Date: February 22, 2011

To: Jackie Rodgers

From: Cheryl Floreen, MS, CIH, CESM

Enclosed below are my comments on the questions listed in the Vol 75, No. 246 of the Federal Register dated December 23, 2010. The Docket number is HS-RM-10-CBDPP and apply to the Chronic Beryllium Disease Prevention Program. Thank you for the opportunity to submit these comments.

Electronic submissions may be sent to jackie.rogers@hq.doe.gov.

1. DOE currently defers to the Occupational Safety and Health Administration (OSHA) for establishing the permissible exposure limits (PEL) and uses an action level as the administrative level to assure that controls are implemented to prevent exposures from exceeding the permissible exposure limits. Should the Department continue to use the OSHA PEL? Please explain your answer and provide evidence to support your answer.

Response - The DOE should not continue to identify or reference the OSHA PEL for beryllium as compliance in this rule. Referencing this limit as compliance identifies that an exposure at or greater than the PEL levels is acceptable. However, this conflicts with other rule requirements for DOE's expected actions and control measures to be put in place based upon monitoring results. The DOE action level is currently set at one/tenth of the OSHA PEL or 0.2 ug/m3. The OSHA standard has been shown to be wholly inadequate to prevent beryllium sensitization and CBD. OSHA identified this in their bulletin published in May 2002 regarding beryllium exposure in dental labs. http://www.osha.gov/dts/hib/hib_data/hib20020419.html

Additionally, the recently published NIOSH DHHS Publication Number 2011-107, NIOSH Alert Preventing Sensitization and Disease from Beryllium Exposure, dated February 2011, states that cases of beryllium sensitization and CBD have been reported in which exposure were below OSHA PEL of 2.0 ug/m3 and the current NIOSH REL of 0.5 ug/m3. http://www.cdc.gov/niosh/docs/2011-107/ The document also identified that airborne concentrations of beryllium must be kept as low as possible, since a safe exposure limit for beryllium has not been determined.

2. Should the Department use the 2010 ACGIH threshold limit value (TLV) of 0.05 µg/m [3] (8-hour time-weighted average of 0.05 microgram of beryllium, in inhalable particulate matter, per cubic meter of air), for its allowable exposure limit? Please explain your answer and provide evidence to support your answer.

Response: Yes, the Department needs to strongly consider adopting the revised TLV as an allowable exposure limit and use this value as the defined action level in the rule. Prior to the 10 CFR 851 regulation in 2007, a standard practice implemented by DOE and its contractors within

the was to implement the most current OSHA PEL and/or ACGIH TLV as part of their industrial hygiene program. This was based upon the credence provided by the Department to these values and supported by DOE contractors, i.e. these values presented the most up-to-date information regarding workplace standards and based on current research. With the exception of the NFPA codes, the introduction of the dated standards in the 10 CFR 851 has introduced a similar situation for the Department that OSHA finds itself in right now; unable to update allowable exposure limits from over thirty years ago, which are known to be nonprotective of worker health. It is argued that these values are not valid for compliance because of a lack of consideration of technical and economic feasibility. This is not a valid argument based on the following which shows actual use of the technology.

The criteria for particle size-selective sampling for inhalable, thoracic, and respirable aerosol fractions became internationally accepted in the early 1990s. (ref. CEN Standard EN 481, Workplace Atmospheres- Size Fraction Definitions for Measurement of Airborne Particles; and ISO 7708, Air Quality- Particle Size Fraction Definitions for Health-Related Sampling. One of the problems associated with this is the perceived notion that there is a lack of commercially available sampling instruments that meet the criteria. The IOM sampler and the Button Sampler are example of commercial products that are readily available for use and have been field tested with different kinds of dust in the laboratory and in the field. (Ref, Linnainmaa, M., Laitinen,J., Petti(2008) 'Laboratory and Field Testing of Sampling Methods for Inhalable and Respirable Dust', Journal of Occupational and Environmental Hygiene, 5: 1, 28-35, First Published on: 01January 2008.) It has been demonstrated that sampling via the use of an inhalable dust sampler collect several times the mass that could be collected by 37-mm cassettes.

Sampling via these methods has been completed and it is demonstrated that beryllium exposures are being currently evaluated in this manner. (Ref, Dufresne,A., Dion, C., …Perrault, G. (2009) 'Beryllium Aerosol Characteristics in the Magnesium and Aluminum Transformation Industry in Quebec: A Comparison of Four Different Sampling Methodologies', Journal of Occupational and Environmental Hygiene, 6: 11, 687-697, 01 November 2009.

