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November 5, 2015

OSHA Docket Office
Docket No. OSHA–H005C–2006–0870
U.S. Department of Labor
Room N-2695
200 Constitution Avenue. NW
Washington, DC 20210

Re: Occupational Exposure to
Beryllium and Beryllium Compounds

Dear Sir/Madam:

ORCHSE Strategies, LLC (ORCHSE) welcomes this opportunity to comment on the Occupational Safety and Health Administration's (OSHA) August 7, 2015 Federal Register notice seeking comments on its Notice of Proposed Rule Making (NPRM) Occupational Exposure to Beryllium and Beryllium Compounds.

ORCHSE Strategies (formerly known as ORC Worldwide and more recently as Mercer HSE Networks) is an international occupational safety, health, and environmental consulting firm that has for more than 40 years specialized in providing a wide array of services to American businesses. Currently, more than 120 large (mostly Fortune 500) companies in diverse industries are members of one or more of ORCHSE's Occupational Safety and Health networks. The focus of these groups is to promote effective occupational safety and health programs and practices in business, to facilitate constructive communications between business and government agencies responsible for establishing national occupational safety and health policy, and to advocate responsible business positions to regulators. The activities of ORCHSE's Occupational Safety and Health networks are based on the premise that providing safe and healthful working conditions is of mutual importance to employers, employees and government agencies.

It should be noted that member companies of ORCHSE's Occupational Safety and Health networks may have provided substantial information, opinion, and advice to ORCHSE in the development of its comments. However, the following comments are solely those of ORCHSE and may differ from the views and comments of individual member companies.

I. General Comments

OSHA's NPRM, Occupational Exposure to Beryllium and Beryllium Compounds, represents an effort on the part of the Agency to be flexible and to consider different,

more practical and cost effective approaches to protecting worker health in beryllium work environments. At first glance the NPRM appears to have the characteristics and provisions of previously proposed OSHA Section 6(b) health standards, which have been largely consistent and clear regarding the expectations employers would be required to meet and the methods most likely to provide effective worker protection.

Unlike those proposals, however, the Beryllium NPRM is fraught with deviations from the "standard" approaches taken in other health standards, an overwhelming number of regulatory alternatives, and conflicts with existing OSHA regulations. ORCHSE Strategies encourages OSHA, through reliance on its extensive body of knowledge and best judgment, to consider adherence to the effective worker protection measures and good industrial hygiene practices that appear in standards such as Asbestos, Benzene, Chromium, Formaldehyde, Lead, Methylene Chloride, and Vinyl Chloride. Beryllium is at least as hazardous as any of these substances, therefore the requirements for worker protection should be equivalent.

ORCHSE Strategies, LLC comments will address its concerns within each section, as requested in the NPRM. Additional comments and recommendations appear in the Specific Recommendations section that follows the OSHA's Specific Issues section.

II. OSHA's Specific Issues

Health Effects

1. ORCHSE Strategies, LLC believes that OSHA has made a correct determination that beryllium presents risks of lung cancer, sensitization, CBD at 0.1 $\mu g/m^3$ acute beryllium disease, and hepatic, renal, cardiovascular, and ocular disease at higher exposures. ORCHSE is not aware of other studies that provide contradictory information.
2. OSHA has adequately identified and documented the adverse health effects of exposure to beryllium.
3. ORCHSE is not aware of additional studies or information that would change the determination of material health impairment.

Risk Assessment and Significance of Risk

4. ORCHSE Strategies is not aware of other studies or data that should be considered in evaluating risk for sensitization, CBD, and lung cancer.
5. We believe that OSHA has made a correct determination that there is significant risk of material health impairment through lung cancer or CBD over a working lifetime of exposure to beryllium at the current TWA PEL of 2 $\mu g/m^3$, and that this risk would be substantially reduced by the proposed TWA PEL of 0.2 $\mu g/m^3$ and the alternative TWA PEL of 0.1 $\mu g/m^3$.

6. No comment
7. No comment

(a) Scope

8. The scope of the standard has been defined correctly.

(b) Definitions

9. ORCHSE believes that OSHA has defined the Beryllium lymphocyte proliferation test appropriately.
10. The definition of CBD Diagnostic Center should be revised to allow off-site interpretation of trans bronchial biopsy pathology, which we understand to mean interpretation by a fully qualified physician located elsewhere. As OSHA has recognized, there are concerns as to whether a sufficient number of facilities will meet OSHA's definition of a CBD diagnostic center. This affects whether the diagnostic centers will be reasonably accessible. If OSHA allows off-site interpretation of trans bronchial biopsy pathology, this may increase the number of facilities that qualify as CBD diagnostic centers, which could increase accessibility. In other contexts, OSHA has approved the concept of off-site reading of tests. For example, in OSHA's proposed silica standard, the Agency included a requirement for chest X-rays to be interpreted and classified by a NIOSH-certified "B" reader. This clearly requires off-site interpretation in most instances, as OSHA stated that there were only 242 "B" readers. OSHA has not stated (nor is ORC HSE aware of) any compelling reason why interpretation of trans bronchial biopsy pathology must be performed on-site. Therefore, OSHA should revise the definition of "CBD Diagnostic Center" as follows. (Additions are underlined, and deletions are shown in double strikeout font.)

> CBD Diagnostic Center means a medical diagnostic center that has on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD) that includes bronchoalveolar lavage, trans bronchial biopsy and ~~interpretation of the biopsy pathology, and~~ the beryllium bronchoalveolar lavage lymphocyte proliferation test (BeBALLPT). Interpretation of the transbronchial biopsy pathology may be performed on-site or off-site.

