

Advisory Board on Toxic Substances and Worker Health

June 30, 2022

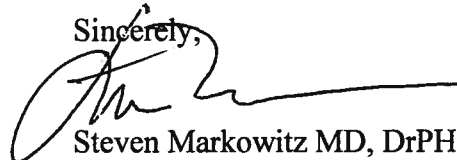
Mr. Martin J. Walsh
Secretary of Labor
Department of Labor
200 Constitution Ave.
Washington, DC NW 20210

Honorable Secretary Walsh:

On behalf of the Department of Labor Advisory Board on Toxic Substances and Worker Health, I submit the attached Advisory Board Recommendation that was adopted unanimously at the Board's meeting on June 29, 2022.

We sincerely hope that our advice is useful to the Department. We thank you for the opportunity to serve as Board members and wish the Program continued success in meeting the needs of the United States energy employees. Please let us know if there are questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steven Markowitz', with a long horizontal flourish extending to the right.

Steven Markowitz MD, DrPH
Chair

Advisory Board on Toxic Substances
and Worker Health

Advisory Board on Toxic Substances and Worker Health

Recommendation on Borderline Beryllium Lymphocyte Proliferation Test

The Board recommends that the Department of Labor communicate to Congress the need for a technical amendment in the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) that will recognize that covered individuals as defined in The Act and who have three borderline beryllium lymphocyte proliferation test results, have beryllium sensitivity.

Rationale

Beryllium lymphocyte proliferation test Some individuals who have been exposed to beryllium develop an immune reaction to the metal, which can remain silent without symptoms or illness (beryllium sensitization) or can progress to cause persistent symptoms and organ damage (chronic beryllium disease). Beryllium sensitization is detected through testing the reactivity of cells (lymphocytes) that are contained in venous blood or, much less commonly, in the lungs. The blood beryllium sensitization test, called the beryllium lymphocyte proliferation test (BeLPT), is the most widely used, scientifically accepted means to determine if a person is immunologically reactive to beryllium and at risk for subsequent chronic beryllium disease. The beryllium lymphocyte proliferation test, like all medical tests, has both strengths and limitations as an indicator of immune system reactivity and as a predictor of progression to chronic beryllium disease. It can be falsely positive or falsely negative. The latter can occur when a truly sensitized person is on a medication that suppresses the immune system (e.g., steroids), causing the immune cells to fail to react to the beryllium challenge of the BeLPT. Even in the absence of immunosuppression, some people react to beryllium but in a manner that is only weakly abnormal, leading to a BeLPT test result that is labeled as “borderline” by the testing laboratory. However, whether a person has a falsely negative test result due to immunosuppression or a borderline BeLPT test result, they are still at risk of progressing to chronic beryllium disease and require access to diagnostic testing and ongoing monitoring.

Borderline BeLPT Uncommonly, persons have persistent borderline BeLPT test results on multiple BeLPT tests. A large study of 19,396 BeLPT tests among 7,820 DOE workers yielded 37 people (~0.5%) who had two consecutive borderline BeLPT test results (1). However rare, this group is important in applying an equitable definition of who has beryllium sensitivity. A widely recognized published study, using BeLPT test results from DOE workers, concluded that people who work in a beryllium-using environment with a reasonable population prevalence of chronic beryllium disease (2%) and have three borderline BeLPT test results are 91.2% likely to have beryllium sensitivity (2).

The virtual equivalence between repeated borderline BeLPT test results and frankly abnormal BeLPT test results have led professional organizations, beryllium disease experts, DOE contractor medical providers, and government agencies to conclude that a person with three borderline BeLPT tests should be treated as if their BeLPT test result was abnormal. These include the American Thoracic Society (3), National Jewish Health (4), Department of Energy (5), OSHA (6), Washington State (7), and the Energy Facility Contractors Group (4)

Gap in the EEOICP Act The EEOICP Act provides benefits for covered beryllium employees at a Department of Energy facility or beryllium vendor facility if they develop beryllium sensitization or chronic beryllium disease. The Act defines beryllium sensitivity as “established by an abnormal beryllium lymphocyte proliferation test performed on either blood or lung lavage cells.” The Act provides for ongoing medical monitoring for covered employees with beryllium sensitivity and requires beryllium sensitivity as an element in diagnosing a covered employee as having “established chronic beryllium disease” after January 1, 1993. The Act currently does not recognize or comment on the significance of a borderline BeLPT test result.

Proposed Act Modification A solution to this gap is a small modification in the language of the Act to the following: “The Act defines: “Beryllium sensitivity as established by an abnormal beryllium lymphocyte proliferation test performed on either blood or lung lavage cells **or three borderline beryllium lymphocyte proliferation tests performed on blood cells.**” (The new text is added in bold) [Title 42, Chapter 84, Subchapter XVI, Part B, Section 73841, (8)]. The administrative, resource, and fiscal impact of the proposed change will be minor in that the number of DOE workers with three borderline LPT’s is a small fraction of the number of workers tested for beryllium sensitivity or who have an abnormal BeLPT.