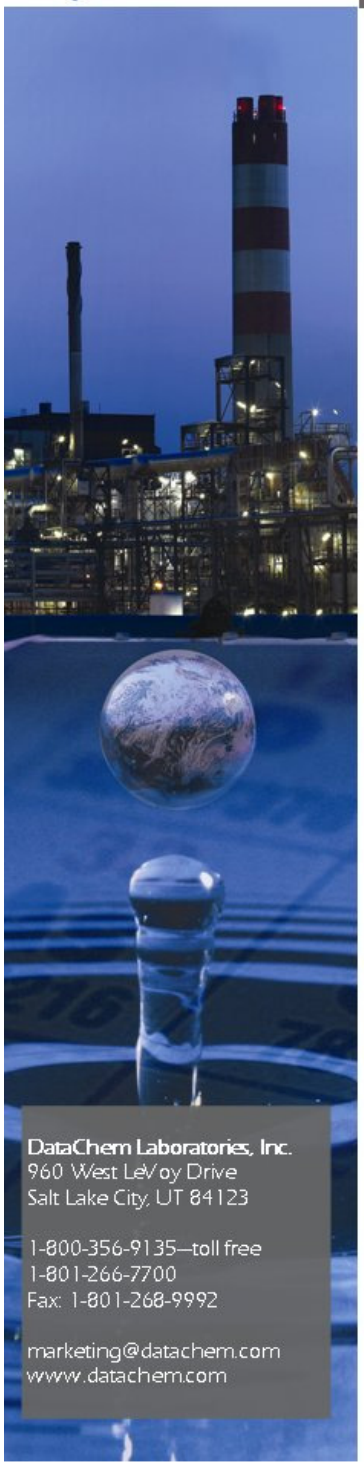
Currently, one contractor at the INL has initiated inhalable sampling for beryllium using the IOM sampler and associated inhalable sampling method as part of their approved Chronic Beryllium Disease Prevention Program. This is one of the most sampled contaminants the contractor continuing assesses during waste handling operations at a RCRA permitted TSD. Samples have been taken in this manner since July 2010 and continue to date. The laboratory used for the analysis has not changed. The analytical technique employed by this laboratory has also not changed. Following sampling units are sent as a whole to the laboratory and sent back to the contractor following analysis. Cleaning using an ultrasonic cleaner is performed by the contractor. No significant concerns, either with time or cost have been identified with the use of the IOM. A higher initial cost per unit on sampler ($112 vs. 10-15 for CFC). Besides the initial investment in the sampler head ($112 per sampler), sonic cleaner, and the time expended for cleaning the unit, there have not been any additional perceived costs by the contractor regarding this method versus the CFC.

There has been a longstanding concern that analytical laboratories would not be able to perform the needed analysis via current sampling and analytical techniques using the IOM sampler, if the

ACGIH TLV was adopted. From the attachment below, it appears that certain commercial laboratories have a detection limit of 0.007ug/sample for beryllium. See attachment below.

DATA CHEM LABORATORIES, INC.

Beryllium



Problem: Beryllium is a naturally occurring metal that is extremely light-weight, hard, non-magnetic, and is a good conductor of heat and electricity. Its characteristics make it suitable for many applications in the aerospace, nuclear, electronics, ceramics, and manufacturing industries. A significant disadvantage is the toxicity of its dust, fumes, and soluble salts. Lung damage is the primary threat from inhalation exposures to beryllium-contaminated air. Adverse health effects range from beryllium sensitization (allergic reactions) to chronic beryllium disease (CBD) and lung cancers.

Solution: DataChem Laboratories, Inc. offers low-level analysis of beryllium in Industrial Hygiene and Environmental matrices, including analysis for the more insoluble forms of beryllium (i.e. "high-fired" beryllium oxide).

DataChem has processed over 100,000 beryllium samples for government and industrial clients over the past several years, routinely providing 24 hour TAT for air and wipe samples. DataChem is staffed and equipped to offer high volume sample throughput on a rush basis to meet any and all project needs.

- EPA regulations stipulate that beryllium emissions from a stationary source may not exceed 10 grams in a 24-hour period and that ambient air concentrations averaged over a 30 day period must be less than 0.01 micrograms per cubic meter.
- NIOSH recommends a maximum occupational exposure of 0.5 micrograms per cubic meter over a 10-hour time-weighted average (TWA).
- Current OSHA regulations specify a beryllium exposure limit of 2 micrograms per cubic meter over an 8-hour TWA.
- The Department of Energy has established an action limit for beryllium at 0.2 micrograms per cubic meter.