(d) Exposure Monitoring

11. No comment
12. ORCHSE believes that allowing discontinuation of monitoring based on one sample below the action level is not appropriate. Two consecutive samples taken at least seven days apart, that show exposure to be below the action level, should be required to allow monitoring to be discontinued. This approach is consistent with other OSHA health standards. If it proposes

changes to what other standards require, OSHA should provide a rationale for why doing so is warranted. If an explanation is not provided, the Agency appears to undermine the credibility of both its existing standards and the proposed beryllium standard.

(e) Work Areas and Regulated Areas

13. No comment
14. ORCHSE believes that, as in other OSHA health standards, regulated areas have a greater purpose than simply to warn employees about the hazards and risks therein. Having to establish regulated areas provides an incentive to employers to reduce employee exposure to airborne beryllium to levels where respiratory protection would not be required.

(f) Methods of Compliance

15. Engineering controls are used in most situations.
16. The controls listed are appropriate. No additional options are needed.

(g) Respiratory Protection

17. Where employees are required to work in regulated areas, that is, where respiratory protection must be worn, they should be provided the option of choosing PAPRs.

    Comfort is a significant factor in the ability of employees to wear respiratory protection consistently, especially during an entire work shift, and/or under hot or stressful conditions. Employees experiencing discomfort, which is likely with negative-pressure respirators, are more apt to remove or otherwise compromise the effectiveness of their respirators while in the workplace. It is thus prudent for employers to provide the type of respiratory protection employees are more likely to use consistently and correctly.

    PAPRs should be specified as appropriate respiratory protection where highly reliable performance is required, such as regulated areas in which the TWA or short-term exposure level is greater than the protection factor of a negative-pressure respirator.

(h) Personal Protective Clothing and Equipment

18. No comment
19. Beryllium is highly toxic and hazardous at very low levels of exposure. In question 22, OSHA states that “small particles (<10 mg) may not be visible to the naked eye, and there are studies suggesting that small particles may penetrate the skin, beyond which beryllium sensitization can occur (Tinkle et

al., 2003).” Using “visibly contaminated” as a criterion for determining when PPE is required seems therefore contradictory and out of step with the intent of the standard. According to companies that currently work with beryllium, amounts of beryllium that may be significant to employee health are not visible, at least when airborne. In addition, a quantifiable amount of beryllium on surfaces that is hazardous has not been established, therefore it is impossible to say whether or not visibility is related to hazardousness. From an employee protection point of view, requiring PPE for those who are working with beryllium or in beryllium work areas is very important. Even small skin abrasions that become exposed to beryllium can put employees at risk[1].

(i) Hygiene Areas and Practices

20. The requirement is reasonable as it stands. OSHA should not amend the provision.

(j) Housekeeping

21. Prohibiting dry sweeping or brushing to clean surfaces in beryllium work areas is appropriate. Where HEPA-filtered vacuuming has been tried and found not effective, OSHA should specify that wet-cleaning methods be used and proven not effective before dry sweeping or brushing be permitted. If dry-cleaning methods are required, respiratory and other personal protection should be required to avoid worker exposure to airborne beryllium or contamination of skin.
22. Because visible contamination is not an inappropriate criterion for determining whether or not a hazard exists, all material to be recycled should be decontaminated regardless of perceived surface cleanliness. Where municipal or commercial disposal workers may come in contact with materials from beryllium work areas, those materials should be in bags or other containers.

(k) Medical Surveillance

23. No comment
24. Several of the medical surveillance requirements of paragraph (k) should be revised:
    a. OSHA should revise paragraph (k)(1)(i)(B) to apply only to workers who are confirmed positive for sensitization to beryllium. This paragraph requires employers to provide medical surveillance to “each employee showing signs or symptoms of CBD, such as shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue.”

[1] Beryllium Chemistry and Processing, by Kenneth A. Walsh; ASM International, Jan. 1, 2009; pp.509.

However, nothing is said regarding whether the worker actually is exposed to beryllium. As written, this paragraph would require employers to offer medical surveillance to personnel displaying any of the listed symptoms who never have been exposed to beryllium. The symptoms are not unique to CBD; they may be indicative of many other conditions, including:

- Decompression sickness, arterial gas embolism or air embolism
- Coronary artery disease or impending heart attack
- Lack of physical conditioning
- Side effects of medication

OSHA's intent is to focus medical surveillance for CBD on workers who are exposed to beryllium. Because sensitization is a precursor to CBD, the requirement to offer medical surveillance based on symptoms of CBD should be limited to workers who are confirmed positive for sensitization.

For the reasons stated, OSHA should revise paragraph (k)(1)(i)(B) to read as follows. (Additions are underlined, and deletions are shown in double strikeout font.)

(B) For each employee ~~showing~~ who has been confirmed positive and shows signs or symptoms of CBD, such as shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue…

b. Paragraph (k)(1)(i)(D) should be revised if OSHA's final rule requires CT scans, such that it applies only to exposures that occurred while working for the current employer, because there is no way realistically to design a compliance program for paragraph (k)(1)(i)(D) as interpreted in the preamble.

Employers would be required to offer CT scans to any workers who were exposed to airborne beryllium above a specified level for more than 30 days in a 12-month period for five years or more. In the preamble (page 47799, column 2), OSHA states this requirement can include exposures that occurred at a prior employer. If the final rule continues to require CT scans, OSHA should apply the triggering criteria (30 days of exposure in a 12-month period for 5 years) only to exposures that occur while working for the current employer.

