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Jacqueline D. Rogers
Office of Worker Safety and Health Policy
Office of Health, Safety and Security
U.S. Department of Energy
Docket No. HS–RM–10–CBDPP
1000 Independence Avenue, SW
Washington, D.C. 20585

Dear Ms. Rogers:

Contract DE-AC05OR22725, Department of Energy, Oak Ridge National Laboratory Response to Request for Information Concerning the Chronic Beryllium Disease Prevention Program

Oak Ridge National Laboratory (ORNL) appreciates the opportunity to participate and provide meaningful feedback on issues related to the Department of Energy (DOE) Chronic Beryllium Disease Prevention Program (CBDPP) final rule, 10 CFR 850. We recognize the value and applaud DOE's consideration to include shareholders in the decision-making process to assist in shaping the course of actions regarding the Department's CBDPP. ORNL's response to the DOE request for information questions published in the December 23, 2010 *Federal Register* (Docket No. HS–RM–10–CBDPP) is provided in the enclosure.

Please contact Kevin Petherick at (865) 574-5967 if you have any questions concerning our responses to the request for information.

Sincerely,

Joseph N. Herndon, Director
Environment, Safety, Health and Quality

JNH:jlk
Enclosure

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ORNL Response to 10 CFR 850 Request for Information Questions

	DOE Question	ORNL Response
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.	DOE should continue to use the Occupational Safety and Health Administration (OSHA) beryllium permissible exposure limit (PEL) as the regulatory limit and the action level as an administrative level in the Chronic Beryllium Disease Prevention Program (CBDPP) rule, 10 CFR 850. Contractors at DOE sites administer their CBDPPs to ensure that employee exposures to beryllium are maintained below the action level, rather than the PEL. For all intents and purposes, the action level is the *De Facto* regulatory limit due to the specific requirements in 10 CFR 850 which are triggered if exposures are above the action level. This drives DOE contractors to maintain employee exposures as low as reasonably achievable but in no case greater than the action level. For these reasons, no change in the regulatory PEL or action level is recommended.
2	Should the Department use the 2010 ACGIH threshold limit value (TLV) of 0.05 $\mu g/m^3$ (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.	American Conference of Industrial Hygienist (ACGIH) threshold limit values (TLVs) are an expression of scientific opinion that are based solely on health factors and do not consider the analytic or technical feasibility required to implement and meet established TLVs. At present, use of the 2010 ACGIH beryllium TLV is not viable and should not be utilized as the allowable exposure limit in 10 CFR 850 due to the following technical and analytic issues: The predominance of American Industrial Hygiene Association (AIHA) accredited DOE and commercial laboratories performing beryllium analysis do not have quantification limits that are sufficiently low to implement the new ACGIH beryllium TLV. Selection of an analytic method with a limit of quantification (LOQ) or reporting limit (RL) that is at least ten fold lower than the exposure limit is a peer accepted industrial hygiene practice. An exposure limit at or near the quantification limit does not allow adequate statistical analysis of sample distribution or trends. The higher quantification limits at analytic laboratories does not support adoption of the much lower ACGIH beryllium TLV at this time. Typical activity/task duration where there is a potential for exposure to legacy beryllium at non-production facilities are much less than four (4) hours which does not allow for collection of a sufficient volume of air to implement the 2010 ACGIH TLV for beryllium. With a RL of 0.01µg, a minimum air volume of 2,000 liters is needed to achieve 1/10 of the new beryllium TLV which is desirable to support statistical analysis. The minimum volume of air necessary to reach 0.05 $\mu g/m^3$ (e.g. 100% fraction of the new TLV) with an RL of 0.01 µg is 200 liters, which translates to a 50 minute sample time at four (4) liters per minute volumetric flow rate. The CBDPP final rule focuses on production facilities rather than on Research and