DataChem Laboratories Detection Limits::

Air Filters and Swipes	0.007 µg/sample by ICP
Water	0.3 µg/L by ICP 0.07 µg/L by ICP-MS
Soil	0.02 µg/g by ICP 0.305µg/g by ICP-MS

For a complete list of our services, visit us at www.datachem.com

DataChem Laboratories, Inc.
960 West LeVoy Drive
Salt Lake City, UT 84123

1-800-356-9135—toll free
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Fax: 1-801-268-9992

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At the time of inquiry, additional information was obtained by contacting Datachem directly (now ALS) regarding this detection limit. The value is within 1/5 of the ACGIH TLV of 0.05ug/m3, meeting the need to demonstrate validity. It was indicated the detection limit applied to both MCE filters by NIOSH 7300 and 7303 (modified), and also for swipes (Ghost wipes and Whatman filters). Minimum volume for personal samples is 75 liters for the detection limit using the 0.2ug/m3 action limit and 150 liters at the .05ug/m3. This could be achieved with a sample volume taken from one hour and fifteen minutes at 2 liter per minute. It was also stated microwave digestion is used to detect BeO and using the same ICP analytical technique. Information presented here somewhat differs that what has been presented by DOE contractor laboratories at various BSHC meetings. Some commercial laboratories consider the analytical methods they employ to be proprietary. As a result, the DOE should thoroughly investigate and/or obtain information from the AIHA accreditation program regarding the detection limits that are being advertised by AIHA accredited laboratories for beryllium to truly assess the capability of achieving the analytical detection limit needed to report in comparison to the ACGIH TLV of 0.05 ug/m3. This would aid in determining the answer to this question.

3. Should an airborne action level that is different from the 2010 ACGIH TLV for beryllium (8-hour time-weighted average of 0.05 microgram of beryllium, in inhalable particulate matter, per cubic meter of air) be established? If so, what should be the level? Please explain each of your answers and provide evidence to support your answers.

Response - No. The action limit in the rule should be the same. My opinion is supported by the response provided in Question 2.

6. What is the best method for sampling and analyzing inhalable beryllium? Please explain your answers and provide evidence to support your answers.

Response - Pls see response provided to Question 2.

7. How should total fraction exposure data be compared to inhalable fraction exposure measurements? Please explain your answer and provide evidence to support your answer.

Response - The results of these sampling method measurements cannot be compared directly because different samplers are used. Overall, the conduct of inhalable sampling and the inhalable sampler technique is somewhat new to the IH community within the US. Some studies have been presented in the literature as to how to identify and apply a correction factor when using IOM to compare against CFC. However, a larger issue looms over this when considering the objective for the results and expected use within the department. Conventional IH wisdom is that a valid sampling and analytical technique must exist to determine the exposure results consistently and with a degree of accuracy and precision. Unless the Department can directly show the results of comparable studies (i.e. CFC vs. IOM) for beryllium analysis, comparison between the two should not be made. One study published within the last two years compared the results of beryllium sampling in the Magnesium and Aluminum Transformation Industry.

(Ref, Dufresne,A., Dion, C., …Perrault, G. (2009) 'Beryllium Aerosol Characteristics in the Magnesium and Aluminum Transformation Industry in Quebec: A Comparison of Four Different Sampling Methodologies', Journal of Occupational and Environmental Hygiene, 6: 11, 687-697, 01 November 2009.)

The above study concluded an "undersampling" of beryllium using the 37mm cassette vs. the IOM sampling. This has also been identified in other studies as well. The results of several paired samples in this study showed that the level of exposure based on the ration of the inhalable dust concentration to the total dust concentration ranged from 1.2 to greater than 3.0 and also tended to be greater for workplaces where the aerosol was expected to be coarser. The study showed that while beryllium was not or just barely detected in respirable dust for some samples, it was clearly detected in the inhalable samples. The study recommended that inhalable samples should remain the tool for estimating the risk of exposure to beryllium until a clear dose response is established. This is conventional wisdom that needs to be applied to the DOE rule, particularly in light of recent events of Be sensitization and CBD cases (Hanford and LLNL) where personnel have been identified that had little, if any known or suspected exposure to beryllium.

> 8. Should surface area action levels be established, or should DOE consider controlling the health risk of surface levels by establishing a low airborne action level that precludes beryllium settling out on surfaces, and administrative controls that prevent the buildup of beryllium on surfaces? If surface area action levels are established, what should be the DOE surface area action levels? If a low airborne action level should be established in lieu of the surface area action level, what should that airborne action level be? What, if any, additional administrative controls to prevent the buildup on surfaces should be established? Please explain each of your answers and provide evidence to support your answers.