Concerns with requiring the surveillance of prior-exposed employees include:

- When a company hires a new employee, it is very rare to receive any documentation of previous exposures. The new employer typically

will have no way of knowing that the individual has had precious exposure to beryllium.

- OSHA has imposed no time limit. If a worker had been exposed to beryllium during a 5-year period and subsequently spent decades working for various employers without beryllium exposure, the current employer would have no way of knowing that the surveillance requirement had been triggered.

OSHA can correct the issue by including a discussion in the preamble to the final rule, as follows:

A commenter took issue with a discussion in the preamble to the proposed rule, which suggested that the requirement to offer a CT scan annually could be triggered by exposure that occurred in prior employment with a different employer. The commenter stated that, if the requirement were interpreted as applying to prior employment, employers would often lack information necessary in order to comply. For example, a new employer may not receive exposure records from previous employers. Plus the prior employment may have occurred long ago, with other intervening employment since then. The new employer may not place the worker in a job that involves beryllium. OSHA has considered these concerns, and has concluded that the requirement to offer a CT scan annually is based only on exposures that occurred during current employment.

c. Paragraph (k)(3)(ii)(C), which requires an examination for skin breaks and wounds, should be deleted. Although interruptions of the integrity of the skin may allow greater absorption from exposure to beryllium dust, skin breaks and wounds are temporary. The annual examination is a snapshot in time. Most wounds heal in days, after which the medical examination observations become irrelevant. The medical examination should not focus on transitory conditions of this nature.

It is also unclear in the NPRM what action the employer should take if an employee has a skin break or wound. Because this is an important issue related to the health of beryllium workers, it may be more effective to include a requirement in paragraph (e)(3) or (e)(4), such that employees who are assigned to work areas or regulated areas be required to report skin breaks or wounds before beginning work so that they may receive appropriate protection.

d. Paragraph (k)(3)(ii)(E)(2) appears not to match OSHA's likely intent. It states that if a first abnormal BeLPT result occurs, a second BeLPT must be administered unless a more accurate and reliable test (which does not need confirmation) is developed. In the latter case, the requirement for a second test is waived. What this literally means is that no follow-up test at

all would be administered. The employee would not receive a second BeLPT, nor would the person receive the more accurate and reliable test. So the person would be left with only a single BeLPT (which was positive), and no confirmation of any kind. We suspect that OSHA actually meant that confirmation in some form (whether with a second BeLPT or with the new test) should occur. But the proposed rule does not say that.

We suggest the following wording:

If an employee who has not been confirmed positive receives an abnormal BeLPT result, a second BeLPT is to be performed within one month. ~~This requirement for a second test is waived if~~ If a more reliable and accurate test for beryllium sensitization does not need to be repeated due to variability, repeatability and accuracy of the test methodology, then the employee with one abnormal BeLPT result shall be offered either a second BeLPT or the more reliable and accurate test.

e. Paragraph (k)(3)(ii)(F) requires each employee who was exposed to airborne beryllium above 0.2 mg/m3 for more than 30 days in a 12-month period for 5 years or more to be offered a low-dose helical tomography (CT Scan) every 2 years for the duration of employment. This obligation would begin on the effective date of the final rule, or on the 15th year after the employee's first exposure above 0.2 ug/m3 for more than 30 days in a 12-month period, whichever is later.

On page 47799 of the NPRM, OSHA describes the efficacy of CT scans as a screening tool as follows:

> "In a recent systematic review of CT screening trials for lung cancer, Bach et al. found a significant (20 percent) mortality reduction in the population studied (26,309 men and women between ages 55 and 74, with at least 30 pack-years of smoking history) (National Lung Screening Trial, 2011). The benefits of screening for other populations are less clear at this time. CT screening was not shown to offer significant reduction in mortality in two other, smaller trial populations with at least 20 pack-years of smoking history (DANTE, 2009; DLCST, 2012). In addition, there is yet to be agreement on how to properly compute and set the radiation dose for LDCT. Clarification on such procedural issues will help inform analyses of LDCT-associated radiation exposure and its risks as part of a screening protocol for employees exposed to occupational carcinogens (Christensen, 2014)."

ORCHSE Strategies believes that OSHA has reasonably characterized the current state of knowledge (and literature) regarding LDCT screening for at-risk populations.

However, OSHA states (twice, in fact) that the CT scan is a method commonly used to diagnose lung cancer. While this is true, the use of LDCT as a screening tool has only been demonstrated conclusively as being of value for the narrow application involving heavy historical or current smokers of a certain age. Extrapolation of the results of the non-occupational National Lung Screening Trial for implementation in the occupational setting is premature, and fraught with a number of potential issues and concerns:

- Contrary to OSHA's preamble language and characterization (to wit 47571 and 47798), the goal of occupational medical surveillance is not diagnosis, but rather it is a preventive strategy. Early diagnosis as a consequence of medical screening embedded within a broader surveillance program is a tangible benefit, however definitive diagnostic testing (e.g. CT scans) is outside the purview and scope of occupational surveillance/screening. https://www.osha.gov/SLTC/medicalsurveillance/index.html

- Further, CT scanning should occur only within an integrated health care delivery system, or CBD Diagnostic Center as proposed by OSHA, such that redundancies, inefficiencies and need for "repeat" or superseding CT scans are not conducted, which would lead to additional unnecessary radiation exposure to the participating individual.

- Dose equivalency of a 30 pack-year smoking history to beryllium exposure in relation to a PEL of 0.2 ug/m3 has not been determined, but qualitatively must be orders of magnitude higher than the occupational risk to beryllium in the vast majority of settings. The Christensen, 2014 paper notably states "The benefits of screening for other populations are less clear at this time."

