



February 22, 2011

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, DC 20585

Subject: Request for Information on Proposed Changes to 10CFR850

Reference: Docket No. HS-RM-10-CBDPP

Dear Ms. Rogers:

Lawrence Livermore National Laboratory (LLNL), managed and operated by Lawrence Livermore National Security, LLC (LLNS) appreciates the opportunity to comment on the Department of Energy's (DOE's) Request for Information (RFI). LLNL is firmly committed to the protection of employees' health from impairment due to beryllium exposure and looks forward to working with DOE, OSHA and the ES&H community to advance the scientific understanding of the effect of beryllium exposure on human health. The goal should be a consistent set of standards across affected agencies that are scientifically-based and take into account the benefits, impact on mission and implementation costs, and are balanced against the impact of those costs on other safety and health priorities.¹

In responding to the RFI, LLNL researched relevant peer-reviewed literature and discussed with programmatic and operational personnel who are knowledgeable contributors in putting together a technically sound response.

LLNL is unable to assess cost and mission effects for many of the questions in the RFI without additional information. The questions on airborne and surface action levels do not specify the actions that such levels would trigger which will strongly affect mission and cost impacts.

There is considerable uncertainty in the progression from beryllium exposure to beryllium sensitization to Chronic Beryllium Disease. The overall goals of 10CFR850 should be articulated *vis á vis* this progression prior to determining appropriate airborne and/or surface action levels.

¹ As context for these comments, we note that Lawrence Livermore National Laboratory (LLNL) is not a large-scale beryllium production facility, but a research and development site. At LLNL, both the number of beryllium operations and the quantity of beryllium used has declined in recent years. At LLNL, short-term exposures and small populations of exposed workers in a variety of one-time activities are far more common than process monitoring. LLNL implements occupational exposure limits as part of a comprehensive beryllium safety program, which includes additional protective practices to minimize exposure to beryllium.



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As set forth in the specific responses to the RFI, LLNL believes that DOE should defer from establishing its own permissible exposure limit, but should continue to rely on the current standards established by OSHA, and to adopt changes to those standards following OSHA's rule-making process currently being conducted.

Of course, LLNL and other DOE sites constantly strive to achieve the lowest possible exposure at levels far below those set by the OSHA standards and DOE action limits.

Attached are our responses to the specific numbered questions. In the aggregate, LLNL's recommendations emphasize four major items:

1. The Department should review its immediate and long-term goals for 10CFR850 to clarify the prioritization of minimization of chronic beryllium disease rather than beryllium sensitization.
2. The Department should work with OSHA to update the permissible exposure limit based upon a review of the technical and economic feasibility.
3. Beryllium exposure controls – dermal protection, workplace controls or, when required, housekeeping standards, should not be mandated by the Department but should reflect a site's operational experience and commitment to reduce exposure.
4. Medical screening, surveillance, and removal should remain voluntary.

We look forward to DOE's efforts to amend, clarify, and update 10CFR850 in a way that protects worker health, is based on best-available scientific information, and balances impact on mission, implementation costs, and other safety and health priorities.

Sincerely,



Reginald F. Gaylord
LLNL Beryllium Project Manager

Attachment A: LLNL Comments on Request for Information

cc: De Grange, Constance
Gioconda, Thomas
Johnson, Stephen
Keilholtz, Kirk
Peterson, Barbara
Wuthrich, Steven

DEPARTMENT OF ENERGY
10cfr850
[Docket No. HS-RM-10-CBDPP]
RIN 1992-AA39

Request for Information (RFI) dated December 23, 2010.

Question 1: The Department of Energy (DOE) currently defers to the Occupational Safety and Health Administration (OSHA) for establishing the permissible exposure limits (PELs) and uses an action level (AL) 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?