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		Development (R&D) operations where legacy beryllium contamination is predominately attributable to exempted operations such as use of beryllium articles, and chemical compounds containing beryllium used in research, etc. For example, decades of use of beryllium articles and compounds exempted from the CBDPP rule have contributed to levels of transferable beryllium contamination above the release criteria limit on surfaces of local exhaust system components (e.g. laboratory hoods, duct, filter housings, blowers, etc.) and/or facility and equipment surfaces. Adoption of a lower beryllium exposure limit is problematic when there is no clear dose-response relationship that exists between exposure and sensitization or chronic beryllium disease (CBD). DOE acknowledged the lack of a quantitative dose-response relationship in the preamble to 10 CFR 850 (*Federal Registry,* Volume 64, No. 235, 68875) when establishing the action level. The dose-response to beryllium is not linear and unlike classic pneumoconiosis, high dose exposure is not required to trigger sensitization to beryllium or chronic beryllium disease.
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.	The 2010 ACGIH beryllium TLV should not be established as the new action level for beryllium for technical and implementation issues previously discussed above in request for information (RFI) question number 2. While action levels do vary from standard to standard, OSHA action levels are typically set at one half of the PEL. When selecting an action level, it is imperative that the analytical limit of quantification (LOQ) or laboratory reporting limit (RL) be at least ten fold lower to allow statistical analysis of sample distribution and/or trends. As was previously stated, the overwhelming majority of American Industrial Hygiene Association (AIHA) accredited DOE and commercial laboratories performing beryllium analysis do not have quantification limits that are sufficiently low to implement the new ACGIH beryllium TLV. No change in the current action level specified in 10 CFR 850.23 is recommended.

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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.	DOE should not mandate the technique(s) or method(s) used to evaluate removable beryllium contamination. While there is general consensus across the DOE complex that wet wipes have better collection efficiency than dry wipes on most surfaces, some surfaces may react with wetting agents or be damaged by wet wiping. Studies have demonstrated that the type of wetting agent has a major impact on the collection efficiency. For instance, alcohol rather than water was shown to be a more effective wetting agent when collecting wipe samples on greasy/oily surfaces. DOE should instead allow health and safety professionals to select the wipe sample method and technique best suited for the surface to be evaluated.
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.	While wipe sampling provides information on the level of removable contamination, it cannot be used to extrapolate potential worker exposure to airborne beryllium. The preamble to the CBDPP final rule (*Federal Registry,* Volume 64, No. 235, 68879) states that "No reliable correlation has been established between surface contamination level and airborne concentrations of beryllium." In cases where removable legacy beryllium contamination is located on normally inaccessible upper surfaces, historic exposure and area air sample results below the analytic laboratory reporting limit have shown there is no credible airborne exposure potential for staff working in such areas provided that upper surfaces are not contacted or disturbed. In cases where contaminated upper surfaces will be accessed or disturbed, implementation of appropriate work controls can minimize the generation of airborne dust containing beryllium and the spread of transferable beryllium contamination. ORNL had several instances where optical fluorescence analysis of beryllium wipe samples collected from certain areas demonstrated a high (false positive) bias when compared to results reported by Inductively Coupled Plasma Mass Spectrometry (ICP-MS). It was determined that the high bias was due to strongly fluorescent materials present in the matrix of certain samples. As is true of most analytic methods, each method has both advantages and disadvantages even though each are validated and approved methods for beryllium analysis.

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6	What is the best method for sampling and analyzing inhalable beryllium? Please explain your answers and provide evidence to support your answers.	As discussed in our response to RFI question number 2, technical and implementation issues currently make it unfeasible to implement the 2010 ACGIH beryllium TLV. The optimal analysis method should have an analytical limit of quantification which is at least ten fold lower than an occupational exposure limit or action level. ICP-MS appears to be the preferred analytic method of inhalable fraction beryllium when appropriately modified for high-fired beryllium oxide. Selecting between ICP-MS and ICP - atomic emission spectroscopy (AES) typically comes down to the sensitivity required. ICP-MS is probably best suited for inhalable beryllium because RLs are the lowest. ICP methods in general are preferred over the other techniques because they are typically less expensive, produce accurate and precise results, allow for simultaneous qualitative screening for other analytes, and have well documented methods for handling interferences. While optical fluorescence method for beryllium analysis can provide results in the nanogram range, identifying and correcting for interferences in unknown samples is still being perfected. DOE should allow health and safety professionals to select the sampling and analytic method appropriate to the circumstances.
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.	At present, there is not sufficient information to recommend comparison of total fraction exposure data to inhalable fraction exposure results. Particles between 10-100 µm are not efficiently sampled by 37-mm closed face cassettes (CFC). Comparison of results for total fraction using a 37-mm CFC to inhalable fraction as measured by Institute of Medicine (Werner et al.) or other inhalational fraction samplers is dependant in part on the particle size with the conversion factor increasing with particle size.. Other factors that influence the collection efficiency such as wind speeds and sampler orientation also affect the conversion factor. The particle size of airborne beryllium is anticipated to vary across the DOE complex due to differences in beryllium compounds, operations and processes. Particle size information for legacy contamination is typically not available. For the above reasons, total fraction exposure data should not be compared to results from inhalable fraction exposure monitoring.
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	The Chronic Beryllium Disease Prevention Program (CBDPP) final rule focuses on production facilities rather than on Research and Development (R&D) operations where legacy beryllium contamination is predominately attributable to exempted operations such as use of beryllium articles and "laboratory use" of beryllium compounds in research. For example, decades of use of beryllium articles and compounds exempted from the CBDPP rule can contribute to levels of transferable beryllium contamination above the release criteria limit on surfaces of local exhaust system components (e.g. laboratory hoods, duct, filter housings, blowers, etc.)

