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ENGINEERED MATERIALS

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February 22, 2011

Ms. Jacqueline D. Rogers
Office of Workers Safety and Health Policy
Office of Health, Safety and Security
U.S. Department of Energy
Docket No. HS-RM-10-CBDPP
1000 Independence Avenue S.W.
Washington, D.C. 20585
jackie.rogers@hq.doe.gov

Re: Request for Information
DEPARTMENT OF ENERGY
Chronic Beryllium Disease Prevention Program
Docket No. HS-RM-10-CBDPP

Dear Ms. Rogers:

Brush Wellman Inc. ("Brush") is pleased to have this opportunity to submit information and comments in response to the Department of Energy's ("DOE") request for information ("RFI") on issues relative to its current Chronic Beryllium Disease Prevention Program ("CBDPP"), 75 Federal Register 80734 (December 23, 2010).

Brush has for decades worked in cooperation with the DOE and its predecessor the Atomic Energy Commission ("AEC") in the development of standards and procedures for the safe production and use of beryllium and beryllium-containing materials. In the continuing spirit of cooperation, Brush submits these comments in the hope of helping DOE to refine its CBDPP to enhance worker safety in using beryllium and to avoid unnecessary expenditures in doing so, which has become a pervasive, persistent and increasingly important role of government agencies.

During these decades of cooperation, beryllium has been critical to the mission of DOE and the AEC, and Brush has been the primary supplier of beryllium to the agency. Indeed, Brush is the only fully integrated supplier of beryllium, beryllium alloys and beryllium ceramic in the world. Brush operates the only beryllium mine and primary beryllium manufacturing facility in the United States. Emblematic of the continuing importance of beryllium, in 2010 a new $90 million beryllium metal extraction plant was constructed in Elmore, Ohio and it is currently in the start-up phase. This manufacturing facility was funded by an innovative public-private partnership between Brush and the U.S. Department of Defense under the Defense Production Act. This facility will provide a secure, long-term domestic source of beryllium products for critical defense applications such as optics, satellite structures, aircraft parts and missile defense components.

While beryllium has been used for decades in a wide variety of important defense and civilian applications, there is a growing appreciation of the future needs for beryllium. On December 12, 2008, the Department of Defense's Strategic Materials Protection Board identified and classified

beryllium as the only *"strategic material"* that is *"critical to national security."* This report was issued pursuant to 10 United States Code §187.

On February 2, 2011, the European Commission published a report declaring beryllium as one of 14 critical raw materials for the European Union ("EU"). This report states that the EU will pursue a *"raw materials diplomacy"* to secure sustainable access and supply to these critical raw materials which are characterized by *"a particularly high risk of supply shortage in the next 10 years and which are particularly important for the value chain."* See, *"Tackling the Challenges in Commodity Markets and on Raw Materials,"* Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, (Com 2011) 25. Important uses of beryllium are found in medical imaging and other diagnostic equipment, automotive sensors, and electrical equipment contacts.

Programs for working safely with beryllium have also advanced, and Brush and the DOE have been notable in this regard. Informed by a formal co-operative research partnership program conducted with NIOSH, Brush has developed an 8-step Worker Protection Model which it uses at its beryllium production facilities. To more broadly communicate the Worker Protection Model throughout the supply chain, Brush has developed an Interactive Guide to Working Safely with Beryllium and Beryllium-containing Materials. This award-winning tool is available online at www.berylliumsafety.com. The DOE has also been a major player in the development of safe practices for working with beryllium, most notably with the publication of its proposed CBDPP rule on December 3, 1998 and the adoption of its final rule on December 8, 1999.

Both public and private sector employers which use beryllium in their operations look to DOE and to Brush in benchmarking their safety programs. The current DOE beryllium standard has directly and indirectly affected the commercial sector. For example, some companies have incorporated wipe sample testing of beryllium metal parts as a requirement when transferring beryllium parts between vendors serving the DOE. Because of the influence that the DOE program has on the activities of employers in the private sector, it is important that any new requirements that DOE makes in its CBDPP program are science-based and effective, both in terms of their results in preventing CBD, which is the fundamental purpose of the program, and in terms of cost effectiveness. Expenditures that do not produce measureable improvements consume valuable resources that can be better deployed on practices such as those in the worker protection model which have been shown to better protect workers. In addition, DOE needs to evaluate the potential impacts to downstream commercial users of beryllium-containing materials when proposing changes to its standard along with fully understanding and considering how its actions may shape other agencies' regulatory requirements for beryllium.

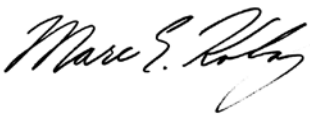
In light of the high profile of the CBDPP and because, as the RFI states, *"DOE now has nearly 10 years of job, exposure and health data [for thousands of workers] as well experience in implementing the rule,"* Brush is frankly disappointed in the RFI. The fundamental disappointment lies in the failure of DOE to share with the public, before it solicited comments by publishing the RFI, the results to-date regarding the effectiveness of the 1999 CBDPP. An understanding of how well the CBDPP is working and where it is not working is essential to improving the current CBDPP, as well as to the specific questions DOE has posed regarding potential changes to certain portions of the CBDPP rule.

In addition, given the many provisions of the CBDPP, which has 21 specific program requirements, it is disappointing and surprising that DOE would seek input on only a few of those elements, some of which are the subject of multiple questions. For example, given the reliability and accuracy problems with the BeBLPT blood test, it is surprising that DOE has not requested data and information on this subject. In sum, by not disclosing performance data on outcomes

under the CBDPP and by soliciting comments on only a few hand-selected program requirements, DOE has created uncertainty as to whether it has asked the right questions in its effort *"to decide whether its current CBDPP can be improved."* 75 Federal Register at 80734.

While the attached comments respond to the 11 numbered questions presented by the RIN, Brush believes that DOE can obtain more valuable data and information from Brush and other commenters if we are provided a more thorough understanding of the effectiveness of the current CBDPP and a less constrained opportunity for input as to whether and how it can be improved. We strongly recommend that DOE perform a complete technical review of the health outcome and cost effectiveness of its CBDPP and issue a new RFI based on its findings.

Sincerely yours,



Marc E. Kolanz, CIH
Vice President
Environmental Health & Safety

MEK/elm

Comments of Brush Wellman Inc.
On the Request for Information
By the Department of Energy
Concerning the Chronic Beryllium Disease Prevention Program
75 Federal Register 80734
(December 23, 2010)
(Docket No. HS-RM-10-CBDPP)

February 22, 2010

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PRELIMINARY COMMENTS

Brush Wellman Inc. ("Brush") submits these comments in response to the Request for Information ("RFI") regarding the Chronic Beryllium Disease Prevention Program ("CBDPP") published at 75 Federal Register 80734 (December 23, 2010). The RFI states that the DOE *"is considering establishing new requirements in several sections of the CBDPP rule (10 C.F.R. part 850)"* and *"is gathering data, views, and other relevant information to develop a renewed standard for CBDPP at its facilities."* Id. The RFI further states that *"DOE would like to have more data and information to decide whether its current CBDPP can be improved, and if so, how it can be improved."* Id. To this end, commenters are directed to answer 11 specific numbered questions and where possible *"include the mission and cost impact implied by the question and your answer."* Id.

Before responding as requested by the RFI to the numbered questions, Brush would like to offer several observations as to the approach which DOE has taken through this RFI and to provide some general information.

Assessing and Communicating Results under the Current CBDPP

The CBDPP covers thousands of workers, which makes it the largest program of its kind in the world. As noted in the RFI, *"DOE now has nearly 10 years of job, exposure, and health data, as well as experience implementing the rule, since CBDPP was fully implemented in January 2002."* Id. By reviewing published studies and attending DOE conferences on the CBDPP, Brush is aware of a sampling of how the CBDPP has performed. However, in approaching the fundamental question of *"whether its current CBDPP can be improved,"* DOE first needs to assess the question of "whether its current CBDPP is working" and share its data with the public. Responding to the issue of whether the current CBDPP can be improved and, if so, what improvements should be made depends on an assessment of the outcomes under the current program. What data show that the CBDPP is working? What data show that the CBDPP is not working? Are the data insufficient to show whether the CBDPP is working or not? This fundamental assessment needs to be made and shared if DOE's consideration of revising the CBDPP is to proceed in a logical, science-driven manner in which the public can have meaningful input.

DOE's effective communication of data and other information regarding the results of the current CBDPP is crucial to any rulemaking. As succinctly stated by OMB Administrator Cass R. Sunstein in a recent memo to the heads of all executive departments, and agencies and independent regulatory agencies:

> *"Federal agencies play a critical role in collecting and managing information in order to promote openness, increase program efficiency and effectiveness, reduce burdens on the public, and improve the integrity, quality, and utility of information to all users within and outside the government."* (Citing 44 USC §3506(b)).