LLNS Response to Question 1: DOE should defer to the OSHA 8-hr Time Weighted Average (TWA) PEL but it is recommended that the department work with OSHA to update the standard for beryllium. The current PEL may not be adequately protective of workers, but this concern can be addressed through the establishment of a more conservative action limit. In the interests of consistency across industries, DOE should defer to permissible exposure limits as set through the OSHA rule-making process.

Discussion: LLNS believes that OSHA is the appropriate regulatory agency for setting the permissible exposure limit for beryllium. The OSHA PEL is the recognized regulatory limit to protect workers against the health effects from exposure to a hazardous substance. While evidence shows that strict adherence to the PEL is not sufficient to prevent Chronic Beryllium Disease (CBD), OSHA is currently conducting a scientific peer review of its draft risk assessment and is scheduled to perform an economic peer review in 2011¹. Recognizing that the OSHA PEL established in 29CFR1910.1000 may not be sufficiently protective, LLNL has utilized the more conservative AL of 0.2 µg/m³ as an 8-hr TWA since 1998 to initiate additional protective practices (e.g., work area controls, personal protective clothing, and respiratory protection) to minimize exposure to beryllium. DOE drives additional protective practices through 10CFR850.23 – Action Level. This in effect has become the default exposure limit established by DOE for beryllium.

LLNS recommends that the Department:

- Review and articulate its immediate and long-term goals for 10CFR850 (e.g. CBD vs BeS and CBD)
- Work with OSHA to update the occupational exposure limit based upon a review of the economic and technical feasibility.

Question 2: Should the Department use the 2010 American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV®) of 0.05 µg/m³ (8-hr TWA of 0.05 micrograms of beryllium, in inhalable particulate matter, per cubic meter of air), for its allowable exposure limit?

LLNS Response to Question 2: LLNL's response to this question assumes that by "allowable exposure limit," the Department is referring to permissible exposure limit, as defined in the current 10CFR850.22. LLNL disagrees with the use of the TLV® in this context. If the Department is referring to action limit,

¹ OSHA Regulations: Unified Agenda [<http://www.dol.gov/osha/regs/unifiedagenda/fall2010/1218-AB76.htm>]

as defined in 10CFR850.23, LLNL notes that the ACGIH TLV®, while more technically defensible than the current action limit, represents a highly conservative action limit for the following reasons:

- ACGIH performed no economic and technical feasibility in releasing its TLV®
- TLV® is based upon a lifetime weighted average which may not be an appropriate metric of risk (e.g. long-term constant exposures in a production environment vs. short-term variable exposures in research and development)

There is no technical basis for the standardization of sample collection and analytical protocols to meet the ACGIH TLV, which would impose a significant operational burden for the sites to independently develop this capability. In addition, for short-term exposures, significantly more expensive analytical methods (mass spectrometry) may be required to meet required detection limits for the TLV than are currently employed for industrial hygiene analysis.

Discussion: Unlike OSHA, the ACGIH TLV®-TWA process focuses on the health effects from exposure to chemicals without regard for, and not considering economic and technical feasibility. The 1988 ACGIH TLV® policy statement² states [**emphasis added**]:

- TLVs® are only one of multiple factors to be considered in evaluating specific workplace situations and conditions.
- TLVs® are guidelines and **not designed to be used as standards**.
- TLVs® **are not** consensus standards.
- TLVs® **do not** take into consideration economic and technical feasibility or the availability of acceptable methods to determine compliance during development.

The beryllium TLV® represents a 40-fold reduction from 2.0 µg/m³ to 0.05 µg/m³ and specifies the sampling measurement as inhalable dust. This will require changes in operational and programmatic equipment to meet the technical requirements for such a measurement.

