Miller, Diane M. (CDC/NIOSH/EID)

From: Vandyke, Mike [VandykeM@NJC.ORG]
Sent: Monday, May 12, 2008 1:47 PM
To: NIOSH Docket Office (CDC)
Cc: Maier, Lisa; Mroz, Peggy; Barker, Lisa; Mayer, Annyce
Subject: 120 - NIOSH Alert: Beryllium
Attachments: NIOSH-120_Beryllium_Alert Comments _NJMRC.pdf

Attached are comments from National Jewish Medical and Research Center.

Thank you for the opportunity to comment on this important document.

Mike Van Dyke, CIH,CSP
National Jewish Medical and Research Center
Division of Environmental and Occupational Health Sciences
1400 Jackson St.
Denver, CO 80206
(303)398-1034
Fax (303)398-1452
Cell (970)691-1404
vandykem@njc.org

Comments on Docket NIOSH-120:
NIOSH Alert Preventing Chronic Beryllium Disease and Beryllium Sensitization
2008 DRAFT

Comments Provided by:

Lisa Maier, M.D., MSPH, Peggy Mroz, MSPH, Michael Van Dyke, MS, CIH, Annyce Mayer, M.D., MSPH, and Lisa Barker, BS, CCRC, ASCP
National Jewish Medical and Research Center
Denver, CO
Correspondence email: vandykem@njc.org

Overall Comments

We commend the authors on a well constructed document that distills some very difficult concepts to a level comprehensible by a worker population. However, we believe that the document should provide stronger language to indicate that in order to work "safely" with beryllium materials, specialized controls and health and safety expertise are required. We have added specific comments to address this below. In addition, more examples of processes that may cause high exposures should be inserted throughout the document. Finally, it is important to let employees and employers know that beryllium disease can result in significant impairment, loss of ability to work, etc. Consideration should be given to using a different or additional case that highlights that beryllium disease may be more than just mild or asymptomatic. Consistent language for BeLPT test results as abnormal or normal, and not positive or negative (in the cases) would be helpful. Finally, it would be helpful if the references are numbered and not included by author, as this takes up significant space and detracts from the message of the document.

Specific Comments

Summary (Pages iii through v)

As the function of the document is to alert employers and workers about the hazards of beryllium exposure, it is important to provide more information to identify the populations at risk. To this end, a statement such as: "Workers in industries including nuclear weapons, beryllium production, copper beryllium foundries, beryllium and beryllium alloy machining, electronics manufacturing, metal recycling, nuclear energy, aircraft fabrication and maintenance, aluminum smelting, and dental laboratories have developed both beryllium sensitization and chronic beryllium disease. In addition, it is believed that workers in facilities that previously fabricated beryllium containing materials may also be at risk." may be helpful on the first page. Another option may be to include a table of all the industries in which BeS and CBD have been identified in the main document and to reference it here or to reference the appendix early on.

Workers Section

Consider adding the following bullets.

- Avoid performing tasks that produce particles from metal that may be inhaled, such as machining, cutting, sanding, filing, or grinding, without ventilation devices to remove the dust at its source of generation.
- Understand the proper controls for performing work such as casting or welding of beryllium containing materials.
- Protect your family by changing work clothes and shoes as well as showering before leaving work or getting in your car.

Consider changing the "Participate in medical surveillance.." bullet to include the issue that surveillance also detects health effects at an early stage, which may limit impairment:

- Participate in medical surveillance so that risks related to job tasks can be identified and prevented as soon as possible and to detect beryllium sensitization and/or chronic beryllium disease at the earliest possible stage, which may improve long term health.

Consider adding an additional "Seek medical attention.." bullet such as:

- Seek Medical attention for any rash or nonhealing cuts from beryllium.

The last bullet "Do not store or consume…" is out of place. Consider moving this bullet to the section describing other safety measures.

Employers Section

Consider adding the following bullets.

- Isolate beryllium operations to a designated area of the workplace and develop procedures to prevent migration of beryllium contamination to other areas of the facility.
- Perform wipe sampling to evaluate the effectiveness of procedures to prevent migration of beryllium contamination from designated work areas.
- Insure that employees, supervisors, and managers are held accountable for following established procedures for minimizing exposure to beryllium.

Consider changing the bullet "Monitor airborne…" to:

- Perform air monitoring on all beryllium operations with the potential to create airborne beryllium to identify high exposure operations and document the effectiveness of efforts to reduce airborne exposures.

Consider changing the bullet "Inform workers…" to include others that may be in the facility and at risk of exposure:

- Inform all workers, contractors, and visitors about the….

Change the bullet "Avoid the use of cleaning methods…" to

- Prohibit the use of cleaning methods…

We have found that it is possible for all workplaces to replace dust producing cleaning methods with safer activities.