"Facilitating Scientific Research by Streamlining the Paperwork Reduction Act Process" (December 7, 2010).

Premature Focus on Revising the PEL and Action Level in the CBDPP

The current CBDPP rule incorporates by reference the current permissible exposure limit ("PEL") adopted by the Occupational Safety and Health Administration ("OSHA") for beryllium or any more stringent PEL that OSHA may adopt. 10 C.F.R. §850.22. OSHA is engaged in a rulemaking

to consider revisions to the beryllium PEL and is in the peer review stages. 75 Federal Register 79806-07 (December 20, 2010). Questions 1, 2, 3 and 6 of the RFI indicate that DOE is considering adopting a PEL for the CBDPP instead of deferring to OSHA. Laying aside questions as to DOE's authority and competency to adopt a PEL and questions of deference, redundancy of expenditures, and efficiency in proceeding to do so, a practical question arises as to what would be the benefit to workers of reducing the PEL or the action level under the CBDPP.

Under the CBDPP, the PEL plays a very limited role. The limited role of the PEL is demonstrated by Table 8 in the DOE's preamble to the adoption of the final CBDPP rules. 64 Federal Register 68854, 68863 (December 8, 1999). Table 8, entitled "Levels At Which The Provisions Of The CBDPP Apply," is reproduced here.

Table 8.–Levels At Which The Provisions Of The CBDPP Apply			
Provision	Worker exposure or potential exposure levels (8-Hour TWA)		
	Be operations/ locations[1]	≥Action level (0.2 µg/m^3)	≥PEL (8-hr TWA) (2.0 µg/m^3)
Baseline Inventory (850.02)	X		
Hazard Assessment (850.31)	X		
Initial Exposure Monitoring (850.24)	X		
Periodic Exposure Monitoring (850.24)		X	
Exposure Reduction and Minimization (850.25)	X[2]	X[3]	X[4]
Regulated Areas (850.26)		X	
Hygiene Facilities and Practices (850.27)		X	
Respiratory Protection (850.28)	X[5]	X	
Protective Clothing and Equipment (850.29)	X[6]	X	
Housekeeping (850.30)	X[7]		
Release Criteria (850.21)	X[8,9]		
Medical Surveillance (850.34)	X[10]		
Training and Counseling (850.37)	X[11]		
Warning Signs (850.38)		X	

Thus, only one part of one of these 14 specified elements is uniquely triggered if monitored exposure to airborne beryllium equals or exceeds the current OSHA PEL of 2.0 µg/m^3. This element is part of the "Exposure Reduction and Minimization" rule, 10 C.F.R. §850.25(a), which states that the employer "must assure that no worker is exposed above [the OSHA PEL]."

[1] Applies to beryllium operations and other locations where there is a potential for beryllium contamination.
[2] Responsible employers must implement actions for reducing and minimizing exposures, if practicable.
[3] Responsible employers must establish a formal exposure reduction and minimization program, if practicable.
[4] Responsible employers must reduce exposures to or below the PEL.
[5] Responsible employers must provide respirators when requested by the worker.
[6] Responsible employers must provide protective clothing and equipment where surface contamination levels are above 3 µg/100 cm^2 during non-operational hours.
[7] Housekeeping efforts must maintain removable surface contamination at or below 3 µg/100 cm^2 during non-operational hours.
[8] Removable contamination on equipment surfaces must not exceed 0.2 µg/100 cm^2 when released to the public or for non-beryllium use.
[9] Removable contamination on equipment surfaces must not exceed 3 µg/100 cm^2 when released to other beryllium handling facilities.
[10] Responsible employers must provide medical surveillance for all beryllium-associated workers.
[11] Training is required for all workers who could be potentially exposed. Counseling is required for beryllium-associated workers diagnosed with CBD or beryllium sensitization.

In addition, the role of the action level is also constrained because, as Table 8 shows, 10 of 14 specified elements of the CBDPP apply to all *"beryllium operations and other locations where there is a potential for beryllium contamination."* Id. In other words, these 10 elements apply simply based on potential exposure without having demonstrated any level of exposure to airborne beryllium.

Employers with airborne concentration below the action level must also *"implement actions for reducing and minimizing exposure, if practicable."* 40 C.F.R. §850.25(b)(2). In addition, all employers covered by the CBDPP, even those with exposure below the action level, *"must implement exposure reduction and minimization actions using correctional hierarchy of industrial controls (i.e., engineering controls, administrative controls, and personal protective equipment in that order)."* 10 C.F.R. §850.25(c). The current CBDPP requires all covered employers to implement all practical means to reduce and minimize exposure to airborne beryllium. This requirement applies to employers with exposures both above and below the action level.

Brush Wellman's Beryllium Worker Protection Model

Brush Wellman has developed and applied since 2001 an enhanced Beryllium Worker Protection Model[ii]. This model employs an recommended exposure guideline (REG) of 0.2 µg/m^3 for exposure to beryllium (measured as total particulate) for the prevention of CBD, subclinical CBD, and beryllium sensitization. This model seeks to maintain exposures below 0.2 µg/m^3 95% of the time, in accordance with the AIHA Exposure Assessment Manual. At those areas and operations that cannot be controlled at this level, workers wear respiratory protection full-time.

The effectiveness of the Beryllium Worker Protection Model is being assessed by Brush and NIOSH which are engaged in a research partnership that emphasizes rapid research-to-practice applications. The model has been effective to-date in reducing the detection of beryllium sensitization in new employees to background rates found in the non-occupationally exposed population.[iii] Thus far, there have also been no new cases[12] of clinical or subclinical CBD in new workers hired since the implementation of the model. In 2008 Brush and NIOSH were jointly awarded the National Occupational Research Agenda Partnering Award for Worker Health and Safety.

To help communicate the elements of the Beryllium Worker Protection Model to Brush's customers and other downstream users, in 2009 Brush launched a computer-based tool called "The Interactive Guide to Working Safely with Beryllium and Beryllium-Containing Materials" ("Interactive Guide")[iv]. By responding to a series of questions, an employer or employee can receive a customized guide with specific information on how to work safely with materials, including an identification of the need for additional controls on operations or processes. The Interactive Guide is available on CD or online at www.berylliumsafety.com.

CBDPP Elements Not Addressed in the RFI

The RFI notes that new research related to CBD has been published since 1999. A considerable amount of this research relates to elements of the CBDPP program for which the RFI does not request any comments. Brush believes that in any rulemaking to change the CBDPP, DOE needs to take a hard look at many other elements of the program in light of subsequently published research and the DOE's own experience under the current rule.

[12] One case of subclinical CBD has been diagnosed in a new worker who had worked previously in a former primary beryllium production facility. It is impossible to determine the origin this person's health outcome.

Chief among the unaddressed elements is the use of the BeLPT blood test, also referred to as the BeBLPT. The CBDPP requires employers to provide a BeLPT to beryllium workers as part of a baseline medical evaluation, periodic three-year evaluation, and emergency evaluation of any worker exposed to a beryllium emergency. 10 C.F.R. §850.34(b). One or more positive BeLPT can be the basis for a written medical opinion that it is appropriate to remove a worker from beryllium exposure which in turn requires the employer to offer medical removal. 10 C.F.R. §850.35(a).

The problems with the BeLPT are several and persistent.[v, vi] The problems begin with the fact that there is no gold standard for beryllium sensitization. Therefore, it is an open question as to how well each of a handful of proprietary BeLPT protocols detects beryllium sensitization. Use of the proprietary procedures has produced an occasion-high level of intra-laboratory variability (test-to-test) and fluctuations in laboratory stability. When results of the different protocols have been compared, inter-laboratory variability has been high. Use of the BeLPT has yet to be shown to confer a proven medical benefit, including where medical removal occurs. Furthermore, repeated testing of individuals who test positive and continue to have occupational exposure to beryllium show that a significant percentage will test negative in subsequent tests.

COMMENTS ON DOE QUESTIONS NOS. 1-11

QUESTION 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

If the DOE chooses to invest its resources in replacing the OSHA PEL, it should adopt 0.2 µg/m^3 for an 8-hour exposure to total beryllium where it is technically and economically feasible to achieve. This level is similar to DOE's current action level, a PEL adopted by the State of California and the results of studies that have found it to be an effective OEL in reducing potential beryllium health risks when used as an integral part of a comprehensive beryllium safety model.

