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November 5, 2015

David Michaels, PhD, MPH
Assistant Secretary of Labor for Occupational Safety and Health
Department of Labor
Room N–2625
200 Constitution Avenue NW
Washington, DC 20210

Attention: OSHA Docket Office, Docket No. OSHA-H005C-0870

Dr. Michaels:

On behalf of the American Thoracic Society (ATS), we want to thank the Office of Occupational Safety and Health Administration for the opportunity to comment on 29 CFR Part 1910 Occupational Exposure to Beryllium and Beryllium Compounds; Proposed Rule. The **ATS strongly supports OSHA's efforts to put forth a stricter comprehensive standard to monitor and reduce exposure in the workplace and implement medical surveillance in beryllium using industries**. Ongoing occupational exposures to beryllium in the workplace based on the current OSHA beryllium standard continue to result in significant respiratory disease and health effects.

The ATS and its members have unique expertise and experience in the evaluation, care and research of beryllium related health effects, including chronic beryllium disease, the precursor to disease, beryllium sensitization, and lung cancer, as well as the medical surveillance of workers for these health effects. As a result, the ATS recently published "An Official American Thoracic Society Statement: Diagnosis and Management of Beryllium Sensitivity and Chronic Beryllium Disease" in 2014 based on a review of the literature and the expertise of its members (appended to these comments). Because of our expertise and experience, the ATS has a compelling interest and is uniquely qualified to comment on the proposed beryllium standard.

Summary of ATS comments:

The ATS supports the OSHA proposal to **reduce the permissible exposure limit (PEL) to beryllium to 0.2 µg/m^3 with an action level of 0.1 µg/m^3.**

It also supports a comprehensive program that includes **exposure assessment, reduction of exposures in the workplace, medical surveillance to detect beryllium health effects, an option for medical removal, and training to reduce exposures and risks of beryllium health effects.** Furthermore, the ATS recommends that **OSHA expand the scope of the current standard** to include workers in other industries who work with beryllium. The ATS supports **expanded eligibility for medical surveillance** to employees who are exposed in "beryllium areas," as long as beryllium exposure (above or below the action level) is documented in the workplace. The ATS agrees with OSHA that significant risk of health effects remain at the proposed PEL of 0.2 $\mu g/m^3$, as current data outlined in the ATS Beryllium Statement, as well studies cited by OSHA, indicate that beryllium health effects including beryllium sensitization and CBD can develop with bystander and low levels of exposure. Finally, the ATS **does not support the use of low dose CT scans** as medical surveillance for lung cancer in beryllium workers as there is no current data to support such an approach in this population. With recognition of the detrimental health effects due to beryllium, the Department of Energy put standards in place to reduce exposures and provide medical surveillance to reduce the health effects due to beryllium exposure; we laud OSHA for recommending similar measures for non-federal workers.

Q1,2: In regards to health effects, the ATS **supports the inclusion of beryllium sensitization, CBD, and skin disease as the major adverse health effects** associated with exposure to beryllium at or below 0.1 $\mu g/m^3$ and acute beryllium disease at higher exposures based on the currently available epidemiologic and experimental studies.

Q4: The ATS supports the analysis of OSHA's risk assessment based on the currently available data. Information on downstream users of beryllium is not well understood and it would be helpful if OSHA was able to obtain that information from the sole source beryllium manufacturer in the US.

Q5-7: The ATS agrees with OSHA's preliminary risk assessment that there is significant risk of CBD at the current PEL and that this risk is reduced although still present at the proposed PEL. It is reasonable to use BeS and CBD as the significant health endpoints to drive the risk analysis. Of note, WorksafeBC in British Columbia, Canada recently reviewed the evidence and reduced the PEL to 0.05 $\mu g/m^3$ in the context of achieving exposures as low as reasonably achievable (ALARA). Even PELs this low are unlikely to prevent all health effects for example to those with potential by-stander exposure risk (see ATS Statement Online Supplement). The ATS supports the proposed PEL of 0.2 $\mu g/m^3$ with the goal to keep exposures ALARA.

Q9: The **ATS agrees with the definition of the BeLPT** proposed in the docket, although **it recommends that OSHA modify the definition of beryllium sensitization** to indicate that a "confirmed positive" include two abnormal test results (where there are 2 stimulation indices that are above the test background), or an abnormal and a borderline (where there is one stimulation index above the test background level) test result. These test results need not be from consecutive BeLPTs or from a second abnormal BeLPT result within a two-year period of the first abnormal result. These recommendations are based on the many studies cited in the docket, as well as those of Middleton, et al. (2006, 2008, and 2011), which showed that an abnormal and a borderline result provide a positive predictive value (PPV) similar to that of two abnormal test results for the identification of both beryllium sensitization and for CBD.