- As is axiomatic with screening procedures, the test should impart a clear mortality benefit to those screened. For LDCT scanning, this has not been demonstrated through peer-reviewed research of occupational cohorts.

- While there appears to be a slowly growing acceptance among health care providers of LDCT scanning for lung cancer in the general population, if a qualifying candidate, this acceptance is not

universal. Concerns remain about over-diagnosis, false positive findings, radiation dose (especially on a cumulative basis), follow-on invasive procedures and attendant complications, etc. Thus, until such practical issues are resolved or clarified, deploying LDCT scanning for beryllium-exposed workers should be deferred[2].

ORCHSE therefore supports Regulatory Alternative #18, which would drop the CT scan requirement from the proposed rule.

25. Paragraph (k)(6)(i) requires the employer's designated physician to consult with the employee about referral to a CBD diagnostic center "that is mutually agreed upon by the employer and the employee." The very next paragraph, however, [(k)(6)(ii)] appears to impose an open-ended obligation to provide a referral to "a" CBD diagnostic center," without specifying that it must be the same center that the employer and employee agreed on. OSHA should revise paragraph (k)(6)(ii):

    (ii) If, after this consultation, the employee wishes to obtain a clinical evaluation at the agreed-upon CBD diagnostic center, the employer shall provide the evaluation at no cost to the employee.

    Further, ORCHSE believes that mutual agreement on a CBD diagnostic center is not necessary, but is rather a courtesy to the employee. We suggest that OSHA include this statement in paragraph (k)(6)(i): Where employee and employer disagree on where to send the employee, the nearest CBD diagnostic center will be used.

26. No comment
27. ORCHSE has concerns regarding the requirements surrounding the PLHCP written medical opinion:
    a. Paragraph (k)(4)(iv) requires employers to provide information from previous medical examinations "after obtaining a medical release from the employee." This requires the employer to get the release, because that is a pre-condition to providing the records, however, employees are not compelled to sign a release. If an employee refuses to sign a release, the employer would be placed in a no-win situation in that the employer would be prohibited by HIPAA from disclosing the records, but required by OSHA to provide them.

[2] Lung Cancer Screening. Davis AM, Cifu AS. JAMA 2014 Sep 24;312(12):1248-9.
Overdiagnosis in Low-Dose Computed Tomography Screening for Lung Cancer. Patz EF, et al. JAMA Intern Med. 2014;174(2):269-274.

ORCHSE suggests the following re-wording of the requirement: Information from records of employment-related medical examinations previously provided to the employee, currently within the control of the employer. This requirement is waived if the employee declines to sign a medical release.

b. OSHA should revise paragraphs (k)(3) and (k)(5) to require compliance with actions that are under the employer's control. ORCHSE suggests the following edits: (Additions are underlined and deletions are shown in double strikeout font.)

(k)(3) Contents of examination.
(i) The employer shall ~~ensure~~ request in writing that the PLHCP advise the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination.

(ii) The employer shall ~~ensure~~ request in writing that the employee be offered a medical examination that includes:

- No changes are needed to any of the subparagraphs to address this issue. ORCHSE will comment separately on a few of the individual subparagraphs for unrelated reasons.

(k)(5) Licensed physician's written medical opinion.
(i) The employer shall request in writing that the licensed physician provide ~~obtain~~ a written medical opinion ~~from the licensed physician~~ within 30 days of the examination~~, which contains~~. The employer shall request in writing that the written medical opinion contain:

- No changes are needed to paragraph (k)(5)(i)(A).
- No changes are needed to paragraph (k)(5)(i)(B).
- No changes are needed to paragraph (k)(5)(i)(C).

(ii) The employer shall ~~ensure~~ request in writing that neither the licensed physician nor any other PLHCP reveals to the employer specific findings or diagnoses unrelated to exposure to airborne beryllium or contact with soluble beryllium compounds.

c. OSHA should revise paragraph (k)(5) to avoid imposing liability on employers for situations beyond their control, such as if a physician deviates from the proposed requirements for examinations or written opinions.

d. OSHA has proposed numerous requirements that apply to physicians. For example, the proposed rule says the written opinion shall:

- Be received within 30 days.
- Contain any recommended limitations on exposure.
- Contain a statement that the physician has explained various things to the employee.
- Not reveal unrelated diagnoses.

The proposed rule also says the physician or other licensed health care professional must:

- Advise the employee of the risks and benefits of participation.
- Inform the employee of the right to opt out.
- Include a medial and work history that emphasizes past and present exposure, smoking history, and any history of respiratory system dysfunction.
- Provide a physical examination that emphasizes the respiratory tract.
- Examine the skin for breaks and wounds.
- Provide certain specified pulmonary function tests.
- Provide a blood/serum BeLPT at specified frequencies.

ORCHSE agrees in principle that these points should be addressed (except the examination for skin breaks and wounds). All of these points, however, are usually beyond the employer's control. In most cases (i.e., in every case except where the physician is employed directly by the company), the employer has no ability to dictate the timing or content of the written opinion, or to compel the PLHCP to perform the listed tests and evaluations. The employer can make requests, but the physician or other health care professional is in control.

There is an inherent problem when OSHA proposes mandatory provisions that are beyond the employer's control. As these proposed regulatory provisions currently are worded, the employer would be in violation of the standard if the physician happens not to perform some specified test, or not to mention something in the written opinion. The employer would similarly be exposed to liability for penalties and abatement if the physician includes remarks about an unrelated diagnosis that the rule prohibits from being included in the written opinion. Further, if the physician takes more than 30 days to deliver the written opinion, the employer would be in violation. In addition, the employer could not abate

the condition. Under these circumstances, penalizing the employer would be unfair.