The DOE has not applied its action level *"to assure that controls are implemented to prevent exposures from exceeding the permissible exposure limits."* In practice, the DOE has used its action level as its occupational exposure limit for beryllium. The CBDPP requires employers above the action level to reduce exposures to below the action level and, if practical, to minimize and further reduce any exposures below the action level. 10 C.F.R. §850.25(b). Since the implementation of its CBDPP, DOE has not studied the efficacy of its action level or beryllium safety program elements. However, in many respects, the DOE's application of its action level and its CBDPP program requirements have several components which align with the beryllium safety model adopted by the beryllium industry. This industry safety model includes the use of a recommended exposure guideline of 0.2 micrograms beryllium per cubic meter of air (µg/m^3) as an 8-hour time-weighted average measured by the traditional total beryllium sampling method. This safety model was developed as a result of the research partnership between Brush Wellman Inc. and NIOSH which began in 1997. The model has now been in use for approximately 10 years at Brush Wellman facilities and NIOSH/BWI research studies at those facilities have demonstrated that based on results to-date the model effectively reduces detected beryllium

sensitization to levels observed in the general population. Moreover, to-date there have been no new detected cases[12] of subclinical CBD or clinical CBD in new workers hired since the effective adoption of the model at several plant sites.

The DOE's continued use of the OSHA PEL is confounded by California OSHA's 2006 enactment of a 0.2 µg/m^3 PEL which creates two different requirements for those DOE controlled or managed operations within the State of California. If DOE departs from the OSHA PEL, it is in the best interests of workers exposed to beryllium for DOE to adopt a PEL for beryllium that is consistent with California and that is as part of an effective beryllium safety model.

Based on the large number of personal lapel samples and the completeness of the data set over the respective study periods, the studies by Cummings, Bailey[vii], Madl[viii], Schuler[ix] and Johnson[x], briefly described below, provide the most complete and thorough studies upon which the DOE should base its selection of a PEL for beryllium. Based on a critical analysis of the data and findings in these studies which give no consideration of technical or economic feasibility, we believe the preponderance of the evidence supports the adoption of a PEL of no lower than 0.2 µg/m³.

A. The study by Cummings, et al. provides an analysis of the effectiveness of Brush Wellman's beryllium worker protection model including the use of an REG of 0.2 µg/m^3. This study demonstrated that this exposure control model, in use since 2000, had been effective in reducing the detection of beryllium sensitization from over 8% to 1% with no detection thus far of new cases of subclinical or clinical CBD in new workers.

B. In 2010 Bailey et al. used the BeBLPT to assess the impact of a new beryllium safety model implemented in early 2000 at the world's largest and only United States primary beryllium materials production plant. Although the BeBLPT is not an FDA-approved test and there are no standard protocols for administering the test, it can be used by experienced epidemiologists for research purposes. Bailey used the detection of two positive BeBLPTs as a risk marker for CBD sensitization, prevalence and incidence rates were compared for workers hired before and after the implementation of the new safety model using available cross sectional and longitudinal surveillance data. Sensitization prevalence was 8.9% for the pre-safety model Group and 2.1% for the new safety model group. Though not evaluated or reported as part of this study, through the involvement of scientists from Brush Wellman, we know that none of the sensitized persons identified in the employee group using the new safety model have been diagnosed with subclinical or clinical CBD with the exception of one new worker who was previously employed in a building that formerly contained a primary beryllium production facility. Although beryllium production in this facility ceased in the 1950s the building and site are known to contain significant residual beryllium contamination. It is possible that an important component of this person's beryllium exposure occurred in this previous employment. Overall the study concluded that *"This investigation is consistent with other studies in indicating that a comprehensive preventive program can have an impact on reducing sensitization in beryllium-naïve workers."*

C. The study by Madl, et al. with over 3800 personal samples was published in 2007. The Madl study uses four different methods to reconstruct historical exposures of each worker. These analyses provide a more complete picture of exposure response. This comprehensive analysis concludes that beryllium sensitization (BeS), subclinical chronic beryllium disease (sCBD) and clinical chronic beryllium disease (cCBD) occur as a result of exposures greater than 0.4 µg/m^3 and that maintaining exposures below 0.2 µg/m^3 95% of the time may prevent BeS, sCBD and cCBD in the workplace. A major challenge for

evaluating the exposure-response relationship for BeS and CBD is that most studies have used inconsistent sampling and exposure assessment methodologies and definitions for BeS and CBD[xi]. These differences have often prevented direct comparisons between studies, as well as the identification of a clear exposure-response relationship for BeS and CBD. In the study by Madl et al., a large data set of 3,831 personal lapel and 616 general area samples provided an opportunity to use several methods to reconstruct each worker's exposure prior to the ascertainment of BeS or the diagnosis of subclinical or clinical CBD, followed by an exposure-response analysis to determine whether a threshold for BeS and CBD could be identified. Four different methods were used to reconstruct historical exposures of each worker as industrial hygiene data were pooled by year, job title, era of engineering controls, and by complete work history (life-time weighted average) prior to diagnosis.

The Madl study concludes, "*Results showed that exposure metrics based on shorter averaging times (i.e., year versus complete work history) better identified the upper bound worker exposures which could have contributed to the development of BeS or CBD. It was observed that all beryllium sensitized and CBD workers were likely exposed to beryllium concentrations greater than 0.2 µg/m^3 (95th percentile) and 90% were exposed to concentrations greater than 0.4 µg/m^3 (95th percentile) within a given year of their work history. Based on this analysis, it would appear that BeS and CBD generally occurred as a result of exposures greater than 0.4 µg/m^3 and that maintaining exposures below 0.2 µg/m^3 95% of the time may prevent BeS and CBD in the workplace.*"

The authors note that in several important respects their study was the first of its kind:

"An effective OEL is one that reduces or eliminates the risk of an adverse health effect or outcome in the majority of the working population. Unlike many other chemicals, identifying the exposure metric upon which to derive the OEL is particularly difficult for beryllium due to its immunologic pathogenesis. Historically, epidemiologic studies have studied BeS and CBD prevalence in relation to the mean or median beryllium concentration for the longest or most recent job title held. In general, these studies have found that certain job titles or operations may pose an increased or lesser risk of BeS and CBD, but none have shown an exposure-response pattern for these endpoints. The majority of these studies reconstructed worker exposures based on broad job classifications and have not evaluated the beryllium exposures which may have contributed to the identification of BeS or diagnosis of CBD in each worker. Our analysis is not only the first to reconstruct worker exposures to beryllium based on individual work history, but also is the first to evaluate a variety of exposure reconstruction methods and their influence on the exposure-response patterns for BeS and CBD. The results of our analyses show that the magnitude of the upper bound exposures, which may have led to the development of BeS and CBD, is typically not reflected in historical exposure estimates that are averaged over several years (e.g., LTW). Given the immunologic basis of BeS and CBD and that these endpoints have been documented, in some cases, as a result of relatively short-term exposures (e.g., < 1 year), it is important to not only understand central tendency estimates of exposure but also upper bound exposures.

In addition to understanding the plausible range of exposures which may contribute to the identification of BeS and diagnosis of CBD, for purposes of deriving an OEL, it is important to characterize the level of exposure below which the risk of disease is not substantially increased. The majority of studies conducted to date have involved cross-sectional studies which have not included adequate control comparison groups or an evaluation of worker-specific exposures. The analysis described in this study was the first to derive

exposure estimates specific to each beryllium sensitized worker and CBD case. Because individual work exposures were derived based on specific job history and exposure data, this analysis provides a better understanding of the range of exposures to airborne beryllium that is associated with BeS or CBD. Based on this analysis of beryllium sensitized and CBD workers, it would appear that BeS and CBD generally occurred as a result of exposures greater than 0.4 µg/m^3 and that maintaining exposures below 0.2 µg/m^3 95% of the time may prevent BeS and CBD in the workplace."

D. Schuler, et al. with over 650 personal samples demonstrates that exposure levels of 0.2 µg/m^3 and below are not associated with sCBD. The Schuler 2005 study performed a cross-sectional survey to examine prevalence of beryllium sensitization (BeS) and CBD, and relationships between BeS and CBD and work areas/processes at a copper beryllium alloy strip and wire finishing facility. The study concludes:

"*Sensitization and CBD were associated with an area in which beryllium air levels exceeded 0.2 mg/m^3, and not with areas where this level was rarely exceeded.*

Employees at this copper beryllium alloy facility had similar prevalences of sensitization and CBD as workers at facilities with higher beryllium air levels."

E. The DOE should carefully consider the strength of the scientific evidence in the findings of Johnson et al. 2001 as it considers identifying a PEL that is preventive of a material impairment of health. There is no beryllium facility study that has more air sampling data than the United Kingdom Atomic Weapons Establishment in Cardiff, Wales. This facility effectively prevented clinical CBD for over 30 years. The Johnson et al. study includes over 217,000 personal samples using an exposure assessment strategy that monitored every worker on every day for 36 years. The Johnson study demonstrated that the Cardiff beryllium control model achieved compliance with the United Kingdom 2 µg/m^3 8-hour Maximum Exposure Limit (MEL) over 98 percent of the time and prevented cCBD.