Response - Surface area action limits need to be clearly established within the rule as there is no other available, reliable method by which beryllium contamination can be identified, thereby assuring that surfaces that may become contaminated with beryllium can be anticipated when planning work. The new NIOSH 9100 method provides a mechanism by which this can be achieved.

The use of airborne sampling and the results do not specifically identify whether a facility component or area is or was contaminated with beryllium. The results from such sampling are based upon the specific interaction the worker may perform and if there was any contact with the beryllium contamination. However, if the work did not involve any specific activity where the worker disturbed the material, the airborne sample would not pick it up. The beryllium may still be present in the workplace and present a hazard to subsequent workers. Work control judgments are being based upon the results of such sampling. If the result does not exceed the action level, additional work maybe done in the facility without the need for any specific controls, when they should be. This is a problem with the current rule as written. The rule needs to clearly identify the use of surface sampling as it pertains to development of the beryllium hazard inventory and its application to the hazard assessment process. Support for this approach is clearly demonstrated by recent DOE investigations. This includes the results of the July 2010 DOE HSS

Assessment of the Hanford Chronic Beryllium Disease Prevention Program and the recent Office of Enforcement Action at LLNL. The crux of these observed issues are all associated with the lack of knowing if beryllium contamination exists and subsequent work being performed by employees in these areas.

> 11. Currently, after the site occupational medicine director has determined that a beryllium worker should be medically removed from exposure to beryllium, the worker must consent to the removal. Should the Department continue to require the worker's consent for medical removal, or require mandatory medical removal? Please explain your answers.

Response - The Department needs to change its approach and perspective for medical surveillance testing in totality as described in the current rule. There has been numerous studies and papers presented recently in the support of the medical surveillance testing as the viable means for detecting beryllium sensitization within a potential exposed group. (Reference, Managing Health Effects of Beryllium, National Academy of Sciences, 2008). This independent study concluded that "Epidemiologic studies have shown that BeS and CBD occur in setting where airborne exposure to beryllium is below the current standard of 2 ug/m3, but do not indicate clearly how much lower such a standard would have to be protective…. Thus the committee concludes that it is not possible to estimate a chronic-inhalation-exposure level that is likely to prevent BeS and CBD in settings where beryllium has the potential to become aerosolized." Additionally, the recent NIOSH Alert (February 2011), Preventing Sensitization and Disease from Beryllium Exposure recognizes the value of the beryllium lymphocyte proliferation test (BeLPT) as part of the medical surveillance program for addressing the risk of beryllium exposure and identifying sentinel cases which may also indicate that co-workers are at risk. NIOSH makes similar recommendations as was made in the NAS report. In addition to the workplace fixes, focus needs to be place on reducing worker exposure but also having workers participate in workplace medical surveillance (over a period of time) so that risks related to job tasks can be identified and prevented by an employer provided medical surveillance program using the beryllium lymphocyte proliferation test. The current rule does not require any worker to participate in the medical surveillance, either initially or in the future.

Currently, any statistics that the Department or Department contractors may have regarding the medical surveillance program and results is only as good as the participation rate of the potentially exposed workers. Here at the INL recent participation rates range from 33% -45% of one affected contractor worker population having agreed to having one BeLPT test and then opting out, to less than 1% participation in another contractor workforce. Allowing worker nonparticipation in a medical surveillance program definitely affects any judgments made as to whether current or future control measures are preventing beryllium sensitization.

The whole premise of medical surveillance is to monitor the work force (and its health) over period of time employed in the work that has the potential to expose the individual. If the individual can continue to choose to not participate, the Department will never fully know what is actually going on within the areas/worker population that it has control over. Serial testing via the BeLPT has proven to be effective in interpreting inconclusive or false negative/positive results of the BeLPT. (Base Document will be forwarded in separate email to you)

The costs incurred upfront by requiring this testing for potentially exposed individuals needs to be balanced against what costs could or might be incurred in the future by these same individuals seeking compensation under the Former Worker Compensation Program. The BeLPT represents the current state-of-the art in determining BeS and focus needs to be provided in the rule so that workers do not view this as a detriment to future employment, but one of protecting their health.

Jackie, the following references and attachment support the comment indicated in my response submitted to you yesterday for Question 11. Thank you.

http://erj.ersjournals.com/content/32/3/543.full

http://www.uptodate.com/contents/chronic-beryllium-disease-berylliosis/abstract/14