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	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.	and/or facility and equipment surfaces. Also compounding this issue is dealing with facility and equipment surfaces where decades of settled coal fly ash has resulted in surface beryllium contamination. Establishing a surface contamination action level is problematic as there is not reliable and defendable correlation that exists between surface contamination levels and airborne concentrations of beryllium. For example, the presence of beryllium on normally inaccessible facility surfaces such as on top of overhead ducts, conduit, lines, beams, etc., does not constitute a health risk if contaminated surfaces are not contacted or otherwise disturbed. Rather than establishing a surface contamination level for building surfaces, establishment of a long term area airborne action level would be preferable. Application of administrative controls to prevent the buildup of surface contamination levels from beryllium settling out on surfaces is geared to production facilities and not legacy contamination at R&D facilities. Rather than adding additional administrative controls to CBDPP rule that may not be applicable to every operation or facility, a higher degree of worker protection may be achieved when administrative controls are selected based upon facility-specific hazard assessment information. Rather than incorporate generic administrative controls to prevent buildup of dust on facility surfaces, health and safety professionals should be allowed to develop, and assist management to implement, tailored controls that target exposure parameters identified during a compressive facility specific hazard assessment.
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.	ORNL's policy is not to transfer equipment or other items to the general public or to another DOE facility for use in a non-beryllium area that may potentially contain removable beryllium contamination on normally inaccessible surfaces or that has been sealed with hard-to-remove substances. However, with respect to the question, it is a best management practice to maintain warning labels to alert individuals or entities of known potential hazards. In addition to providing hazard warning information, use of beryllium warning labels in such cases may minimize future litigation for transfers to the general public. No change to the equipment/item labeling requirement specified in the release criteria (10 CFR 850.31) is recommended.

ORNL Response to 10 CFR 850 Request for Information Questions

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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.	Use of aggressive air sampling as the basis for clearance of facility areas is not recommended. As older DOE facilities typically have a greater potential for legacy radiological contamination on inaccessible surfaces, aggressive sampling is not advisable. Many factors affect the potential for resuspension of dust including the type of disturbance (airflow vs. mechanical), air velocity and direction, adhesion forces on the particle, the intensity of the disturbance, the type and texture of surface, particle size distribution, physical and chemical characteristics of the particles, etc. For example, surface beryllium contamination on oily or greasy surfaces would not be re-entrained in the air easily. The preamble to the CBDPP final rule as well as Section 4.2.11 of DOE G 440.1-7A, "Implementation Guide for use with 10 CFR Part 850, Chronic Beryllium Disease Prevention Program", specify that the release criteria phrase "equipment and other items" "does not include real property or buildings." The CBDPP final rule specifies housekeeping surface contamination limits for "operational areas" however it does not implicitly establish surface contamination limits for release of facility areas in non-operational areas. It should be noted that the existence of removable beryllium contamination on normally inaccessible facility surfaces does not necessarily constitute a health concern. Worker contact with contaminated surfaces and/or re-entrainment of dust containing beryllium due to disturbance of contaminated surfaces is required for beryllium to be a credible exposure concern. Rather than establishing a facility surface contamination level or an aggressive air sampling criteria, the Department should instead consider development of a sampling method to quantifiably determine re-entrainment potential for accumulated dust containing beryllium (e.g. transferable beryllium contamination) on facility surfaces.
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.	While mandatory medical removal of workers is required by several OSHA substance-specific standards such as lead and cadmium when bioassays exceed a trigger limit, there is also a mandatory requirement for employers to enroll affected workers in such medical surveillance programs. As testing for beryllium sensitization is currently voluntary under the CBDPP rule, a requirement for mandatory medical removal of workers with confirmed beryllium sensitization could have the unintended consequence of decreasing worker participation in the voluntary beryllium medical surveillance program. No change to the medical enrollment or removal provisions under 10 CFR 850 is recommended.