The DOE should not adopt a PEL that defines beryllium sensitization (BeS) as an adverse health effect as it is contrary to common definitions of adverse health effect as established by scientific experts and agencies worldwide. Today, the term beryllium sensitization (BeS) refers to the recognition of beryllium by the immune system which may be detected via an in-vivo patch test, an in-vitro blood test (beryllium blood lymphocyte proliferation test), or in-vitro test of lung cells (bronchoalveolar lavage lymphocyte proliferation test) obtained during a surgical procedure called bronchial lavage used to discriminate beryllium disease from other similar diseases. Beryllium sensitization is not the same as a chemical sensitizer because there are no clinical symptoms and, as such, persons whose blood tests positive for beryllium sensitivity are not considered to have a health effect or a material impairment of health.

QUESTION 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

The DOE should not use the American Conference of Governmental Industrial Hygienists (ACGIH®) ACGIH® Threshold Limit Values (TLVs®) TLVs® as the basis for its PEL for beryllium or any other allowable exposure limit or action level because TLVs® *"are not developed for use as legal standards and ACGIH® does not advocate their use as such."* and because the ACGIH® gives no consideration to economic and technical feasibility when establishing a TLV®.

The ACGIH® is a restricted-membership professional society comprised mostly of government health and safety professionals which allows only highly limited participation of health and safety professionals working in the private sector. In its Policy Statement on the Uses of TLVs® and BEIs®, the ACGIH® advises that TLVs® *"are not developed for use as legal standards and ACGIH® does not advocate their use as such."* This is primarily due to the fact that the ACGIH® gives no consideration to economic and technical feasibility when establishing a TLV® as is required by most regulatory agencies when developing an OEL. We believe that an assessment of technical and economic feasibility is an important part of the regulatory process and it is required by regulation that DOE conduct such an evaluation as part of any new regulation of beryllium. Secondly, the ACGIH® states that *"It is not appropriate for individuals or organizations to impose on the TLVs® and BEIs® their concepts of what the TLVs® and BEIs® should be or how they should be applied or to transfer regulatory standards requirements to the TLVs® and BEIs®."* Lastly, the ACGIH TLV® development methodology does not incorporate a scientific consensus process nor are their deliberations conducted in an open and transparent manner.

When adopting the CBDPP, DOE stated: *"The incorporation of any new ACGIH TLV in this rule would require that the DOE conduct rulemaking on the specific exposure level and present the scientific basis for public comment."* 64 Federal Register at 68873 (December 8, 1999). DOE stated further its belief that *"based on existing scientific evidence, that such a rulemaking is premature,"* as *"it is difficult to determine the exposure level necessary to eliminate the risk of contracting CBD."* Id. DOE has not done what it said it would do, in that the RFI does not present the scientific basis for public comment that DOE has identified as potentially justifying incorporation of the ACGIH TLV. It is clear, however, that the scientific basis ACGIH cited to support the TLV for beryllium is flawed in several critical respects.

ACGIH® improperly ignored upper-bound exposure data and based the 8-hour TLV® on long-term mean and median data.

Prior to ACGIH® adopting the proposed changes for beryllium and compounds, Brush Wellman provided extensive comments to and met with ACGIH® to explain our scientific concerns with the information and data they were using to justify the changes to the TLVs® as well as to provide information supporting an appropriate occupational exposure limit. For example, we encouraged ACGIH® to pay particular attention to the statistical expression of the TLV® and the underlying studies. In meetings with the ACGIH®, we found the discussion surrounding the topic of the TLV® Committee's use of the mean/median data as a basis for its beryllium TLV® recommendation of particular interest. During our discussions, Dr. Cohen (then ACGIH® Chairperson) expressed her belief that it is important to consider upper-bound exposure data such as 95th percentile data when setting an 8-hour TLV®. Her statement is also in agreement with AIHA's statistical approach to analyzing exposure data, which Brush Wellman also supports and uses. However, Dr. Gordon, as the TLV® Committee Chairperson, expressed his opinion that he believes the mean/median data should be used to set the 8-hour TLV® and that the 95th percentile should be used to set short-term exposure limits. This issue remains especially important since the two key studies ACGIH® used to support its 2009 TLV® (Madl, Kelleher) both recognized the importance of the

upper tail of the exposure distributions when it comes to determining an appropriate OEL for beryllium. In fact, the Kelleher paper stated:

> *"Comparisons of our data with occupational exposure limits, however, must be made with caution because occupational exposure limits are based on the upper tail of the exposure distribution rather than on measures of central tendency."*

Despite the ACGIH® Chairperson's scientific opinion, the TLV® Committee Chairperson ignored her opinion and ignored all of our key comments. Among others, the U.S. Department of Energy (DOE), the DOE sponsored Beryllium Health & Safety Subcommittee and the Aluminum Association of America all submitted key comments aligning with Brush Wellman's. Their comments were also ignored.

The ACGIH's® interpretation of Kelleher, the primary study used to justify the 0.05 µg/m^3, is flawed and does not support the use of 0.05 µg/m^3 as a TLV or a PEL.

ACGIH® should not have relied on Kelleher 2001 because this study of a large beryllium machine shop had an insufficient amount of exposure data. Kelleher obtained a total of 100 personal samples on about 25 job titles, with only 4 samples collected for some jobs where CBD was observed (EDM operator). The results of the beryllium air sampling found greater than 9% of the air sample results to be in excess of the 2 µg/m^3 PEL, and the results ranged from 0.006 to 22.62 µg/m^3. All samples were collected during a single survey by the authors and then used as the basis for their cumulative exposure metric. A major concern is whether the samples collected by Kelleher accurately estimate worker exposure.

In comparison, Schuler 2005 represents a study where the American Industrial Hygiene Association (AIHA) exposure assessment guide recommended number of air samples to assess worker exposure is met with both an ample number of workers (N=153) and excellent exposure data (N>15/job classification). As previously discussed, this study found that exposures consistently below 0.2 µg/m^3 did not result in beryllium sensitization or CBD. Kelleher's collecting of less than the AIHA recommended number of air samples does not provide a sufficiently robust data set to perform analyses with reasonable statistical confidence. In fact, the AIHA Exposure Assessment Guide identifies serious concerns with small sample sizes and cautions against ignoring sample results in excess of a PEL. The AIHA guide makes the following pertinent statement:

> *"Because of the inherent variability of workplace exposures, statistically guaranteeing that all exposures are below a guideline (or Occupational Exposure Limit - OEL) is usually impossible; however, demonstrating statistically that no more than a given percentage of exposures are greater than the standard with some confidence is possible. The most common procedure of this type is the tolerance limit approach. This approach will permit the industrial hygienist to determine whether one can have, for example, 95% confidence that no more than 5% of the exposure exceed the standard. An industrial hygienist can select whatever percentages are appropriate in light of an agent's toxic effects, warning properties, and general uncertainty or the population dose-Response relationship. Unfortunately, tolerance limits are very sensitive to sample size and the distribution's standard deviation. With small sample sizes, this test has limited power to provide good confidence in an extreme percentile estimate, particularly for highly variable exposure profiles. One should not infer from this discussion that exposures above an OEL can be ignored when the 95th percentile exposure is less than the OEL. Good industrial hygiene practice dictates that all exposures above an OEL be investigated. A measured overexposure is a signal that the work environment for all members of the exposure group*

might be a problem or that there are individuals within the exposure group who routinely experience significantly greater exposures than the other employees --- due to different work practices or effectiveness of controls."

A second major concern is the typical problem with converting cumulative exposure metrics to TLVs® using annualized median data. The cumulative exposure metric used by Kelleher is a summation of averaged annual median air sample data for a given job, and multiplied by time in that job. The summation of median data used to create this metric ignores 50% of the exposures above the annual median that are referred to as important by the AIHA Exposure Assessment Guide. More important, it ignores the AIHA's guidance that no more than 5% of samples should exceed the TLV® with 95% confidence. This type of data analysis represents the no effect level most comparable to a TLV® because a TLV® is applied in practice as a not to be exceeded value. The proposing of a TLV® based on a no effect level created using annual median data does not meet the basic tenets of the AIHA Exposure Assessment Guide. The use of median data tends to mask important aspects of workplace exposures relevant to exposure health risks by simply not considering the health significance of the upper half of the measured exposure values. Even the Kelleher study cautions against the use of its central tendency data when considering an OEL for beryllium where it stated:

"Comparisons of our data with occupational exposure limits, however, must be made with caution because occupational exposure limits are based on the upper tail of the exposure distribution rather than on measures of central tendency."