28. No comment
29. Yes. Clinical laboratories performing the BeLPT should be required to have accreditation from the College of American Pathologists or another accreditation organization approved under the Clinical Laboratory Improvement Amendments (CLIA).
30. No comment
31. As stated earlier in our comments, ORCHSE believes that there is a substantial possibility that employers may have difficulty complying with the requirement to provide OSHA with the results of BeLPT testing, since employees may not want to provide such a release of private medical information.

(l) Medical Removal Protection

ORCHSE supports medical removal, but does not support making it optional. OSHA should revise section 1910.1024(l)(2) to make medical removal mandatory. If OSHA regards medical removal as necessary to protect the health of affected employees, an employee showing signs of health impairment such as beryllium sensitization or CBD should be removed from the work area regardless of his or her preferences.

OSHA's offer of choice of respiratory protection as an adequate means to protect an affected employee is contrary to its stated preference for the hierarchy of controls. Respirators are not reliable means of protection over the long term. While respirators have a legitimate place in protecting workers, a respirator is not as robust as medical removal. Indeed, the very underpinnings of industrial hygiene, entirely apart from medical removal, recognize that a more robust control (such as engineering controls) should be utilized where feasible, before relying on respirators. OSHA has adhered to that philosophy in other portions of the proposed beryllium standard. For example, section 1910.1024(f)(2) requires engineering and work practice controls first, even if they cannot fully achieve the PEL. Only then may respiratory protection be used.

In addition, employees' conversion to sensitization may not be related to inhalation, but possibly to skin absorption or ingestion, problems not addressed by respiratory protection. This bolsters the case for mandatory medical removal.

Employees have vulnerabilities that make it inappropriate for them to decide whether or not to choose medical removal and to continue working in an at-risk situation. They may be influenced by many factors, including fear of losing employment and income, despite the income protections offered through the standard. Objective criteria must be used to protect employee health; the employer

bears ultimate responsibility. Therefore it is the employer's duty, based on clinical test results, to provide that protection.

Mandatory removal has been OSHA's traditional approach. When compared with the medical removal protections of previous OSHA health standards, this proposal seems less than adequate. For example:

- OSHA's standard for occupational exposure to lead has medical removal provisions at 29 CFR 1910.1025(k). When the level of lead in worker's blood exceeds a specified concentration, OSHA says "the employer shall remove" the employee from work that involves exposures above the action level. (See 1910.1025(k)(1)).
- OSHA's standard for occupational exposure to cadmium has medical removal provisions at 29 CFR 1910.1027(l)(11). When a physician determines that an employee's condition warrants removal, OSHA says "The employer shall . . . remove" the employee from the work that has the exposure. (See 1910.1027(l)(11)(A), (B)).

It is very difficult to understand why OSHA would abandon this protective hierarchy in the medical removal provisions, and allow workers – entirely at their own discretion – to remain in working conditions that have already harmed their health, if they simply promise to use a respirator, especially in light of OSHA's finding that substantial health risk exists at or below the Action Level of 0.1 $\mu g/m^3$. In fact, National Jewish Health writes that "While there is no level of exposure to beryllium that is considered "safe", it is thought that exposures *below 0.01 microgram per cubic meter as an 8-hour time-weighted average (TWA)* may be safe for both sensitized and diseased workers."

This deviation from sound industrial hygiene principles is even more puzzling when we contrast the provisions of the lead standard to those of the beryllium standard. Under the lead standard, medical removal is required due to nothing more than elevated levels of lead in the blood – without any requirement for objective symptoms. In contrast, under the beryllium standard, an employee could actually manifest chronic beryllium disease, and still choose to remain in a role with significant beryllium exposure.

OSHA should follow its previous practice, which more robustly protects workers. OSHA should make the following changes:

- Revise section (l)(1) to read as follows: (Additions are shown in underlined font; deletions are shown in double strikeout.)

  (l) Medical removal. (1) If an employee works in a job with exposure at or above the action level and is diagnosed with CBD or confirmed positive

for sensitization, the employer shall remove the employee from work having an exposure to beryllium at or above the action level~~. The employee is eligible for medical removal.~~

Delete paragraph (l)(2) and all its subparagraphs.

Revise paragraph (l)(3) to read as follows:

(3) If medical removal is required: ~~the employee chooses medical removal:~~

No changes are needed in subparagraphs (l)(3)(i) through (l)(3)(iii) due to this issue.

No changes are needed in paragraph (l)(4) due to this issue.

32. No comment
33. Confirmed beryllium sensitization and CBD are appropriate triggers for medical removal. Given that CBD is a chronic, progressive lung disease with no known cure, it is imperative that signs of health impairment be found early and exposure be terminated to avoid further impairment.

(p) Appendices

34. ORCHSE sees no disadvantages to including both appendices in the final rule. As more information about effective practice becomes available, OSHA may wish to augment the Appendices to provide additional advice to employers.
35. It may be useful to employers to have access to information available through other sources, such as DOE, National Jewish Health, and NCBI. These web sites could be added to the Appendices.

General

36. With respect to whether the triggers to initiate certain provisions of the standard are appropriate, ORCHSE believes that they are, with one exception. The criteria for the establishment of a beryllium work area are vague and thus unworkable in a standard. OSHA is encouraged to use common terminology and practices throughout its regulations, to eliminate confusion and increase compliance and worker safety. As written, the requirements to establish work areas wherever employees may have exposure to airborne beryllium regardless of the level, appear to impose a cost burden to employers that could be substantial.

