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February 8, 2019

H. Alexander Acosta, Secretary Department of Labor  
200 Constitution Avenue, N.W.  
Washington, D.C. 20210

RE: Docket No. OSHA 2018-0003 Revising the Beryllium Standard for  
General Industry

Secretary Acosta:

On behalf of the American Thoracic Society (ATS), we appreciate the opportunity to comment on the Office of Occupational Safety and Health Administration's 29 CFR Part 1910 Revising the Beryllium standard for General Industry Notice of Proposed Rule Making. The ATS strongly supports OSHA's rule adopted on January 9, 2017 to provide a comprehensive general industry standard to reduce beryllium exposure and implement medical surveillance in beryllium-using industries. These include industries using alloys of beryllium, small operations and buildings where legacy materials are present. The ATS and its members have unique expertise and experience in the evaluation, care and research of beryllium-related health effects, including beryllium sensitization and chronic beryllium disease, and lung cancer, as well as the medical surveillance of workers for these health effects. The ATS 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). The ATS is thus uniquely qualified to comment on the proposed modifications to the beryllium standard put forward to clarify, simplify and/or improve compliance with the current beryllium standard.

**Summary of ATS comments:**

The ATS has concerns regarding OSHA's proposed changes related to 1) Chronic Beryllium Disease (CBD) diagnostic centers, 2) the definitions of beryllium sensitization and chronic beryllium disease, and 3) the addition of "visual" to describe dust.

The ATS recommends that a clinical evaluation for chronic beryllium disease should evaluate lung function, including gas exchange (e.g. with



full pulmonary function testing) and chest imaging, and the services should be provided by the CBD diagnostic center in a timely manner. These services do not need to be performed exclusively by a pulmonologist, but instead a physician with beryllium expertise.

The ATS does not support OSHA's requirement that the examination at the CBD diagnostic center be provided within 30 days of the employer receiving documentation of beryllium sensitization nor do we support OSHA's proposed alternative that the employer provide a video or phone consultation with the CBD diagnostic center within 30 days. The requirement for all CBD evaluations to be scheduled and completed within 30 days is an unrealistic timeframe. Instead, we propose that the employer offer and schedule the evaluation with a CBD diagnostic center within 30 days of receiving documentation of beryllium sensitization or need for referral to a CBD diagnostic center.

The ATS does not agree with the removal of beryllium sensitization from the "confirmed positive" definition of beryllium lymphocyte proliferation test (BeLPT) testing results, as this differs from the medically accepted interpretation of BeLPT testing results and the ATS Statement on beryllium. In addition, the repeated use of the terminology "confirmed positive" without describing what is confirmed positive, namely sensitization to beryllium, is confusing.

The ATS strongly disagrees with the OSHA proposal to require at least two BeLPT tests within 30 days in order to confirm CBD, as there is no scientific evidence to support this time frame. The ATS supports that repeat BeLPT testing be offered to an employee within 30 days of the first abnormal or borderline test. However, the ATS recommends that confirmation of beryllium sensitization can be performed up to at least 3 years after the initial abnormal or borderline test, in order to improve diagnostic accuracy.

The ATS strongly urges OSHA to use the diagnostic criteria for CBD diagnosis as outlined in the ATS Statement, rather than OSHA's newly proposed criteria.

The ATS requests that OSHA clarify that the addition of "visual dust" is in reference to dermal contact and should not be misconstrued to eliminate the need for comprehensive beryllium air monitoring and medical surveillance.

### **Detailed Comments on the Proposed Changes:**

#### **Proposed Changes Related to CBD Diagnostic Centers:**

**1. OSHA is proposing to amend the CBD diagnostic center definition to add the term "*pulmonologist be on staff*" and not require pulmonary function testing as part of the clinical evaluation but instead that "*the CBD diagnostic center must have the capacity to perform appropriate diagnostic testing ...*"**

The ATS notes that a clinical evaluation at a CBD diagnostic center does not need to be conducted by a pulmonologist, although a pulmonologist should be available for consultation or "on staff" (but not on site) in order to perform a bronchoscopy with bronchoalveolar lavage (BAL) and biopsies if needed. A physician conducting the evaluation should have expertise in beryllium health effects and could be either a pulmonologist, occupational medicine or internal medicine or



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other specialist able to interpret the testing as stated above. The CBD diagnostic center should have the capability to perform the diagnostic evaluation in a timely fashion.