A third major concern is Kelleher's assumption that exposures at the subject machine shop had not changed significantly over time and claims that the review of the historical data supports this assumption. Unfortunately, Kelleher's assumption does not have a reasonable factual foundation and is scientifically unsupportable. First, no actual data are provided to support the assumption other than a summation of averaged median and mean data. Second, the number of samples which comprise the data evaluated is not provided. Brush Wellman has factual records which show the sampling frequency at the subject facility in 1989 was 16 samples per year. This number of air samples is statistically insufficient to draw any conclusions. Third, the time frames Kelleher selected for historical analysis exclude data from the years 1985 to 1988. During these four years, others in the beryllium industry, including the Brush Wellman and Cardiff, England beryllium operations, experienced peak production rates. Both Brush Wellman and Cardiff experienced a significant increase in beryllium air measurements during those years. Based on this information, and studies by others correlating changes in production volume with changes in the patterns of exposure, it is only logical that the subject machine shop would have had a corresponding production peak along with the rest of the industry and a corresponding increase in beryllium air measurements during this period.

A fourth flaw in ACGIH's® use of Keller's study is that the study inflates the number of cases of CBD by expanding the currently accepted definition of CBD (sensitization with granulomas) to include mononuclear cell infiltrates and lymphocytosis in place of granulomas.

The DOE should not adopt a PEL or action level for beryllium that requires the use of the inhalable sampling method to assess exposure. The ACGIH® premise for adopting the inhalable particle concentration sampling method for the TLV® is not based on any study comparing total sampling and inhalable particulate sampling or any study where a beryllium exposure risk was identified or quantified using this method.

Basing the TLV® on inhalable beryllium is scientifically unsupportable because ACGIH® had no study which measured inhalable beryllium. Thus, there are no exposure data to support the 0.05

µg/m^3 TLV®. The ACGIH® based its position upon the hypothesis that BeS may occur due to deposition of beryllium particulate anywhere in the respiratory tract because *"…there is no evidence that BeS cannot occur throughout the respiratory tract…"* The ACGIH® did not provide any scientific evidence to support its hypothesis and we know of no evidence to support their hypothesis. There is also no evidence that BeS **can** occur throughout the respiratory tract. Also, BeS is not an "impairment of health" or "adverse effect" as described in the TLV® Basis.

In addition, there is no epidemiological or health study of beryllium sensitization or CBD that used inhalable particle exposure data. There is also no known conversion factor from the total sampling method to the inhalable sampling method for beryllium. Therefore the relevancy of this metric to risk is unknown and speculative. There are no quantitative data on which to base an inhalable sampling method TLV®.

The ACGIH Statement of Position Regarding the TLVs® and BEIs® states:

> *The TLVs® and BEIs® represent a scientific opinion based on a review of existing peer-reviewed scientific literature by committees of experts in public health and related sciences*.

This statement of position should eliminate speculation and requires that opinions be based on a critical review of the existing literature. Since there are no studies that can be called upon to validate or invalidate the use of an inhalable particulate samplers, the ACGIH® should have deferred to the existing body of science which is based on total particulate sampling.

Given the above, the DOE should not adopt the OEL for beryllium based on the ACGIH® naming of the inhalable sampling method to assess exposure.

The DOE should use CBD as the appropriate end-point for setting an OEL for beryllium. The ACGIH® decision to use beryllium sensitization as a health end-point conflicts with the ACGIH® BEI® Committee Feasibility Assessment for Beryllium which previously determined that CBD was the appropriate end-point for setting a TLV® for beryllium. The BEI® Feasibility Assessment for beryllium states, *"CBD is the critical endpoint for setting a* TLV® *-TWA."*

The CBDPP is designed to prevent CBD. 64 Federal Register at 68855 (December 8, 1999). The TLV is not, but should have been, designed on this basis.

Paragraph 5 of The Statement of Position Regarding the TLVs® and BEIs® states:

> *"ACGIH® TLVs® and BEIs® are health-based values. ACGIH® TLVs® and BEIs® are established by committees that review existing published and peer-reviewed literature in various scientific disciplines (e.g., industrial hygiene, toxicology, occupational medicine, and epidemiology). Based on the available information, ACGIH® formulates a conclusion on the level of exposure that the typical worker can experience without adverse health effects. The TLVs® and BEIs® represent conditions under which ACGIH® believes that nearly all workers may be repeatedly exposed without adverse health effects."*

The BEI® Committee concluded the "adverse health effect" was CBD and the BEI® represented conditions under which ACGIH® "*believed nearly all workers may be repeatedly exposed without adverse health effects."* It must be inferred by the ACGIH® position statements that BEI® activities are on par with TLV® activities. It is, therefore, not a logical outgrowth of the BEI® activity to have

a TLV® based on a non-physiological health endpoint without justifying why the BEI® determination, approved by the ACGIH® Board of Directors, was ignored when nothing changed with regard to what constitutes an adverse health effect since the BEI® Committee's determination that CBD was the appropriate endpoint.

In choosing beryllium sensitization (two positive BeBLPT results) as an adverse health effect, ACGIH® failed to recognize that the purpose of a TLV ® is to prevent a material impairment, unhealthy or a dangerous effect and, in some cases, reasonable freedom from irritation, narcosis, nuisance, or other forms of stress.

As a background, the following definitions summarize the different forms of beryllium disease and a beryllium-induced immunological Response.

Acute Beryllium Disease (ABD) is an acute toxic chemical pneumonitis resulting from high exposure to soluble beryllium compounds (beryllium salts such as beryllium fluoride and beryllium chloride) or low-fired beryllium oxide. ABD has not been seen for decades and low-fired beryllium oxide has not been commercially available since 1950.[xii] The onset of symptoms of ABD was usually immediate, but could be delayed from several hours up to 3 days. Symptoms included dyspnea, fatigue, fever, night sweats and cough. Pulmonary function tests revealed obstructive lung disease with impaired gas exchange. Most of the cases of ABD usually resolved completely. However, some were fatal or were followed by development of chronic beryllium disease.[xiii] Cases of ABD have only been shown to occur when airborne concentrations of soluble beryllium salts or low fired beryllium oxide exceed 100 µg Be/m^3.[xiv] Airborne exposures to beryllium metal, beryllium oxide or beryllium alloy fumes or dust are not associated with acute or short-term respiratory reactions.

*Chronic beryllium disease (C*BD)

Clinical CBD (cCBD) was diagnosed, before the late 1980's, when clinical symptoms were observed along with changes in chest x-rays or lung function tests. In 1951, it was suggested that CBD was an immune-mediated disease and subsequently the term beryllium sensitization was initially defined by the beryllium skin patch test (BePT).[xv] The use of the BePT was curtailed because simultaneous experimental application of multiple tests sensitized members (positive patch test) of control populations and because it was suggested that the test might exacerbate existing cCBD.[xvi]

The clinical course of cCBD is considered highly variable since the symptomatic disease may not develop or it may develop slowly over time. The earliest manifestations of clinical chronic beryllium disease (cCBD) are the symptoms of shortness of breath, dry cough, or wheeze, and in some, night sweats or fatigue. In addition to cCBD, these symptoms may be found in persons with other lung diseases and in persons with no diagnosable disease.[xvii] Chest radiographs can be normal, but often range from small nodular opacities, with an upper level predominance, to formation of conglomerate masses.[xviii] Progression may lead to weight loss, cor pulmonale with heart failure, disability and death.

Subclinical CBD (sCBD) is a term that originated in the late 1980s when a change in the criterion for diagnosis of CBD was first suggested.[xix] The diagnosis of subclinical CBD (sCBD), which is also referred to as surveillance CBD, is based on abnormal lymphocyte proliferation tests for beryllium sensitization in blood or lung fluid and the presence, upon lung biopsy, of non-caseating granulomas. Granuloma formation can exist with no symptoms or physical impairment of health. With subclinical CBD, there are no clinical symptoms and there is no measurable impairment.

Beryllium sensitization (BeS), as it is used today, refers to the recognition of beryllium by the immune system which may be detected only via an in-vivo patch test, an in-vitro blood test (2 positive BeBLPT results), or in-vitro bronchial lavage testing using soluble salts of beryllium such as beryllium sulfate. Beryllium sensitization is only definable as a test result. Beryllium sensitization is not a health effect, illness or disability. With beryllium sensitization, there are no clinical symptoms and there is no measurable impairment.