    We recognize that the proposed TWA PEL is not low enough to protect all workers from potential adverse health effects, and that OSHA's assessment

indicates that risks of developing sensitization and CBD in workers exposed at or below the proposed PEL or to dermal contact with beryllium still exist. We recommend that OSHA consider alternative approaches to protecting those workers and at the same time enabling employers to manage their work areas properly and implement their exposure control plans effectively. One consideration is using a measureable threshold for demarcating work areas, such as the Action Level.

With respect to commenting on the relationship between these triggers and the Regulatory Alternative, ORCHSE believes that OSHA's request adds an infeasible layer of complexity to the commenting process. Too many alternatives are presented, creating multiple options that require an excessive amount of time to address, particularly within the comment period given.

OSHA should return to its previous approach of making a recommendation for a standard's parameters based on its best assessment of the risk and necessary protective measures, then describe its rationale in the preamble. This makes the evaluation of the standard much easier to respond to, and saves commenters time, which is a scarce commodity in today's business environment.

III. ORCHSE Additional Concerns

In addition to the comments provided in response to OSHA's specific questions, ORCHSE offers the following:

1. OSHA should clarify that section 1910.1024(a)(2) exempts "articles" even if they are processed, unless the processing releases beryllium to an extent that negates the definition of an "article."

   The hazard communication standard states that an article is not allowed to "release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical." OSHA has proposed to exempt "articles" (as defined in the hazard communication standard) from this beryllium standard, so long as the employer does not process the article. See 1910.1024 (a)(2). It is generally appropriate to exempt articles. It is also appropriate to set boundaries around the exemption. OSHA's proposed boundary is unclear, however.

   Coverage under the beryllium standard should not turn on whether the employer has processed the article. Coverage should turn on whether – in a particular workplace -- the item actually meets OSHA's definition of an "article." OSHA should clarify that the type of "processing" that would subject an article to the beryllium standard releases beryllium in amounts incompatible with the definition of "article." In

contrast, other types of processing (without releasing beryllium) should not subject the article to the beryllium standard.

If the item is not an article because it is being processed in a manner that produces exposure, the beryllium standard should apply. Conversely, if the item is an article because it is handled in such a way that it does not produce beryllium exposure, the beryllium standard should not apply.

There are at least two ways in which OSHA could address this concern. Either approach would be satisfactory.

The first option would be to revise section 1910.1024(a)(2) as follows: (Additions are shown in underlined font; deletions are shown in double strikeout font.)

(2) This section does not apply to articles, as defined in the hazard communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium ~~and that the employer does not process~~. If activities in a workplace, such as processing, cause the item to fail to meet the definition of "article" in the HCS, this section applies in that workplace.

Alternatively, if OSHA does not wish to revise the wording of the standard, a discussion of this issue in the preamble of the final rule would be sufficient. Such as discussion might read more or less as follows:

A commenter suggested that paragraph 1910.1024(b)(2) is unclear. That paragraph exempts "articles" (as defined in the hazard communication standard) unless the employer processes the article. The commenter suggested that the exemption for articles should apply unless the processing releases beryllium in amounts that exceed those allowed in the definition of "article" (i.e., "very small quantities, e.g., minute or trace amounts of a hazardous chemical"). OSHA agrees with the commenter. If the nature of processing does not release beryllium in a manner that would fail the definition of an "article," the exemption applies. If processing in one workplace causes excessive release of beryllium (i.e., more than is allowed for an article), the item may nevertheless be exempt as an "article" in a different workplace where its handling does not release beryllium.

2. OSHA should clarify that section 1910.1024(g)(1)(iv) tailors the requirement for respiratory protection to the needs of the situation.

Section 1910.1024(g)(1)(iv) states that "each employee" must use respiratory protection during "emergencies." The proposed definition of "emergency" is "any uncontrolled release of airborne beryllium." Our concern centers on the words "each employee" and "any uncontrolled release." The wording of the section appears to require that every employee in the entire facility wear a respirator when there is an uncontrolled release of beryllium, regardless of their exposure.

ORC HSE recommends that OSHA revise paragraph (g)(1) as follows: (Additions are underlined.)

(1) The employer shall provide at no cost and ensure that each affected employee uses respiratory protection during:

OSHA should also revise the definition of "emergency" as follows:

Emergency means any uncontrolled release of airborne beryllium that has the potential to cause exposures in excess of the Action Level.

3. ORC HSE supports OSHA's decision not to require measurement of beryllium contamination on surfaces.

   In the preamble (page 47796, column 1), OSHA states a preliminary decision not to require employees to measure beryllium contamination on surfaces because the Agency does not have the necessary data to understand the relationship between the degree of surface contamination and risk of skin absorption. We agree. A mandatory regulatory requirement for monitoring should be reserved for situations where the results of the monitoring, compared to clear objective criteria, will drive appropriate outcomes. In the absence of clear objective criteria for evaluation of the monitoring data, it is appropriate for an agency such as OSHA to leave that type of monitoring to the discretion of the employer.

   ORCHSE would like to offer as a research tool the Brookhaven National Laboratory Surface Wipe Sampling Procedure IH75190 for metals. The procedure provides a uniform methodology to collect representative samples of beryllium surface contamination. The document accompanies these comments in the Docket.

4. OSHA should revise paragraphs (d)(2)(i) and (d)(2)(ii) to allow historic monitoring data and objective data taken from conditions that are more challenging (higher exposure potential) than the workplace where the employer would apply the data.