Q10: Once an individual is determined to be sensitized, the ATS agrees with OSHA that **workers should be sent for evaluation to a diagnostic center**. A CBD diagnostic center should have a physician(s) and other personnel who is/are able to provide expertise regarding beryllium health effects and be able to perform testing for evaluation of CBD (as outlined in the ATS Statement), including pulmonary function testing with diffusion capacity according to ATS criteria, chest radiography, and bronchoscopy with bronchoalveolar lavage (BAL) and transbronchial biopsies as needed. A CBD diagnostic center would need to be able to process the BAL cells appropriately and ship them to a laboratory that conducts appropriate diagnostic testing within 24 hours. The ATS recommends ongoing evaluation for progression from sensitization to CBD every 1-3 years.

Q17: The ATS agrees that it is essential for **employers to provide employees with respiratory protection** in settings where beryllium engineering and or administrative controls may not be adequate and/or feasible, in accordance with the OSHA Respiratory Protection Standard (29 CFR 1910.134), which determines the level of respiratory projection required based on an exposure assessment for a given task and workplace and the OSHA PEL. Furthermore, the ATS agrees that a tight-fitting, powered air-purifying respirator (PAPR) provides superior protection to non-PAPR air-purifying respirator.

Q19: The ATS **supports OSHA's standard to use personal protective equipment (PPE) to reduce exposure to skin** and, thus, the risk of sensitization. However, the use of "visibly contaminated" as a trigger for PPE is problematic for multiple reasons, and the ATS recommends removing the word "visibly". The ATS believes that it is important to limit skin exposure to soluble and insoluble beryllium to the extent possible, as skin exposure to both forms of beryllium increases risk of beryllium sensitization. The amount of skin exposure that increases risk is unclear and visual inspection cannot accurately estimate the amount of beryllium or its chemical state. Use of "visibly contaminated" is also not supported by the literature cited, which demonstrates skin exposure and sensitization in work settings considered clean, with no visible contamination.

Q23/24. The ATS **supports the periodic evaluation of workers using the surveillance approach described in the ATS statement.** The purpose is to identify those with sensitization and potentially CBD, as well as to define the risk of various work exposures, jobs, and tasks. Once an employee has been determined to have sensitization, s/he should be offered the ability to undergo clinical evaluation at a CBD diagnostic center initially and on a 1-3 year basis to determine if they have progressed to CBD. If symptoms develop in an individual who is exposed to beryllium, diagnostic evaluation should commence immediately.

The ATS recommends that medical surveillance consist of a review of the work history with emphasis on past and present exposure, smoking history, and any history of respiratory symptoms or skin rash or lesions as outlined in the standard as well as the BeLPT.

Many current worker surveillance programs rely solely on the BeLPT as prior studies (including those cited by OSHA) have demonstrated that physical/medical examination, spirometry and chest radiographs are neither sensitive nor specific for sensitization or CBD. The BeLPT is a relatively easy to use test, with no more difficulties in interpretation, implementation or follow up than other screening tests.

Workers should be educated that a physical exam and clinical evaluation is recommended if they develop beryllium skin disease. However, it is not clear that a yearly physical exam is warranted for skin disease alone.

The ATS recommends that OSHA require workforces to track sensitization and disease and use this along with exposure monitoring in a comprehensive program to define work areas that should be targeted for reduction in exposures and changes in work practices and medical surveillance, to ultimately reduce the risk of sensitization and disease. Current medical surveillance programs include workers with the potential for bystander or direct beryllium exposure in beryllium areas and not only in areas where exposure is at or above the PEL or action level. The difficulty with using these exposure cutoffs or the currently defined "regulated area" to dictate medical surveillance is that a workplace may not measure or realize when an exposure is at or above the action level or PEL. There is no ability to measure exposures daily or in most workplaces even weekly or monthly, to determine if an area otherwise meets the criteria as a regulated area. Furthermore, the studies that OSHA sites and those noted in the ATS statement have revealed cases of sensitization and CBD in workers with seemingly trivial or unrecognized exposures. Current experience and research indicates that an abnormal BeLPT and sensitization may be the first sign that beryllium exposures have been sufficient to put workers at risk of CBD; these sentinel case findings of sensitization and CBD have prompted reduction in exposures when used alone and/or in combination with exposure monitoring.

The ATS recommends that **the CT scan requirement for medical surveillance be eliminated**. The data reviewed by OSHA clearly demonstrate that beryllium is a carcinogen. The risk of lung cancer at the proposed standard is less clear. Although beryllium is a potential lung carcinogen, the use of low-dose helical CT scan for screening lung cancer has not been studied in the population in question. Therefore, there are concerns about the clinical effectiveness, safety, and cost effectiveness of this procedure, particularly in the non-smoking population.

Q26: The ATS recommends that all medical examinations and procedures required by the standard must be performed by or under the direction of a licensed physician. Given the multi-organ involvement, atypical presentations, and complex medical and legal issues related to the beryllium standard, it is reasonable that medical surveillance be performed by or under the direction of a licensed physician.

The American Thoracic Society appreciates the opportunity to provide comments on the proposed beryllium standard. We would be happy to answer any questions or provide follow up information if and as needed.

Sincerely,

Atul Malhotra, M.D.
President
American Thoracic Society

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