There should be some advice on the type of work clothes to provide, as there is some evidence to suggest tightly woven cotton clothing is more effective in protecting the skin than polyester fabrics.

Consider changing the bullet "Conduct medical surveillance..." to indicate as above that a function of surveillance is to detect disease and to prevent more severe forms of disease. The statement about progression to "clinical CBD" is not clear and should be removed. For example, consider the following:

- Test all workers who come in contact with beryllium dusts, fumes, and beryllium-containing suspensions for beryllium sensitization using the beryllium lymphocyte proliferation test (BeLPT).
- Use results of BeLPT testing to identify higher-risk jobs and processes to prioritize prevention efforts and to evaluate their effectiveness in decreasing the risk of sensitization.
- Ensure that sensitized workers... (3) receive continuing medical follow-up and counseling about measures that may prevent progression to chronic beryllium disease and more severe forms of the disease.

Main Document

At the beginning of the main body of the document, a statement such as: "Workers in industries including nuclear weapons, beryllium production, copper beryllium foundries, beryllium and beryllium alloy machining, electronics manufacturing, metal recycling, nuclear energy, aircraft fabrication and maintenance, aluminum smelting, and dental laboratories have developed both beryllium sensitization and chronic beryllium disease. In addition, it is believed that workers in facilities that previously fabricated beryllium containing materials may also be at risk." would be helpful, as noted above. This would be the appropriate place to include a table of all the industries in which BeS and CBD have been identified.

Consider adding "healthcare professionals who evaluate and treat beryllium-exposed workers" to the list of those who need to know about this alert.

Background Section

This section provides a great deal of useful information on the properties of beryllium. However, it would be helpful to have more information that relates to hazard identification in this section. For example, there is no information on specific processes or products in which beryllium may be encountered in this section as this information has been relegated to the appendix. As the use of beryllium has become more widespread, identification of potentially hazardous industries and processes has become a major difficulty for employers and employees. It would be helpful to put the list or industries and products from the appendix in this main section of the document. In addition, additional industries such as aluminum smelting and non-ferrous metal foundries should be mentioned as having potential exposure either in this section or in the appendix.

The last paragraph of the background section might also include reference to cases being identified in workers thought to be only minimally exposed (e.g., secretary and security guard).

Health Effects Section

Sensitization Section

Consider revising the first paragraph to keep the focus on exposure. A possibility may be replacing all but the first sentence of the first paragraph with:

- In some people, exposure to beryllium can trigger the immune system of the worker to recognize and respond to inhaled beryllium as a foreign invader. Although the majority of workers exposed to beryllium do not become sensitized, studies of exposed workforces by NIOSH and others have identified sensitization in 1%-14% of workers. The risk of sensitization is determined by the amount of beryllium exposure, but it may be increased by certain genes that have been inherited from each parent.

The second paragraph does a nice job of succinctly describing potential problems with the BeLPT. However, it ends with what could be perceived as a lukewarm (at best) endorsement of the test. This may provide an easy excuse for an employer to choose not to use the BeLPT. While we would agree that on a person-by-person basis, the test can have limitations, there are sufficient literature references (Middleton 2007, Stange 2004) demonstrating sensitivities, specificities, and positive predictive values on par with other screening tests frequently used by the medical community. Consider the following changes:

After the sentence ending "…react to beryllium", consider adding:

- The BeLPT has been used effectively in medical surveillance programs in both private industry and government organizations to identify sensitization among participating workers.

Consider changing "However, the BeLPT is not foolproof:" to:

- However, as with all medical tests, the BeLPT is not foolproof:

After the sentence ending "…may occur." consider adding:

- Repeat testing of abnormal results and serial (yearly or biannual) medical surveillance enhance the effectiveness of the BeLPT in identifying those with sensitization" (reference the Middleton 2007 paper regarding algorithms).

In the fourth paragraph, consider adding the following after the first sentence:

- A complete diagnostic evaluation includes a procedure called bronchoscopy with bronchoalveolar lavage and biopsy. Bronchoalveolar lavage (washing out lung cells) involves placing a small amount of salt water into an area of the lung and removing it with lung cells. A cell count and BeLPT are performed on the lung cells. If the cells of the lung respond to beryllium in the lavage BeLPT – this could be an indication of chronic beryllium disease. A lung biopsy may also be performed to remove small samples of lung tissue. These tissue samples are examined under a microscope.

To the end of the fifth paragraph, consider adding:

- Medical follow-up of workers with sensitization will identify progression from BeS to CBD at an early stage.

The first sentence in the last paragraph of this section, "Screening beryllium-exposed workers for sensitization…" is a difficult concept for workers to understand. Consideration may be given to removing this first sentence. It would be helpful to again stress that screening not only detects high risk job processes, but also identifies health effects and that early detection may allow determination of CBD at an early stage, which may ultimately limit impairment, as noted above.