   Paragraphs (d)(2)(i) and (d)(2)(ii) have various subparagraphs dealing with historic monitoring data and objective data, that require the data to "reflect workplace conditions closely resembling" current conditions. Data from dissimilar workplace conditions, however, should be allowed to qualify as objective data or historic monitoring data where they pertain to a workplace with a higher potential for exposure. If data from a more challenging environment demonstrate that exposures are below a trigger level (e.g., TWA PEL, STEL, or Action Level), one may infer with confidence that workers with less potential for exposure are also not exposed above that level. Even if the two work environments do not "closely resemble" each other, the data are still valid for screening workplaces that have a clearly lower risk of exposure.

ORC HSE recommends that OSHA revise paragraphs (d)(2)(i) and (d)(2)(ii) as follows: (Additions are underlined.)

(i) Where the employer has conducted exposure monitoring for beryllium and relies on these historical data, provided that:

(A) The work operations and workplace conditions in place when the historical monitoring data were obtained reflect workplace conditions either closely resembling, or presenting a clearly higher exposure potential than, the processes, material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations;

(B) The characteristics of the beryllium-containing material being handled when the historical monitoring data were obtained closely resemble, or present a clearly higher exposure potential than, the characteristics of the beryllium-containing material used during the job for which initial monitoring will not be performed; and…

[Note: no changes are needed to (d)(2)(i)(C).]

(ii) Where the employer relies on objective data to satisfy initial monitoring requirements, provided that such data:

[Note: no changes are needed to (d)(2)(ii)(A).]

(B) Reflect workplace conditions closely resembling, or having a clearly higher exposure potential than, the processes, material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations.

5. OSHA should revise sections (n)(1)(ii)(F), (n)(4)(ii)(A) and (n)(5)(i) to allow the use of unique personal identifiers other than the social security number (SSN) in records required by this standard because it is important to safeguard SSN numbers to prevent fraud and identity theft.

   To address this issue, many employers issue each employee a unique personal identification number, different from the SSN. The vast majority of employee-related records within such employers' organizations are coded to the employee number rather than to the SSN. ORCHSE acknowledges that a few existing OSHA standards already require the SSN, and companies comply with those requirements where they exist. Many of OSHA's standards do not require the social security number however.

ORCHSE suggests that OSHA revise the following paragraphs as follows: (Additions are underlined.)

(n)(1)(ii)(F): The name, social security number or other unique personal identification number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

(n)(4)(ii)(A): Name and social security number or other unique personal identification number, and job classification;

(n)(5)(i): At the completion of any training required by this standard, the employer shall prepare a record that indicates the name, social security number or other unique personal identification number, and job classification of each employee trained, the date the training was completed, and the topic of the training.

6. OSHA should revise the definition of "confirmed positive" Blood BeLPT in 1910.1024(b) to use the more accurate language found elsewhere in the standard.

OSHA defines "confirmed positive to mean either:

- Two abnormal BeLPT results, or
- "The result" of a more reliable and accurate test.

This definition states that if a different test is "more reliable and accurate" than the BeLPT, a single test result constitutes "confirmed positive." That makes sense if the new test is so much more reliable and accurate that it needs no further confirmation. While that is one possible future outcome, the opposite is also foreseeable; a new test may be somewhat more reliable and accurate than the BeLPT, but may still need confirmation. For this reason, OSHA should use the more accurate language that is found in paragraph (k)(3)(ii)(E)(1). The definition would be revised as follows. (Additions are underlined.)

Confirmed positive means two abnormal test results from either consecutive BeLPTs or a second abnormal BeLPT result within a 2-year period of the first abnormal test result. It also means the result of a more reliable and accurate test such that beryllium sensitization can be confirmed after one test, indicating a person has been identified as having beryllium sensitization.

7. OSHA should substantially revise the training requirements in paragraph (m)(4) to recognize that there is no need to include chemical hazard training requirements in a substance-specific standard.

OSHA should revise the training requirements to more closely align with other health standards by deferring to the Hazard Communication Standard (HCS), which

is designed to address training for all hazardous chemicals. The training provisions in the proposed beryllium standard go far beyond what OSHA typically requires in substance-specific standards. Many of these excess requirements are beyond the employer's control and would make it impossible to comply.

The preamble discussion at page 47805 (columns 2 and 3) indicates that:

- OSHA requires training to be delivered in a language and at a level of complexity that accounts for varying educational levels, literacy levels, and language skills, including fluency in English.

- Workers must be able to demonstrate "at all times" that they have retained an understanding of all the topics from the training.

It is not possible for employees to remember "at all times" the complete detail from an annual training event. Neither can an employer realistically design a personalized training program for each employee.

In comparison, other of OSHA's substance-specific standards, such as Vinyl chloride and do not have any provisions specifically labeled as "training." Rather, they require employers to observe "all requirements" of the hazard communication standard. The Benzene standard goes slightly further, requiring compliance with "all requirements" of the hazard communication standard, including training. In addition, it has text labeled "Information and training," which adds the following requirements:

a. Timing: Information and training must be provided at the time of initial assignment, and if exposures are above the action level, annual refresher training is required.
b. Clarification of how to comply with the HCS: In providing the training required by the hazard communication standard, be sure to specifically deal with benzene in each category of required information.
c. Provide employees a copy of the benzene standard, describe the medical surveillance provision, and describe the medical surveillance medical surveillance guidelines in Appendix C.