Considering the above definitions, in the description of the TLV® Basis, it is stated:

> *"The basis on which the values are established will differ from agent to agent (e.g., protection against impairment of health may be a guiding factor for some, whereas reasonable freedom from irritation, narcosis, nuisance, or other forms of stress may form the basis for others). Health impairments considered include those that shorten life expectancy, adversely affect reproduction function or developmental processes, compromise organ or tissue function, or impair the capability for resisting other toxic substances or diseases processes. The TLV® represents the adverse effect(s) upon which the TLV® is based"*

In the Definition of the TLV®, ACGIH® states:

> *"ACGIH® recognizes that there will be considerable variation in the level of biological Response to a particular chemical substance, regardless of the airborne concentration. Indeed, TLVs® do not represent a fine line between a healthy versus an unhealthy work environment or the point at which material impairment of health will occur*."

In proposing a PEL, the DOE should be guided by the above written principles and especially recognize that beryllium sensitization as measured by a lymphocyte proliferation response in a laboratory is not a "*material impairment of health"*.

Tests for sensitization today are conducted not on the person, but on blood separate from the person. Sensitization to beryllium is a measurement of lymphocyte proliferation in a laboratory test tube when lymphocytes are challenged with a soluble beryllium salt. Laboratory lymphocyte proliferation has also been identified with many other metals including nickel, hexavalent chromium, titanium, cadmium, gold, palladium, mercury, barium, aluminum, cobalt, copper, and zirconium.[xx,xxi] Documentation of TLVs® for metals have historically been based on protection against material impairments and not laboratory detection of immune responsiveness.[xxii]
It is important for DOE to keep in mind that establishing occupational exposure limits for metals have historically been based on protection against material impairments and not laboratory detection of immune responsiveness when no health effect is evident.[xxiii]

There has been uncertainty and debate surrounding the identification of a safe airborne exposure level for workers for several years. Some scientists have gone so far as to state that there is no safe exposure level for beryllium. Such statements are both wrong and inflammatory. Every person is exposed to airborne beryllium via windblown dusts (all soil contains beryllium), emissions from the combustion of coal and tobacco smoke. Additionally, many household products, such as ceiling tiles, fertilizers, detergents, charcoal and kitty litter, contain beryllium. Since everyone is exposed to airborne beryllium-containing particulate, it is the collection and careful evaluation of good quality worker exposure data which is crucial to understanding CBD and in setting appropriate occupational exposure limits.

In addition to the lack of substantive merit, DOE should not use the 2010 ACGIH TLV because the process under which it was developed does not comport to the process that DOE or any other federal agency must follow in developing PELs or action levels.

The President has made clear his desire for the highest level of scientific transparency and integrity within the Executive Branch. *See* Memorandum for Heads of Executive Departments and Agencies, "Scientific Integrity" (Mar. 9, 2009). So that the public may *"trust the science and scientific process informing public policy decisions," "there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking." Id.* Each Executive Branch agency, including the Department of Energy, is required by Presidential directive to subject scientific or technological information considered in creating policy *"to well-established scientific processes, including peer review where appropriate,"* and to *"make available to the public the scientific or technological findings or conclusions relied on in policy decisions." Id.* These directives are designed to *"ensure the integrity of scientific and technological information and processes on which [DOE] relies in its decision making or otherwise uses or prepares." Id.* The processes include peer review because it is *"one of the important procedures used to ensure that the quality of published information meets the standard of the scientific and technical community."* Office of Management and Budget Final Information Quality Bulletin for Peer review at 2 (December 15, 2004) (noting that *"a transparent process, coupled with the selection of qualified and independent peer reviewers, should improve the quality of government science."*).

In addition to these core principles, the President has more recently announced particular guidelines to govern an agency's regulatory activities. *See* Executive Order 13563, "Improving Regulation and Regulatory Review" (Jan. 18, 2011). This Executive Order directs that the regulatory system protect public health and safety *"while promoting economic growth, innovation, competitiveness, and job creation."* To achieve those ends, the Order generally requires regulations to be *"based on the best available science"* promulgated only after *"public participation and an open exchange of ideas." Id.*, § 1. It requires agencies to use the *"best, most innovative, and least burdensome tools for achieving regulatory ends,"* accounting for both benefits and costs. *Id.* Stated otherwise, it requires agencies to ensure that its regulatory requirements are based on the best science, represent achievable goals, and use the most cost-effective means of achieving those goals. The President also affirmed President Clinton's Executive Order 12866 (Sep. 30, 1993) and reiterated its requirements that each agency (1) *"propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs;" (2) "tailor its regulations to impose the least burden on society, consistent with achieving its regulatory objectives . . .;" (3) in choosing among regulatory alternatives, select the one that "maximize[s] net benefits;"* and *(4) "identify and assess available alternatives to direct regulation."* E.O. 13563, § 2. Finally, he affirmed the need for integration of regulations across agencies, and directed each agency to *"ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions." Id.*, §§ 3, 5.

Taken together, these Presidential directives make clear that DOE may only act upon scientific evidence that has been developed openly, with public input, and with scientifically recognized processes such as peer review. It also must, without question, consider whether its mandates are achievable (that is, technologically feasible), whether they are attainable and consistent with the objectives of promoting economic growth and job creation, and whether the agency has selected the most cost-effective means of achieving its regulatory ends.

The process used by the ACGIH in the development of the beryllium TLV failed to meet these high standards for ensuring scientific integrity through transparency, public participation and peer review. The ACGIH process was criticized in testimony before the United States House of

Representatives by Henry Chajet on April 27, 2006. With respect to peer review, Mr. Chajet, who had obtained deposition testimony from ACGIH members, gave these illustrations of the inadequacies of ACGIH's external and internal peer review:

> *"TLV Limits also are not peer reviewed, even when requested by TLV Committee members. As a result, the Beryllium and Copper TLV author admitted that no scientific journal would publish her TLVs".*
>
> *"After being developed in secret by anonymous authors, TLVs are adopted with almost no further review within ACGIH. At one meeting in 2004, the ACGIH Board adopted 60 TLV Limits at once, spending an average four to five minutes considering each. One former TLV Committee member wrote that '[t]here are just too many things to read in real life to let me spend time for a critical review."*

Because ACGIH does not disclose what peer review is conducted, Brush does not know the extent of any peer review of the beryllium TLV. However, Brush is aware that ACGIH did retain one external reviewer of its proposed 2006 Notice of Intended Change which formed the basis for the revised beryllium TLV that was later adopted. That reviewer was not neutral on the subject of what the TLV should be, as he had written an article several years earlier which reviewed the current beryllium TLV under consideration for revision and recommended a 20-fold reduction in the 8-hour TWA exposure limit. That reviewer also was and still is an employee of DOE and was actively involved in the development of the 1999 CBDPP and remains an active DOE resource on beryllium health and safety issues along with this present CBDPP review effort.

ACGIH emphasized that in adopting its TLVs, *"there is no consideration given to economic or technical feasibility."* The above factors strongly caution against the adoption of the beryllium TLV as a PEL or action level.

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

As worded, question No. 3 appears to indicate that the DOE has decided to adopt the ACGIH TLV as an action level using the inhalable particulate sampling method and requires commenters to present and defend any other potential action level. This apparent preferential treatment of the ACGIH TLV by DOE seems very inappropriate and the mere proposal of this question is inappropriate for all of the same reasons as stated in our Response to question No. 2 above. Question No. 3 is also vague as to how a new action level could be applied in a revised CBDPP. Therefore, the DOE needs to review whether any new action level is or is not appropriate based on its choice of a PEL and whether or not the science justifies use of an action level as a prompt for any requirement in a revised CBDPP. Regulatory agencies use action levels to prompt operational decisions and to serve as administrative controls. It is important to note that historically the use of action levels in regulations such as those promulgated by OSHA have ranged from one-half the PEL to actions prompted at the PEL. The DOE should not simply replace its current action level with a new action level. Also, each application of an action level

needs to undergo a technical and economic feasibility assessment with regard to its potential impacts.

QUESTION 4

In the past DOE encouraged, but did not require, the use of wet wipes rather than dry wipes for surface monitoring. DOE's experience with wipe testing leads the Department to consider requiring the use of wet wipes, unless the employer demonstrates that using wet wipes may cause an undesirable alteration of the surface, in order to achieve greater comparability of results across the DOE complex and in response to studies demonstrating that wet wipes capture more of the surface contamination than do dry wipes. Should the Department require the use of wet wipes? Please explain your answer and provide evidence to support your answer.

RESPONSE

Surface sampling whether it be wet or dry is at best semi-quantitative; results cannot be duplicated; has no direct relationship to airborne levels of beryllium; and is not numerically linked to health risk. Simply put, surface sampling results cannot be used as a bright line between safe and unsafe conditions.

Surface sampling, whether wet or dry, will not achieve the goal that DOE sets forth – that is, to achieve greater comparability of results across the DOE complex. It also does not provide a reliable method of monitoring workplace conditions. Instead, the use of wipe sampling has resulted in exorbitant expenditures, often in sampling of naturally-occurring beryllium, with little or no accompanying health benefit. For these reasons, wipe sampling should be abandoned as a means to distinguish between safe and unsafe working conditions.

