

Response to Reviewer Comments

NIOSH Alert: Preventing Beryllium Sensitization and Chronic Beryllium Disease

No responses required or changes made for comments: 1, 2, 8, 9, 17, 19, 34, 40, 41, 45, 65.

3- Reduction of air exposures alone has been ineffective in reducing risk. Our discussion of surface hygiene and dermal protection are industrial hygiene measures which would be novel in most of the beryllium industry.

4- The Alert (Alert tear-out and p. 8, Employers, 5th bullet) states that “no safe exposure limit for beryllium is known.”

5- We changed the (current) 5th bullet (Alert, Tear-out and p. 8, Employers) to “Keep airborne concentrations of beryllium as low as possible, since no safe exposure limit for beryllium is known.”

6- We changed the wording from “may be” to “are.” (Alert, Tear-out and p. 1).

7- The risk from eye exposure is unknown, so we made no change. (Alert, Tear-out and p. 8, Employers, current 8th bullet).

10-12 We added the following language: “The manufacturers or suppliers of materials containing greater than 0.1% beryllium are required to provide this information on material safety data sheets.” (Alert, Tear-out and p. 8, Employers, 1st bullet).

13- Several reviewers mentioned problems with the NIOSH recommended exposure limit (REL), among them the lack of data supporting it as a preventive measure, that it is outdated because it was proposed in 1977, and that it was proposed in an effort to reduce the risk of beryllium-related cancer rather than CBD. We agree with all of these statements; however, it is the NIOSH REL and must be mentioned in the Alert. It also is lower than the current OSHA permissible exposure limit (PEL), which is known to be not fully effective in preventing disease. We have added language that clarifies the genesis of the REL and its limitations. We have also taken the REL out of the tear-out sheet and Recommendations sections (Employers, 5th bullet) and replaced it with “as low as possible.”

14- Rephrased current 13th bullet (Alert, Tear-out and p. 8, Employers) to emphasize skin exposure, which was the intent of the bullet.

15- With regard to marking the plant, we made no changes. With regard to cleaning methods, we added bullets to both the Workers (4th) and Employers (9th) sections that address this issue. (Alert, Tear-out and pp. 7-8).

16, 20 & 22- We added a bullet (6th) that suggests monitoring to document the effectiveness of efforts to reduce airborne exposures. (Alert, Tear-out and p. 8, Employers). Five of the reviewers suggested that if we were going to recommend medical surveillance we also had to suggest appropriate tools, e.g., the beryllium lymphocyte proliferation test (BeLPT). Another four did not want the BeLPT mentioned because of its limitations. We have chosen to add specific language recommending use of the BeLPT to identify beryllium sensitization, along with text that briefly outlines the pros and cons (false positives and false negatives) of the test. Despite its shortcomings, the BeLPT is the only test available to identify sensitization. It is presented as the best tool currently available, although we hope that a better test will eventually be developed. We mention that most cases now diagnosed have few symptoms, but it is unknown how many will progress to symptomatic CBD (requiring medication) or how long that process will take. We currently mention (3rd paragraph CBD section) that the disease can be so mild at time of diagnosis that the worker doesn't suspect he/she has lung disease. We don't specifically refer to

“subclinical disease.” multiple reviewers suggested that the phrase “medical surveillance” was jargon that might not be understood by those outside the medical profession, or otherwise requested more clarity. In the Health Effects section, at the end of the subsection on sensitization, we have added language that defines what we mean by medical surveillance and what its uses are. We also provided details in the Tear-out and Recommendations sections (Workers, 6th bullet; Employers, 14th bullet).

18, 21 & 27- Several reviewers mentioned problems with dermal exposure issues. Five felt the information provided in the Alert was scarce on details about: skin exposure, prevention of skin exposure, keeping surfaces clean, and the effectiveness of gloves. In general, we believe dermal exposure to beryllium should be prevented where possible because research (both recent and not-so-recent) suggests that the dermal exposure-sensitization link is biologically plausible and it may provide an explanation of sensitization in low exposure environments. It is beyond the scope of this Alert to provide specific recommendations for surface cleanliness (note that no standards exist for surface beryllium contamination), and for glove use. It is the employer’s responsibility to implement a program for dermal protection.

23- We changed the order of the genetic and exposure clauses, and subsequent sentences. We did not add “significant risks and bystander” statement as this information is included later (p. 3, 1st full paragraph).

24- Beryllium distributors and the press were added to the list of information providers.

25- We added a statement in 1st full paragraph when “heated or worked to create particles or fumes” (p. 2). We do not know enough at this point to say with surety that unprocessed materials (*e.g.*, ores) confer less risk.