In contrast, the proposed beryllium standard does not rely on the HCS to provide for adequate training. Here is a synopsis of the breadth of the training requirements in the beryllium standard:

- Paragraph (m)(1)(i) requires compliance with "all requirements" of the hazard communication standard. This would include training.
- Paragraphs (m)(1)(ii) and (m)(1)(iii) give instructions on how to comply with the hazard communication standard. These instructions are unnecessary,

because the hazard communication standard by itself is sufficiently detailed to ensure understanding of these principles.

- Paragraph (m)(4) deals with "Employee information and training." It is not clear why these sections are separated from (m)(1)(i), since training is already fully covered in (m)(1)(i).
- Paragraph (m)(4)(i)(A) also says to provide training as required by the hazard communication standard. This is redundant. As noted above, paragraph (m)(1)(i) already requires this.
- Paragraphs (m)(4)(i)(B) and (C) specify the timing: initial assignment and annually.
- Paragraph (m)(4)(ii) and its subparagraphs require that each employee must be able to "demonstrate knowledge" of all sorts of information, including signs and symptoms of CBD, the contents of the written exposure control plan, the contents of OSHA's beryllium standard, the right of access to medical and exposure records, the limitations of protective equipment, and the risks and benefits of each test offered as part of medical surveillance. As clarified in the preamble, this means OSHA would issue citations unless each employee can remember all this information at all times.
- Paragraph (m)(4)(iii) requires supplemental training when there are changes in the workplace.
- Paragraph (m)(4)(iv) requires that a copy of OSHA's standard must be readily available to each employee.

This raises at least the following concern:

Compliance will be impossible. Employers can control what information they provide, but cannot control what information each employee retains. Annual training will likely result in retaining some fraction of the information, but not all the information. If the requirements of the proposed rule are to be taken literally, OSHA will issue citations if any employee, at any moment, is unable to recite any detail on any of the following topics:

- OSHA's beryllium standard
- Signs and symptoms of CBD
- The written exposure control plan
- The risks and benefits of each test that is offered as medical surveillance
- The right of access to records

It is unnecessary for employees to remember all this detail at all times. Written programs and written training materials, experts such as industrial hygienists and medical professionals, and a written OSHA standard will be available to them for reference and consultation.

OSHA should delete all requirements for what employees must retain. Instead, the standard should require the employer only to provide information and training as specified in the HCS.

Paragraph(m)(4)(ii) should be modified to read: (Additions are underlined; deletions are in double strikeout font.)

The employer shall ensure that each employee who is or who reasonably can be expected to have exposure to airborne beryllium has been informed of ~~can demonstrate knowledge of~~ the following: ….

8. OSHA should revise paragraphs (m)(1) and (m)(3) to coordinate the beryllium standard with the HCS.

   Paragraph (m)(1) requires compliance with the HCS, which addresses warning labels for all other hazardous chemicals, so using the same standard for beryllium labels would promote consistency throughout the workplace. This facilitates compliance by the employer and understanding by the employees.

   However, in paragraph (m)(3), OSHA imposes specifications for wording on warning labels. Some of the specifications comply with the HCS, but others do not.

   Specifically, paragraph (m)(3) would require the precautionary statements "Avoid creating dust" and "Do not get on skin." This differs from mandatory appendix C of the HCS, which requires more and different precautionary statements. For example, Appendix C.4.7 of the HCS requires the following precautionary statements for dermal sensitizers:

   - Avoid breathing dust/fume/gas/mist/vapors/spray [Chemical manufacturer, importer, or distributor to specify applicable conditions.]
   - Contaminated work clothing must not be allowed out of the workplace.
   - Wear protective gloves. [Chemical manufacturer, importer, or distributor to specify type of equipment.]

   Also, Appendix C.4.9 requires the following precautionary statements for carcinogens:

   - Obtain special instructions before use.
   - Do not handle until all safety precautions have been read and understood.
   - Wear protective gloves/protective clothing/eye protection/face protection. [Chemical manufacturer, importer, or distributor to specify type of equipment, as required.]

The hazard communication standard also says no labeling for carcinogenicity is required (i.e., the Safety Data Sheet is sufficient) unless the concentration of the carcinogen is 1% or more. In contrast, the beryllium standard would require labeling for carcinogenicity at 0.1% and apply to containers of PPE, etc., where the beryllium-containing material may be only a dusting on a larger substrate.

To address these concerns, OSHA should simply defer to the hazard communication standard.

Suggested resolution:

- Paragraph (m)(1) is correct; no edits are needed.
- Paragraph (m)(3) should be deleted. It is not needed. If employers comply with paragraph (m)(1), which already says to observe "all requirements" of the hazard communication standard, they will automatically address labeling of containers as needed.

9. ORCHSE believes that the effective dates provided for compliance following promulgation of the standard are too stringent and should be extended to allow time to make necessary changes to facilities, broad-based exposure assessments, and delineate work and regulated areas. We recommend an additional six months for the standard to become enforceable.

IV. Conclusion

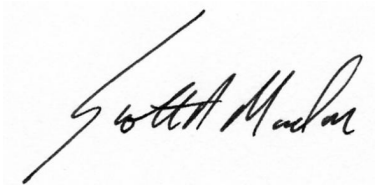
ORCHSE is in general support of this NPRM, including the proposed exposure limits, except where noted above. Comments on the Regulatory Alternatives described on pages 47774 through 47807 of the Federal Register are not provided because a great deal of time is required to address them intelligently, and the comment period was fairly short. In future, we recommend that OSHA put forth fewer regulatory alternatives for commenters to evaluate and instead provide its most reasonable recommendations for what a standard should include, with detailed explanations.

Thank you for the opportunity to comment.

Sincerely,

Dee Woodhull
Partner

Linda Haney
Partner



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