References

1. Stange AW, Furman FJ, Hilmas DE. The beryllium lymphocyte proliferation test: Relevant issues in beryllium health surveillance. *Am J Ind Med.* 2004 Nov;46(5):453-62.
2. Middleton DC, Mayer AS, Lewin MD, Mroz MM, Maier LA. Interpreting borderline BeLPT results. *Am J Ind Med.* 2011 Mar;54(3):205-9.
3. Balmes JR, Abraham JL, Dweik RA, Fireman E, Fontenot AP, Maier LA, et al; ATS Ad Hoc Committee on Beryllium Sensitivity and Chronic Beryllium Disease. An official American Thoracic Society statement: diagnosis and management of beryllium sensitivity and chronic beryllium disease. *Am J Respir Crit Care Med.* 2014 Nov 15;190(10):e34-59.
4. Letter from Lisa Maier, Annyce Mayer, and Kalie Von Feldt to Rachel P. Leiton, February 22, 2018.
5. DOE Beryllium Rule
6. OSHA Beryllium Rule
7. Washington State Department of Labor and Industries
8. Newman LS and Maier LA. Chronic Beryllium Disease. UpToDate. https://www.uptodate.com/contents/chronic-beryllium-disease-berylliosis?search=beryllium%20sensitivity&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1 Accessed June 30, 2022

Advisory Board on Toxic Substances and Worker Health

July 11, 2022

Mr. Martin J. Walsh
Secretary of Labor
Department of Labor
200 Constitution Ave.
Washington, DC NW 20210

Honorable Secretary Walsh:

On behalf of the Department of Labor Advisory Board on Toxic Substances and Worker Health, I submit the attached Advisory Board Recommendation that was adopted unanimously at the Board's meeting on June 29, 2022.

We sincerely hope that our advice is useful to the Department. We thank you for the opportunity to serve as Board members and wish the Program continued success in meeting the needs of the United States energy employees. Please let us know if there are questions.

Sincerely,

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Steven Markowitz MD, DrPH
Chair
Advisory Board on Toxic Substances
and Worker Health

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Board Recommendation on Industrial Hygiene Report Language

(adopted June 29, 2022)

The Board recommends that the Energy Employees Occupational Illness Compensation Program advise its staff and industrial hygiene contractor that claim-related industrial hygiene reports and opinions restrict comparisons of claimants' exposures to toxic substances at Department of Energy facilities to regulatory workplace exposure standards only to cases where sufficient industrial hygiene data exist that are relevant to the claim and that support the comparisons. Comparisons of exposures to regulatory standards must describe the available industrial hygiene data and the specific regulatory limit referenced, with preference for the most current standards. In the absence of specific industrial hygiene evidence, comparisons of claimants' workplace exposures to regulatory standards lacks objective support and may be prejudicial to an appropriate resolution of the claim.

Rationale

In the recent Board review of selected individual claims that were resolved in 2019-2021, Board members noted frequent inclusion in the industrial hygiene reports of conclusory language to the effect that there was no evidence found during the claim evaluation that exposures to toxic substances of said claimant exceeded regulatory standards. In addition, there is a footnote in these reports that exposures to specific toxic substances below regulatory standards will protect most workers against harm caused by the toxic substances in question.

The Board had a very fruitful discussion of these statements and their context with Mr. Jeffrey Kotsch and Mr. John Vance of the Energy Employees Occupational Illness Compensation Program at the Board meeting on May 10-11, 2022. They confirmed the general knowledge held by many Board members that relatively little industrial hygiene data are historically available from the Department of Energy sites and that, when such data are available, they mostly derive from incident-related short-term releases or exposures. While such episodes of exposure can lead to acute or, less commonly, persistent health problems, most chronic occupational diseases that are the subject of most EEOICP claims are due to ongoing exposure to toxic substances over months or years of employment. This applies to cancers, chronic lung diseases, chronic beryllium disease, Parkinsonism, and others. Ongoing exposures were uncommonly measured at DOE sites (and throughout U.S. industry), especially over the last decades of the 20th century. Thus, objective evidence of exposures to toxic substances at any level - low or high, or above or below regulatory standards – is mostly absent in the evaluation of EEOICP claims and attendant industrial hygiene evaluations of these claims.

It is thus, at a minimum, incomplete and, perhaps more correctly, misleading to state that there is no evidence of toxic exposures in excess of regulatory standards when the plain facts of the claim are, in most cases, that there is none to minimal industrial hygiene evidence concerning the relevant exposures. In the absence of industrial hygiene evidence, it would be equally truthful to state that there is no evidence that the claimant's exposures were below the regulatory

standards, implying that exposures may have routinely exceeded such standards. Such a statement would be objectionable for the same reasons.

A critical problem with the current text about not exceeding regulatory standards in industrial hygiene reports is that the medical consultants (or claims examiners if a medical consultant is not used in the case) who are asked to address causation and are given the industrial hygiene reports are very likely to use the conclusions of the industrial hygiene reports in formulating their causation opinions. Whether these physicians are provided with all of the exposure information or not (occupational health questionnaire, employment history, DOE records, and others), the fact is that the physicians will in many, and perhaps most, cases rely on the industrial hygiene expert in the case, whose opinion is expressed in the industrial hygiene report. If the industrial hygiene conclusion is that no evidence exists that regulatory standards (which protect most workers, as also stated in the industrial hygiene reports) are exceeded, many physicians will use such a conclusion to decide that there is no causation, leading ultimately to claim denial.

For these reasons, the Board believes that the industrial hygienist evaluation should adhere to the known facts of the claim combined with the application of their expert opinion regarding activities at DOE sites, but that interpreting the claimant's exposure experience in terms of regulatory standards when no or insufficient industrial hygiene data exist is improper, unfairly tilts the scales against the claimant, and should not be employed.