Chronic Beryllium Disease Section

Consider adding night sweats to the list of symptoms in the third paragraph.

In the third paragraph, consider adding inhaled steroids along with prednisone among the medications used to control symptoms.

In the first sentence of the fourth paragraph, consider changing "usually" to "often"

In the last paragraph, consider indicating that there may be a number of genes involved in risk of sensitization and disease, some of which have not been discovered. Also consider adding to bullet (1) " are found in a large percentage of the (insert) general population.

In the last paragraph, insert a sentence prior to the last sentence that reads:

- It is likely that many other genes are also involved in the disease process, and researchers continue to study this issue.

In the last paragraph regarding genetic testing change the last sentence to:

- The future usefulness of genetic testing remains to be determined.

It seems unlikely that genetic testing will be able to be used in the workplace without concern of discrimination.

Acute Beryllium Disease Section

Consider changing the third sentence to:

- It occurs after exposure to high concentrations of beryllium that are rarely seen in modern industry.

Workforce Surveys Section

A table showing the rates of sensitization and chronic beryllium disease identified in different industries would add useful information.

Throughout this section, the use of the author-date citation style makes the paragraph difficult to read. If possible, put the references at the end of the sentences.

The recent aluminum industry reference should be added to the list in the second paragraph.

Exposure Related Risks Section

The paragraph starting with "When estimates…" is problematic. This paragraph implies to the reader that there is no reason to reduce airborne exposures because there is no relationship between inhaled beryllium and sensitization or disease. Please consider replacing the last paragraph with the following:

- Workers who are exposed to the highest airborne exposures of beryllium are at greatest risk of developing sensitization and chronic beryllium disease. However, the risk of chronic beryllium disease does not appear to be directly related to the total mass concentration of beryllium. Other exposure factors are also important including the chemical form and the particle size of the beryllium exposure. However, nearly all researchers agree that reducing beryllium exposure in general will likely result in a lower overall risk of chronic beryllium disease.

Skin Exposure Section

By stating there was no reduction in new worker sensitization rates after airborne exposure was tightly controlled indirectly implies that reducing airborne concentrations will not reduce health effects. The audience for this alert consists of beryllium workers and employers. Among these employers are those with beryllium exposures that are orders of magnitude higher than the current OSHA standard. While we agree that skin protection is important, it needs to be clearly emphasized that control of BOTH airborne and skin exposures are important.

Consider changing the sentence "NIOSH researchers…" to:

- NIOSH researchers observed that tight control of airborne beryllium exposures without instituting a skin protection program did not prevent ….

It is not clear that it will be helpful for the worker or the employer to be provided with information regarding the studies conducted by NIOSH to date in the sentence starting with "NIOSH laboratory researchers..." Instead consider removing this sentence.

The word "tiny" should be removed from the last sentence.

After the last sentence, consider inserting a sentence such as:

- Workers and employers should also insure that all cuts and abrasions are protected from contact with beryllium particles and solutions.

Prevention Section

The most problematic aspect of the entire document is the lack of advocacy for any particular exposure limit. Employers need concrete guidance on how to best protect their workers. For this reason, it is critical that the document list more details on the "comprehensive preventive program" from the ceramics facility outlined in this section. For example, details of the program should be noted, including the exposure limit that was used in this program (0.2 ug/m3) and the fact that anyone exposed above this level was required to wear respiratory protection. This would

provide more concrete examples for employers, and yet circumvent the difficult situation that the employer cannot be provided with a specific exposure level and that current OSHA standard is not protective.

Case Studies Section

Use "abnormal" BeLPT test result, not positive to be consistent across the document.

In the "lesson learned" from Case 2, it would emphasize the value of medical surveillance as opposed to medical screening if details were presented on what changes were made to the workplace as a result of this diagnosis. How did this worker's diagnosis help prevent disease in other workers?

It might be helpful to add a third case study of a worker with more significant or severe disease to illustrate that exposure to beryllium can result in very serious health effects. This case would reinforce the opening bolded information in this document that says that CBD is potentially disabling and fatal. We would be happy to provide a case from our clinic if necessary.

Current Exposure Limits Section

The introductory sentence in the "Current Exposure Limits" section should include a statement re-emphasizing that no safe exposure level for beryllium has been identified and that adherence to the current OSHA standard does not prevent health effects.

Other Resources Section

Are the other resources limited to government sites? If not, a reference to the National Jewish Medical Center website, as well as the ORISE website should be included.

Conclusions Section

An additional point should be added:

- (1) identify workers exposed to beryllium, who may not know that they are exposed

Recommendations

Note changes for Summary Section (pp. i – v).

Appendix

This section should be referenced at the very beginning or made into a table in the main body of the document.

Consider adding metal machining since there are workforces that machine metals for various other sectors.

Consider making Dental processes a separate bullet.

Consider adding metal production which would include alloys and the aluminum industry