First, although as a matter of standard industrial hygiene practice, wet wipes are generally preferred to dry wipes, wipe surface sampling is at best a semi-quantitative test to sample contamination from a surface, and it does not achieve consistent results. A change from dry to wet surface sampling will almost always collect more material. However, such a change will not make the wipe test any more reliable, repeatable, or comparable between facilities because of the number of uncontrolled variables inherent to surface sampling methods. Those variables include:

1. surface roughness versus the durability of the sampling media
2. physical limitations of the sampled material
3. size and shape of the sampled area
4. surface configuration of the sampled area
5. available surface area
6. porosity of surface
7. surface integrity of the sampled material
8. operator-to-operator differences in sampling technique
9. single operator variation of technique and uniformity
10. pressure applied during sampling
11. degree of moisture used
12. number of filters (media) used to sample the same surface area
13. type of media used to sample
14. analytical difficulties with excessive total contamination (beryllium and non-beryllium)
15. operator ability to measure or estimate surface area on complicated shapes.

For these reasons, if DOE changes its sampling method it also needs to reconsider its removable contamination levels for housekeeping and release criteria. Failure to do so could arbitrarily and immediately void a large number of past evaluations and decisions and essentially sets a new and more costly standard for the future.

Second, DOE's use of a single mandatory surface removable contamination level is not scientifically defensible because of the inconsistencies and limitations inherent in the wipe sampling method, the fact that there is no correlation between surface sample results and air sample results, and the absence of an associated health risk at a measured level. In its 1999 CBDPP, DOE clearly acknowledged the absence of a relationship between surface contamination and the potential for airborne beryllium exposure; and DOE also acknowledged there is no health basis for its operational surface contamination level. These facts have not changed since the 1999 CBDPP.

Since the 1999 CDBPP, however, other studies have continued to question the efficacy of wipe sampling for the purposes that DOE has chosen to use it. In 2007, for example, Dr. Johnson of Lawrence Livermore National Laboratories Hazards Control Department reported on a DOE funded study which found:

- Surface sampling may be at "best" a qualitative assessment tool
- Real-world surface sampling vary by orders of magnitude
- Surface sampling either dry, wet/water, or wet/alcohol appear to be highly variable
- The results support the 1964 findings of Royster and Fisk that surface sampling evaluations are grossly non-quantitative.
- Setting of specific pass/fail surface contamination values can create analytical and compliance issues
- Use of either dry or wet wipe samples to enforce specific quantitative surface contamination level standards has to be seriously questioned
- The sum of five (5) repetitive swipes on the same 100 cm^2 surface area is a good estimate of the total removable particulate material on that surface
- The use of one sampling technician will minimize the human variability (e.g., technique, pressure, consistency)

Moreover, a 2011 study by Dufrense et al.[xxiv] looked at recovery of known very low quantities of beryllium spiked onto smooth plastic, glass and aluminum surfaces and then sampled using various methods including wet wipe and micro-vacuuming. Micro-vacuuming had recovery rates of 0.1 to 12%. Wet wiping had recovery rates of 14-97% with average recoveries over six rounds of testing ranging from 56-79%. The recovery ratio between Operator 1/Operator 2 ranged from 0.6 to 4.2. Even under these highly controlled sampling conditions on smooth uniform surfaces, the sample recovery rates and the inter- and intra-operator variability in results was highly inconsistent.

Third, it is important to note that the real issue with wipe sampling is that it represents an arbitrary non-health based measure of removable contamination levels which are being used as a bright line between safe and unsafe conditions and can be exceeded simply by accumulation of natural dirt. Beryllium is naturally occurring and ubiquitous in the environment. Beryllium is reported as the 44th most abundant element in the earth's crust and is commonly found in all soils, coal, wood, vegetables, foodstuffs, and gemstones such as aquamarine and emerald. As a naturally occurring element, it is present in many earth/mineral based industrial, construction and household products e.g., ceiling tiles, fertilizers, detergents, charcoal, kitty litter, concrete block, concrete floors and the metal and roofing materials that comprise a building's structure. It also occurs naturally in many common materials used in industry every day such as oil dry, oil, steel,

copper, sandpaper, abrasive cleaning materials and grinding wheels. Wipe sampling of natural accumulations of dirt have at times been found to exceed clean-up goal values.

Surface sampling of beryllium-containing particulate is bound by the surface area measure to be sampled (e.g., $\mu g/100\ cm^2$, $\mu g/ft^2$) but such measures do not have any spatial relationship versus the time over which the accumulation of surface contamination occurred. It is almost always unknown as to the timeframe and rate at which contamination has been accumulating on a surface. In the absence of a defined health risk, this fact is a major and significant flaw in the DOE's establishment and use of its release levels in evaluating surface cleanliness which has resulted in DOE spending millions of dollars to clean-up naturally occurring beryllium.

DOE has spent tens to hundreds of millions of dollars pursuing its view of its internal compliance with its removable contamination level with no defined health benefit or a clear technical basis. Dr. Johnson identified over one million dollars spent on one survey at LLNL. The health and safety group at the Oak Ridge Y-12 facility has stated that they have spent 2-3 million dollars per year on wipe sampling for beryllium. A DOE office building in Nevada was tested and torn down at a cost of over 12 million dollars based on the presence of naturally occurring beryllium levels that exceeded the DOEs removable contamination level of 0.2 $\mu g/100\ cm^2$.

In other words, DOE's actions have resulted in questionable testing of numerous buildings and questionable expenditure of many millions of dollars, based on their use of the removable contamination level of 0.2 $\mu g/100\ cm^2$. DOE appears to have performed all of its work despite the fact that its legal authority to do so under the 1999 CBDPP is far from clear.

The CBDPP clearly requires the cleaning of *"beryllium-contaminated equipment and other items"* for release to the general public or to non-beryllium areas of DOE facilities. Such equipment is to be cleaned to a contamination level that is as low as practicable, but not to exceed the higher of the removable contamination level of 0.2 µg Be/100cm^2 or the concentration level of beryllium in soil at the point or release, whichever is greater. However, the DOE clearly explained the scope of its requirement in the following statement found on page 68886 of its 1999 CBDPP rule.

> *"DOE uses the words ''and other items'' after ''equipment'' in section 850.31(a) to cover tools, supplies, documents, etc., and any personal property in beryllium handling areas that may not be encompassed by the term ''equipment.'' The phrase ''equipment and other items'' does not include real property or buildings."*

The above clearly states that the DOE's Release Criteria do not apply to real property and buildings.

For all these reasons, DOE should perform a cost/health benefit analysis of the application of its arbitrary removable contamination level for beryllium since 1999. Moreover, if the DOE insists on establishing a surface limit, it should fund the research needed to quantify what level of contamination poses a risk of becoming airborne at levels that exceed the DOE PEL. The years of wasteful spending on measuring surface levels needs to be evaluated within the context of the mission of the DOE and its obligation to the taxpaying public.

QUESTION 5

Since the use of wipe sampling is not a common occupational safety and health requirement, how do current wipe sampling protocols aid exposure assessments and the protection of beryllium

workers? How reliable and accurate are current sampling and analytical methods for beryllium wipe samples? Please explain your answers and provide evidence to support your answers.

RESPONSE

As stated in detail in Response to question No. 4 above, surface sampling is at best semi-quantitative; test results cannot be duplicated; has no direct relationship to airborne levels of beryllium; and is not numerically linked to health risk. Simply put, surface sampling results cannot be used as a bright line between safe and unsafe conditions.

Unlike air sampling methods, current surface sampling methods cannot be standardized to achieve results consistent enough to assign a standardized margin of error. DOE has not established that surface sampling can meet the data quality objective prescribed by 10 CFR 850 of an accuracy of +/- 25% with a confidence level of 95%.

QUESTION 6

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

RESPONSE

There has been is no study which has identified a best method for sampling and analyzing of inhalable beryllium. In addition, there are no studies which have compared total sampling and inhalable particulate methods for beryllium. It is highly unlikely that such a relationship can ever be established due to the large variation in airborne particulate physical properties which result from the large number of various forms of processing used in beryllium manufacturing operations (e.g. melting, atomizing, grinding, machining, polishing, etc.). These variations are further confounded by the various chemical forms generating vastly different characteristics to airborne particles during similar kinds of manufacturing operations. Our Response to Question No. 2 is also responsive to this question and is incorporated by reference.

QUESTION 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

There is no study which has demonstrated that total fraction exposure data for beryllium is comparable to inhalable fraction exposure data for beryllium. Our responses to Questions Nos. 2 and 6 are also directly responsive to Question No. 7. These questions again imply substantial undue influence by the ACGIH documentation on the course of this rulemaking as inhalable sampling has not been a standard sampling methodology for evaluating employee exposures to air contaminants in the United States.

