<u>Disclaimer:</u> The following response is solely that of the named respondent. It does not represent the position or response of Savannah River Nuclear Solutions, LLC, the respondent's employer, nor that of any other DOE contractor. Respondent is the chairman of the Beryllium Health and Safety Committee (www.sandia.gov/BHSC) ; however, the BHSC is not taking a position on, nor is it responding to, this RFI. It is respondent's understanding that SRNS will be responding separately to this RFI, and that response will articulate the SRNS position.

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 to Question 1: DOE should continue to defer to OSHA for establishing the permissible exposure limit (PEL) for beryllium. There is recognition that the existing PEL may not be adequately protective (reference [1]); however, OSHA is in the process of revising the PEL and its process is required to consider technical and economic feasibility, as well as human health risks. It is also noted that the level of effort expended in response to violations of the DOE action level (0.2 micrograms per cubic meter of air) renders the PEL largely irrelevant. For these reasons, establishment of a DOE-specific PEL would not serve the public interest.

QUESTION 2: Should the Department use the 2010 ACGIH® threshold limit value (TLV®) of 0.05 μ g/m3 (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 to Question 2: The Department should <u>not</u> use the ACGIH® TLV® (actually adopted in 2009, not 2010; see reference [1]). There are three basic reasons:

(1) Issues around the **basis** for deriving the TLV®. The TLV® documentation expressly states that it is intended to protect against beryllium sensitization (BeS) as well as Chronic Beryllium Disease; however, there is disagreement in the scientific community concerning the need to protect against BeS, which is an allergic response, the mechanism of which is not yet clearly understood, that occurs in a fraction of exposed individuals (reference [2]). BeS by itself is not necessarily a disability, much as an allergy of any kind is not necessarily a disability. Although there may be a recommendation that sensitized individuals be removed from working with beryllium, there is insufficient evidence to definitively conclude whether or not continued work with beryllium by sensitized individuals increases the risk of progression to CBD, or what the exposure threshold for beryllium sensitized workers should be (reference [3]).

(2) **Technical feasibility** of TLV® implementation. Although these issues can be addressed, they will be costly to implement, and it is not clear that such implementation will materially improve worker protection programs. Costs include research and

development (R&D) needs which have been articulated numerous times (see, for example, reference [4]), but which have remained largely unfunded, as well as field implementation costs (both initial and ongoing). Initial implementation costs at Savannah River Site have been estimated at \$400,000 (personal communication, Jahn to Brisson, February 17, 2011). These issues include, but are not necessarily limited to, the following:

- Knowledge of particle size distribution and issues surrounding the relevance of the current ISO 7708 penetration curves versus deposition curves, which may be more relevant for beryllium (references [5] through [7]);
- Knowledge of the effects of sampler orientation and wind speed (reference [8]);
- Limitations resulting from the low volumes of air obtained during short beryllium jobs versus laboratory capabilities (references [9] and [10]);
- Limitations of currently available devices to collect the inhalable fraction at sufficient volumes (reference [11 new]);
- Quality control of devices intended to capture the inhalable fraction (reference [12]);
- Evaluation of data below the laboratory reporting limit (reference [13]), which typically forms the majority of results obtained;
- Comparison of inhalable data with historical data (reference [14]);

(3) The **position** of ACGIH® with respect to use of a TLV® as a regulatory standard (reference [15]). This position expressly discourages such use without considering economic and technical feasibility.

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 to Question 3: The current action level of 0.2 micrograms per cubic meter should not be changed unless a technical basis that considers health consequences above the action level, with consideration of implementation costs, is established for the proposed change.

The respondent supports an action level that is protective of workers at DOE sites; however, as previously stated, this must be balanced against technical and economic feasibility. Implementation of the current 10 CFR 850 requirements costs millions of dollars per year (reference [9]). A lower action level would be more costly, and is justifiable only if it can be demonstrated to provide improvements in worker protection that are commensurate with the increased costs. Lower action levels would increase the technical difficulties in demonstrating compliance due to job durations, sample volumes, and the likelihood of additional samples below the laboratory reporting limit.

As noted previously, there are issues with availability of sampling devices that collect the inhalable fraction and also allow sufficient airflow to collect volumes needed

for proper analytical detection. One option that should be considered is to continue use of closed-face cassettes and requiring wall deposits to be collected and included in the sample result (reference [16]). This would require research studies to validate that such an approach would be equivalent to, or could be correlated with, the inhalable fraction, as has been suggested by Harper and Demange (reference [17]).

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 to Question 4: The respondent believes that the basis for any requirement to use wet wipes should be based on improved collection efficiency more than on comparability of data. ASTM International technical committees D22.04 and E06.23 have, by the standards they have developed, taken a *de facto* position that the collection efficiency of wet wipes is superior to that of dry wipes. These include standards D6966, E1728, and E1792. Additionally, OSHA procedures and studies performed in the development of wiping materials for sampling of lead on surfaces have supported wet wiping (reference [18]). Studies comparing wet and dry wiping for beryllium are limted, but support wet wiping (reference [19]). Finally, ASTM D22.04 is currently developing a new specification for beryllium wiping material; this will also prescribe a wetted wipe.

If wet wiping is required, the use of dry wiping will still be necessary in some instances, and must still be permitted in these instances. This primarily occurs when the surface being wiped will be altered or damaged by a wet wipe. ASTM standard D7296 provides a standard method for dry wiping for beryllium for this very purpose.

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 to Question 5: Respondent elects to speak only to the second part of the question; namely, the reliability and accuracy of current sampling and analytical methods.