The ATS is concerned that “having the capacity” but not requiring certain diagnostic tests (or an equivalent) could reduce the potential to diagnose CBD and determine disease severity. Confirmed positive workers should have an assessment of lung function and gas exchange (such as a full set of pulmonary function tests with spirometry, lung volumes and diffusion capacity for carbon monoxide or other similar tests) and also chest imaging.

## **2. OSHA is proposing that the employer provide an initial consultation with the CBD diagnostic center, rather than the full evaluation, within 30 days.**

While the ATS supports measures to demonstrate that an employer has initiated the process of medical examination, it does not support the requirement that the examination at a CBD diagnostic center be provided within 30 days nor the above proposed change to require consultation with a CBD diagnostic center within 30 days. There are few centers with expertise in beryllium-related health effects, making this requirement overly restrictive. It can take weeks to schedule and arrange an appointment. Workers often cannot coordinate travel, work, and personal obligations in this time frame. OSHA’s proposal to have an initial consultation by phone or videoconferencing in 30 days would reduce the effectiveness of the standard, as medical expertise cannot be provided over the phone without an in-person clinical evaluation and review of medical test results. In fact, it would likely be redundant with the role of the physician or other licensed healthcare provider (PLHCP) in answering questions about the process. In addition, a telephone consultation is NOT sufficient to replace in person clinical consultation as no diagnostic testing would be available or diagnosis could be established. This measure would likely reduce the accuracy of beryllium surveillance. As an alternative, the ATS recommends that employers have the obligation to schedule a visit with a qualified CBD diagnostic center within 30 days of notification of positive findings. Retaining the obligation that employers respond within 30 days by scheduling the appointment, but actual patient visit can occur outside that 30-day window, is appropriate considering the potential severity of beryllium-related lung disease.

### **Proposed Changes related to the Definition of Beryllium Sensitization**

## **3. OSHA is proposing to change the definition of confirmed positive by removing the phrase “beryllium sensitization” from the first part of the definition.**

The ATS strongly opposes this change in definition. In the ATS Statement test results that constitute the determination of “confirmed positive” are the definition of beryllium sensitization. Eliminating the medically appropriate term “beryllium sensitization” would reduce worker protections and the right to file for worker’s compensation. In addition, OSHA has proposed a clarification to the definition of CBD as follows: “the agency is proposing chronic beryllium disease to mean a chronic granulomatous lung disease caused by inhalation of airborne beryllium by an individual who is beryllium-sensitized.” It is stated that “This proposed change would clarify OSHA's finding that beryllium sensitization is essential in the development of CBD.” Thus it is important to keep the term “beryllium sensitization” in the definition of confirmed abnormal.



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**4. OSHA is proposing an additional change to confirmed positive which would include clarification that the findings of two abnormal, one abnormal and one borderline, or three borderline results need to occur within the 30-day follow-up test period required after a first abnormal or borderline BeLPT test result.**

