these hearings.