It is important to note that ACGIH states: "When applying this TLV®-TWA it should be kept in mind that it is based on a long-term average concentration³." This ACGIH TLV®-TWA is based upon lifetime time weighted (LTW) average exposures extrapolated from two studies - Kelleher et al. (2001) and Madl et al (2007)⁴. The Madl et al (2007) study represents an analysis of more than 3,800 personal air samples, the largest complete dose reconstruction of individuals identified as BeS or diagnosed with CBD, and differentiates between subclinical CBD and clinical CBD for a plant manufacturing or using beryllium metal, ceramics or alloys. Exposure estimates were determined for workers (n=27) that were either identified as BeS (n=9) or diagnosed with CBD (n=18). For this group of individuals, the number of years worked at the plant prior to diagnosis ranged from 0.4 to 36.1 years. The study utilized several approaches to reconstruct the historical exposure for each worker: industrial hygiene data pooled by year, job title, era of engineering controls, and complete work history (LTW average) prior to diagnosis.

The Madl et al (2007) study noted the following:

- A range of exposures to airborne beryllium is associated with BeS and CBD
- BeS and CBD cases generally occurred as a result of exposures greater than 0.4 µg/m³
- Maintaining exposures below 0.2 µg/m³ 95% of the time may prevent BeS and CBD

² ACGIH Policy Statement (1998) [<http://www.acgih.org/tlv/PosStmt.htm>]

³ ACGIH® ©2009 Beryllium and Compounds documentation.

⁴ Madl et al (2007) built upon and expanded the analysis performed in the Kellerher et al study.

ACGIH TLV® documentation associated with “Beryllium and Compounds” states (LLNS presumes in reference to these studies): “Exposure assessment data does not provide strong differentiation between workplace exposure concentrations or calculated lifetime weighted (LTW) average exposures for workers who develop BeS and those who do not.”

This statement does not align with the workplace exposure study of Madl et al. In general, the authors state that there is a potential threshold for BeS and CBD [See Figure 5 of Madl et al. 2007]. Though this dataset is limited to production/manufacturing operations and represents a relatively small number of individuals identified as BeS or diagnosed with CBD, the dose reconstruction for these individuals highlights a potential dose exposure level and outcome identified for this workgroup. This fact is relevant because the prevention of a material impairment of health, such as clinical CBD, is the appropriate regulatory basis to use when setting an appropriate exposure limit for beryllium. With respect to the methodologies utilized to reconstruct the historical exposures, the methodologies resulted in varying exposure estimates. From these methodologies:

- Exposure metrics with shorter averaging times (e.g., year vs. work history) indicated higher levels of exposure which could contribute to BeS or CBD
- Exposure methodologies resulted in varying exposure estimates
- Exposures-response curves for BeS and CBD suggest higher exposures are required for development of CBD

In terms of an occupational exposure level, the authors concluded that the exposure levels noted for development of BeS and CBD were not reflected in historical exposure estimates (i.e., LTW) and acknowledged that the LTW estimate was most often the lowest exposure calculated of all the methods. The authors proceeded to state that “because the LTW exposure places greatest weight on the job title of longest employment even when there is brief employment in high-exposure jobs and the fact that Be-sensitization can occur within a relatively short duration of exposure (weeks to months), it is biologically plausible that the LTW exposure may not be the best descriptor of Be-sensitization and CBD” and that “any past high-exposure job may be diluted by long-duration, low-exposure jobs and may not be reflective of a true workplace exposure profile that may be responsible for causing BeS and CBD.” It is very plausible; therefore, that actual safe levels of airborne Be would be higher than what the LTW estimates would suggest.

In a teleconference with the lead author of Madl et al., she states that based on their research “the level of $0.05 \mu\text{g}/\text{m}^3$ does not represent an upper bound measurement, but a good target for average exposure levels over an extended period of employment.”