QUESTION 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

As stated in Response to Question No. 4 above, in its 1999 CBDPP, DOE clearly acknowledged the absence of a relationship between surface contamination and the potential for airborne beryllium exposure; and DOE also acknowledged there is no health basis for its operational surface contamination level. These facts have not changed since the 1999 CBDPP. The above response to Question No. 2 is also responsive to this question.

We recommend that the DOE adopt all 8 elements of the Beryllium Worker Protection Model. The Worker Protection Model has been demonstrated to be effective in reducing the detection of beryllium sensitization and in preventing chronic beryllium disease (CBD). The Worker Protection Model is broken down into eight simple elements in an effort to enhance worker understanding, its implementation and acceptance.

1. Keep beryllium out of the lungs
2. Keep beryllium work areas clean
3. Keep beryllium off of the skin
4. Keep beryllium off of clothing
5. Keep beryllium at the source
6. Keep beryllium in the work area
7. Keep beryllium on the plant site
8. Keep beryllium workers prepared to work safely

The main goal of the Beryllium Worker Protection Model is to keep beryllium out of the lungs. Keeping beryllium-containing particles out of the lungs will ultimately prevent CBD. The model originally incorporated an 8-hour action level for beryllium of 0.2 ug/m^3 which was later adopted as a recommended exposure guideline (REG). One of the cornerstones of the Beryllium Worker Protection Model is keeping beryllium work areas clean. The goal is to have work areas visibly clean, well lit, orderly and free of clutter. When work areas are disorganized, cluttered and dirty, it is more difficult to control worker exposure to potentially hazardous materials. Having all surfaces painted and visually attractive will make it easier to determine when surfaces are not visibly clean. As opposed to expending millions of dollars in measuring beryllium on surfaces, the Model's performance criterion of visibly clean is easily and readily understood by both management and workers.

QUESTION 9

Should warning labels be required for the transfer, to either another DOE entity or to an entity to whom this rule does not apply, of items with surface areas that are free of removable surface levels of beryllium but which may contain surface contamination that is inaccessible or has been

sealed with hard-to-remove substances, *e.g.,* paint? Please explain your answer and provide evidence to support your answer.

RESPONSE

We believe DOE should have policies and practices in place to determine the safe disposition of items or equipment along with a practice of warning downstream users/disposers as to the presence of a potential airborne beryllium health risk via transfer documentation and/or labels. However, for materials that meet DOE's release criteria because beryllium has been sufficiently removed and there are no inaccessible internal areas, there should be no warning labels due to the risk of false alarms and resulting confusion over the significance of labels.

QUESTION 10

Should the Department establish both surface level and aggressive air sampling criteria (modeled after the U.S. Environmental Protection Agency's aggressive air sampling criteria to clear an area after asbestos abatement) for releasing areas in a facility, or should the Department consider establishing only the aggressive air sampling criteria? Please explain your answers and provide evidence to support your answers.

RESPONSE

The wording of this question inappropriately reads as a choice between two options, while it should be asking whether use of the aggressive air sampling criteria should be considered at all by the DOE. As stated earlier, the DOE CBDPP removable contamination limit does not apply to the release of real property. Second, based on our review, the USEPA's aggressive air sampling criteria has mostly been applied to building demolitions and residential clean-ups after the September 11th tragedy. The USEPA has applied two forms of testing, modified-aggressive and aggressive. Aside from whether or not there exists any legal authority to impose release criteria for the disposition of real property, it is unclear as to what is meant by releasing areas in a facility. For purpose of our comments we will presume that DOE is attempting to determine how to take an area within an existing facility and move it from a classification of a beryllium Operational Area to an area not subject to the CBDPP. We also assume that DOE will have already cleaned the area via its beryllium abatement practices. In this context, before any sampling, it is first important for the cleaned area to reach a steady state of normal operation in that HVAC systems should be returned to a state of normal operation. Our review shows that the development and use of the aggressive air sampling method has its origin in the testing of buildings for the presence of asbestos prior to demolition of the structure. In other words, the use of aggressive air sampling, using a one-horsepower leaf blower, appears to have been developed primarily to test the potential for asbestos to be released while razing a building. Since this does not appear to be the intent of DOE's question, we recommend that either static area sampling be performed after achieving a steady state operation of the HVAC system in the area or that the USEPA modified-aggressive air sampling approach be used which adds the use of one 20-inch fan operating at a steady state for every 10,000 ft^2 of floor space. We understand that the use of fans is intended to simulate normal worker activity/movement in the area which appears to be a realistic criteria.

QUESTION 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

In promulgating the Chronic Beryllium Disease Prevention Program ("CBDPP" or "Rule"), the Department elected to condition medical removal requirements on employee consent. It did so because *"no medical evidence exists to suggest that removal from exposure will alter the course of the disease,"* and thus *"that it is ultimately the affected worker's decision whether to remain in a job with potential or actual beryllium exposure."* 63 Fed. Reg. 66,940, 66,963 (Dec. 3, 1998) (Proposed Rule). The Occupational Safety and Health Administration, on which the Department relied in formulating the Rule's medical removal provisions (64 Fed. Reg. 68,854, 68,894 (Dec. 8, 1999) (Final Rule)), has similarly been reluctant to mandate medical removal where it was unable to identify *"whether an employee's continued exposure . . . would unduly endanger the employee's health,"* or where it could not *"identify any other objective criteria that could be used to determine when an employee's exposure . . . should be restricted for medical reasons."* 63 Fed. Reg. 50,712, 50,714 (Sep. 22, 1998) (methylene chloride). In the decade since the Department promulgated the Rule, no new medical evidence has been developed that would justify a change in the Department's position on this issue. Specifically, there is no evidence that continued exposure to beryllium after a positive beryllium blood lymphocyte proliferation test ("BeBLPT") result will cause an individual to develop chronic beryllium disease ("CBD") or any of its symptoms. Quite to the contrary, while some individuals who show a positive test result develop CBD, many others do not, and no study has been able to discern whether the amount of beryllium exposure (or lack thereof) correlates to either outcome.

Under these circumstances, the Department was unquestionably correct to decide that employee consent was required to remove an employee from his or her beryllium-exposed job. Particularly where it is unclear that removal will positively impact an employee's health, the employee has a right to work in the job of his or her choice without discrimination based upon perceived health effects. *Cf. International Union, United Automobile, Aerospace, & Agricultural Implement Workers of Am. v. Johnson Controls, Inc.*, 499 U.S. 187 (1991) (policy prohibiting women of child-bearing age from working in lead-exposed positions out of concern for women's reproductive health and fetal health discriminatory under federal anti-discrimination statute). After all, as the Department has acknowledged, medical removal is not consequence free; rather, it results in transferring employees *"from higher-paying, beryllium-exposed jobs to lower-paying, non-beryllium jobs"* which *"might be protective, but it would impair the workers' standard of living."* 64 Fed. Reg. at 68,894. It is not enough to suggest that the salary and benefit continuation requirements of medical removal alleviate this concern, because by their terms these provisions apply only for two years (*see* 10 C.F.R. § 850.35(b)(1)), by which time the employee must have located another job which may or may not pay as much as his or her beryllium-exposed job. Employees who obtain a positive BeBLPT test thus face a choice: to retain their beryllium-exposed job absent any evidence that doing so will make things worse, or to give up that job and face an uncertain employment future. Employees, once educated about their choices by the Department's training and counseling requirements (*see* 10 C.F.R. § 850.37), are fully capable of making this choice for themselves, and there is no empirical or other evidence that justifies the Department – or an employer – making it for them.

The Department should leave the final medical removal decision in the hands of the employee for another, independent reason as well: to protect confidentiality of employee medical information. To be sure, Brush Wellman does not suggest that medical removal by itself constitutes a formal violation of the many federal and state laws that protect confidential medical information. *See*, *e.g.*, Genetic Information Non-Discrimination Act of 2008, § 206(a)(providing that genetic information shall be maintained as confidential); Americans With Disabilities Act, 42 U.S.C. §§ 12112(d)(3)(B), (4)(C); 29 C.F.R. §1630.14(b)(1) (requiring that medical histories and medical information about employees and job applicants be kept confidential); 29 C.F.R. § 825.500(g) (describing confidentiality of information obtained under the Family and Medical Leave Act). However, even if not an explicit violation of these statutes, medical removal represents a public disclosure of the fact that an employee has received a positive BeBLPT test. The choice as to whether to make this disclosure, in light of all available information, should unquestionably be left with the employee, particularly given the lack of medical evidence that removal will have any positive impact on employee health.

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