Surface sampling protocols show wide variability in collection efficiency (references [19] through [22]). This is due to a number of variables including wipe material, pressure applied when sampling, nature of the surface being sampled, and other factors. This variability exceeds the typical uncertainties associated with the analytical methods used for measuring beryllium content. Additionally, while there have been numerous attempts to establish a correlation between surface and air levels (i.e.,

resuspension factors), such a correlation has not been established. For this reason, respondent believes that there are limitations to the value of wipe sampling. However, recent studies have shown a potential risk from dermal exposure to beryllium (reference [23]). For this reason, there is some benefit to a limited wipe sampling regime in tandem with strict housekeeping, personal protective equipment, and restricting individuals with open cuts or sores from work in beryllium areas (as is done in radiological areas).

Regarding the reliability of analytical methodology. It is important to consider both sample preparation and instrumental analysis with respect to the analytical performance. With respect to sample preparation, many labs both within and outside of DOE are modifying the published techniques, so their reliability may not be known. Also, the BHSC round robin on beryllium oxide (reference [24]), conducted in 2009, demonstrates that sample preparation techniques involving sulfuric acid, hydrofluoric acid, or ammonium bifluoride are effective, while those that do not use any of these have less than adequate effectiveness. With respect to instrumental analysis, reliability (in the form of detection limits, precision and bias) is available in the published methods. Generally, the precision and accuracy of an analytical method decline as one approaches the detection limit of the method. Although a desire has often been expressed by DOE-HSS personnel for analytical methods with lower detection limits, support for research needed to develop such methods has been sporadic, fragmented, and has not borne fruit thus far. This is likely to continue to be the case unless a focused R&D effort is established and funded. However, it should be reiterated that current standard analytical methods are reliable within their current detection limits.

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 to Question 6: The term "best" is highly subjective; however, respondent believes that the "best" method would consider cost as well as the efficacy of the sampling and analytical protocols employed. For sampling, respondent believes that research to demonstrate the efficacy of a protocol consisting of closed-face cassette sampling and analysis including CFC wall deposits, as described in reference [xx], could have a significant return on investment for the Department. For laboratory analysis, the two methods with the lowest detection limits are ICP-MS (e.g., ASTM D7439) and fluorescence (e.g., ASTM D7202), with the latter being appreciably less costly to acquire and operate, as well as being field-deployable. However, respondent does not believe that any one analytical method should be mandated. Selection of analytical method should be left up to the laboratory, but should be based on a published standard method and should be validated to demonstrate fitness for purpose.

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 to Question 7: Respondent does not believe that such a comparison can be made, or would be value-added, unless factors that may influence or effect variability in exposure data, such as particle size distribution, can be effectively controlled.

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 to Question 8: Respondent does not believe that a surface area action level should be established, nor should other controls related to surface level (e.g., low airborne action level or administrative controls) be implemented. The reasons are (a) as discussed previously, there is no health-related technical basis at this time for assigning a numerical value for "maximum" allowable surface levels and no correlation between surface levels and air levels, and (b) addition of such a level to the current free release action level and housekeeping level, given the numerous interpretations that have been given to these levels, would add to the cost, confusion, and compliance burden while not necessarily providing the intended benefit to workers. Instead, the focus should be on providing clarifications within the existing framework (i.e., free release and housekeeping action levels) such that contractors may more clearly understand the expectations to assure better and more consistent compliance.

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 to Question 9: Warning labels are appropriate when material handlers could be exposed during the handling of an item (for example servicing a seldom-accessed part or opening a waste container), or to warn the uninformed so as to prevent unplanned beryllium exposures.

Within the concept of hazardous materials management (not simply regulatory authority), warning labels *and supporting characterization data* support the use of a label to warn downstream workers, such as waste handlers and verifiers. Such a practice should continue for transfers of waste or other materials from one DOE entity to another.

With respect to transfers of materials to "an entity to whom this rule does not apply", the same concept should apply. However, it should be noted that many DOE contractors have opted to terminate, or place strict controls on, all such transfers to avoid the potential liability associated with such transfers, either due to errors in characterizing

beryllium contamination in such materials, or due to failure of a receiving party to honor controls associated with such materials.

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 to Question 10: As presented, the question implies that the Department is only inquiring to pair surface action levels as criteria to be met following aggressive air sampling techniques such as recently studied at the Kansas City Plant (reference [25]). The use of aggressive air sampling will not be appropriate at most DOE locations using beryllium due to their radiological nature. Such techniques are not appropriate in areas with radioactive surface contamination that could become airborne when aggressive air sampling is employed. The use of aggressive air sampling should be limited to areas where the risk of surface contamination from beryllium, heavy metals, or biological contaminants is low enough to prevent their becoming a concern when airborne. Due to these limitations, aggressive air sampling criteria would not be value-added.

Establishment of a surface level for releasing areas within facilities, or possibly entire facilities, would be appropriate when coupled with a requirement for a decontamination action followed by a statistically-based sampling plan for surface characterization and a mandated protocol for analysis of the beryllium content. ASTM International has recently published a surface sampling guide, D7569, which would provide valuable guidance in this area.

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 to Question 11: It is respondent's personal opinion that DOE should continue to require the worker's consent for medical removal. DOE and its contractors should provide sufficient risk communication to affected workers for them to make informed decisions. However, since testing is voluntary, mandating medical removal would not be fair to the worker, and would reduce the number of individuals consenting to testing.

In closing, respondent reiterates that the views and opinions expressed herein are his own, and not those of his employer, any other DOE contractor or entity, or the BHSC.

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