The ATS strongly recommends that OSHA NOT establish a 30-day time limit for interpreting repeat BeLPT testing results in deciding whether the results provide evidence of sensitization or “confirmed positive.” There is no scientific evidence to support this time frame and it is not feasible for employers or employees. Prior studies have noted that workers can develop sensitization with combination of BeLPTs up to 10 years after a first abnormal (Kreiss et al Occ Env Med 1997; Deubner [Appl Occup Environ Hyg](#) 2001; Stange et al Am J Ind Med 2004). Furthermore, it will put undue burden and will be logistically challenging for workplaces, especially smaller industries without a medical director or workplace health care provider, and those in remote areas with limited access to healthcare. It would necessitate split testing, increasing costs of surveillance. Most laboratories that perform the BeLPT require 14 days from blood draw to test result. If there is a technical problem with the blood draw and or blood test (e.g. uninterpretable), and a test needs to be redrawn (or there are 2 borderlines and a 3<sup>rd</sup> test is needed) it is logistically impossible to obtain testing within a 30-day period. Most importantly, the ATS is concerned that this measure will reduce the accuracy of diagnostic evaluations for beryllium related health effects as well as referral of workers to a CBD diagnostic center. If an employee has an abnormal test that repeats normal current standards recommend another test be performed to confirm that normal or abnormal result, although there is currently no time limit for this repeat testing. In fact, some data suggest that the risk of a false negative rate is higher for the BeLPT than a false positive (Stange et al 2004). Some current medical surveillance protocols used by the Department of Energy and others recommend waiting a few months to help exclude a false negative and/or help ensure that a test is repeatable.

The ATS recommends that OSHA use a longer time frame than 30 days, such as at least 3 years or longer to allow repeat testing to identify confirmed positive workers, as this is more feasible than 30 days and allows testing from at least two rounds of medical surveillance to provide evidence of a confirmed positive or sensitization. We support that initial repeat testing be offered to an employee within 30 days of the first abnormal or borderline test, but that testing to determine whether a worker is confirmed positive cannot be required to be obtained within 30 days, for the reasons stated above. These measures will help ensure workers are accurately diagnosed with sensitization.

**Proposed Changes Related to the Definition of CBD**

**5. OSHA is also proposing changes to the definition of CBD: OSHA is proposing chronic beryllium disease to mean “a chronic granulomatous lung disease caused by inhalation of airborne beryllium by an individual who is beryllium-sensitized. The proposed definition includes several changes to the current definition of chronic beryllium disease. This proposed change would clarify OSHA’s finding that beryllium sensitization is essential in the development of CBD.**



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The ATS is concerned that these changes in the definition of CBD could create diagnostic confusion. While beryllium sensitization is essential to the development of CBD, demonstrating beryllium sensitization, as well as granulomatous lung disease on lung pathology, can be challenging in certain settings. The ATS recommends that OSHA use the diagnostic criteria for CBD outlined in the 2014 Official ATS Statement, namely: *“The diagnosis of CBD is based on confirmation of an immune response to beryllium and granulomatous lung inflammation on lung biopsy. Depending on the clinical setting, feasibility of certain diagnostic tests, and degree of diagnostic certainty needed, probable CBD can be diagnosed based on differing combinations of diagnostic criteria, including a clinical presentation consistent with CBD, a history of beryllium exposure, evidence of beryllium sensitization (e.g., abnormal BeLPT), radiographic findings, lung histology, BAL findings, and lung function abnormalities.”*

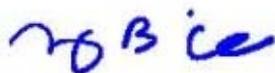
**Proposed Changes related to adding “visual” to dust.**

**6. OSHA is proposing to add “visual” dust as a trigger for many provisions related to dermal contact with beryllium, such as education, medical surveillance, skin protection, and other beryllium monitoring. For example, OSHA proposes modifying the definition of dermal contact with beryllium to cover skin exposure to “visible dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight”.**

The ATS asks OSHA to ensure that while this addition could be helpful, inhalation of a respirable beryllium particulate that is not visible is the major concern for the development of CBD. This measure should not undermine a thoughtful beryllium monitoring program, nor be used to limit beryllium education to workers with exposure to “visual” dust, as workers can develop CBD with exposure to non-visible beryllium dust. The ATS would urge OSHA to clarify that education regarding beryllium health effects be provided to all potentially exposed beryllium workers and that a comprehensive beryllium exposure monitoring program is undertaken by workplaces to limit respirable beryllium exposure. Furthermore, because beryllium products entering a facility may not be labeled as such and users and distributors of the metal are not well known, OSHA should remain vigilant for new applications for beryllium and its alloys and the waste stream of these products, including metal recycling facilities.

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

Sincerely,



Mary B. Rice MD MPH  
Chair, ATS Environmental Health Policy Committee



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