26- We changed the wording to “The risk for workers in other industries depends on their potential exposure to dust particles, fumes, and beryllium-containing solutions and suspensions” (p. 2).

28- We did not move the bullet, but we did add a footnote that states that alloys are the most widely used form of beryllium (p. 1).

29- We removed “might”; suggested sentence is covered in the epidemiologic summary that replaces the Case Studies (and is now integrated into the Background, pp. 2-3).

30- We did not add machining, as the other two categories are more general. We rewrote last sentence to be less cumbersome and more general; target organs are no longer included (p. 2).

31- We added a sentence that mentions machining as one high-risk job (p. 2). We did not add construction workers (p. 3).

32- We believe the evidence is compelling enough to warrant mention, so we did not delete sentences (p. 3). See E in Appendix (Response Doc, p. 79).

33- We added “employers and” before “workers” (p. 3).

35- We made this change, changing the recommended “disease” to “sensitization” (p. 3).

36- The language necessary to describe the BALLPT is pretty high-level and is not necessary to describe sensitization or CBD (p. 4).

37- We agree that the sentence is redundant and have deleted it from the Sensitization section (p. 3).

38- We say “many” not “most.” We do not know what proportion of subclinical cases will progress to clinical disease (p. 4).

39- We changed the sentence to read “The exact number of sensitized workers who will eventually develop chronic beryllium disease is unknown” (p. 4).

42- This was changed to “A worker’s immune system . . .” (p. 3).

- 43- We removed the sentence here because it was a repeat of information from section above (p. 3).
- 44- We made this change, adding “it is thought” (p. 3).
- 46- We added “Other tests, such as chest X-rays, computed axial tomography (CAT) scans, or pulmonary functions tests, can also help make the diagnosis of advanced disease” (p. 4).
- 47- We added a statement describing the single published study that documented progression from sensitization to CBD (p. 4). See also the response to tracking #37 from this same reviewer (above). We also eliminated the Case Reports section and provided a broader epidemiologic review in the Background section (pp. 2-3).
- 51- 1st comment: We cannot insert a risk estimate like this, as one does not exist (p. 4).
- 52- 2nd comment: This change was made (p. 4).
- 53- 3rd comment: No change was made (p. 4).
- 54- 4th comment: The 2nd sentence in that paragraph states that treatment does not cure the disease (p. 5).
- 55& 56- 5th comment: The 1st change was made. The 2nd is covered in a different sentence that was added to the end of this paragraph (p. 5).
- 57- The Genetic Factors section was merged into the CBD section (p. 5). The language was revised in response to other comments addressing this concern.
- 58- 1st comment: The Genetic Factors section was merged into the CBD section (p. 5).
- 59- 2nd comment: Rewriting the Background section resulted in a Health-Related Risks subsection (pp. 2-3). We agree that the emphasis needs to be on exposure, but the natural progression of information requires the genetic paragraph to be part of the Health Effects section.
- 60- 3rd comment: This change was made (p. 5).
- 61- 4th comment: This statement has been rewritten.
- 62- 5th comment: This change was made (p. 5).
- 63- We did not remove this clause, but the wording was changed to “may contribute to” (p. 5).
- 64- 1st comment: This concept is already included (p. 5).
- 66- We included reference to the National Toxicology Program (p. 5).
- 67- We changed the language to read “as low as possible” (p. 5). We were advised by EID policy review that ALARA is not a NIOSH recommendation.
- 68- Sentence 2 was deleted. Under NIOSH in this section, we added “Since no safe exposure limit has been established for beryllium, NIOSH recommends that employers keep airborne concentrations of beryllium as low as possible.” for additional clarity (p. 5). We did not add the first, second and fourth references.
- 69- This sentence was deleted from the text (p. 5).
- 70- The language was revised in response to other comments (p. 6).
- 71- The ACGIH section was merged into a “Other Limits” section (p. 6). ACGIH’s notice of intended change to the STEL (to 0.2 ug/m3) was added.
- 72- This sentence was revised, but differently (p. 6).
- 73- This was added (p. 6).
- 74- The first (now second) sentence has been revised. We added the first reference (pp. 5-6).
- 75- Less-detailed but information from the Case Studies was included in the Background section (pp. 2-3). See F in the Appendix (Response Doc, p. 79).
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79- Less-detailed but information from the Case Studies was included in the Background section (pp. 2-3). See F in the Appendix (Response Doc, p. 79). A broad list of industries is included in the Appendix (p. 12).

80- We have revised the language to be less research-oriented (p. 7).

81- We revised this paragraph differently (p. 7).

82- No changes were made. The suggestions are included in a list that appears in the beginning of the Background section (p. 1).

83- We added the 4th reference (p. 11).