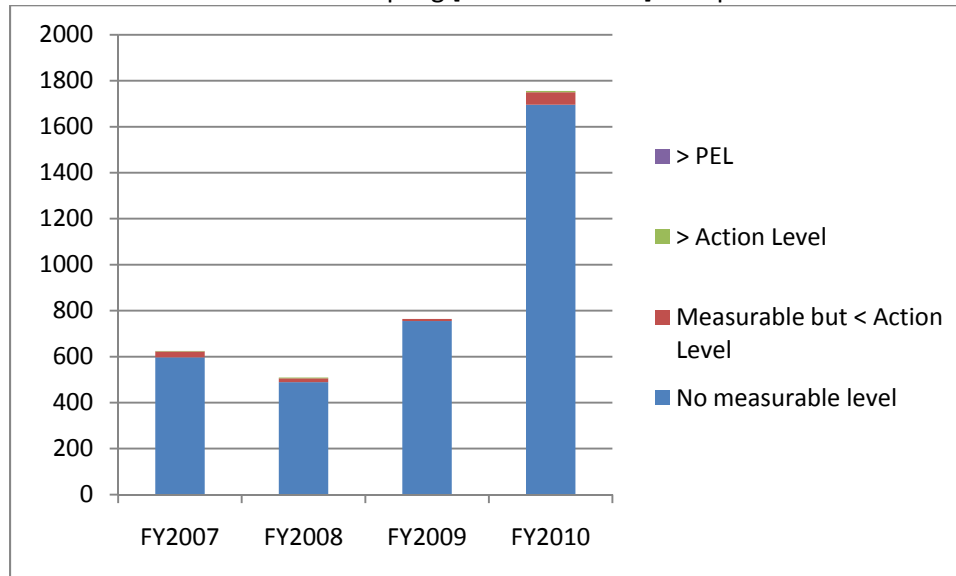
LLNS recognizes that airborne beryllium exposure levels should be kept low to minimize worker exposure. LLNL has consistently utilized regulatory⁵ and industry standards in conducting workplace exposure monitoring to adequately characterize personnel exposures. Activities at LLNL range in duration from 9 minutes to 388 minutes and are not full 8 hour shifts. Further reduction in the PEL or TLV® and application as a LTW may not be an appropriate metric of risk in non-production facilities.

Table 1 below shows the number of samples collected at LLNL and calculated as an 8-hr time-weighted average for operations identified with a potential for airborne exposure such as decontamination & demolition, waste handling & repackaging, and explosive testing from FY2007 to FY2010. These data

⁵ OSHA Technical Manual [TED 01: Effective Date – 6/24/2008]

indicate that measured exposures at LLNL are extremely low, and that further lowering of the AL or PEL would not effect the vast majority of measured exposures.

Table 1: LLNL Personnel Air Sampling [FY2007-FY2010] as represented as an 8-hr TWA:



It should be noted that there is continued disagreement in the scientific community concerning BeS. On one spectrum, BeS by itself is not necessarily a disability, much as an allergy of any kind is not necessarily a disability. On another, BeS is considered a serious adverse health effect. 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. Research and literature suggests that sensitization may have a lower threshold⁶ and multiple pathways of exposure.

Question 3: Should an airborne action level that is different from the 2010 ACGIH TLV® for beryllium (8-hr TWA of 0.05 micrograms of beryllium, in inhalable particulate matter, per cubic meter of air), be established?

LLNS Response to Question 3: LLNL does not support establishing an action level (AL) different from the current value of 0.2 µg/m³ without an economic and technical basis. LLNS currently utilizes a more proactive approach that institutes additional controls (e.g. dermal and respiratory protection) at levels below the action level, and recommends sites maintain flexibility in implementation of such controls. LLNL notes that this answer is dependent upon factors not specified in this question, namely the specific actions such an AL would drive. LLNL recommends that the Department review rationale for supplemental control strategies when the AL or PEL is exceeded (e.g. 850.24(e)(3) – Notification, 850.25 – Exposure Reduction and Minimization).

⁶ Viet et al, 2000

Discussion: Previously, DOE has concluded that existing scientific data does not provide an adequate basis for the establishment of a new exposure limit. The development of an occupational exposure limit (OEL) would require DOE, or other government agency, to consider risk including factors such as economic and technical feasibility. Technical difficulties exist with respect to coming into compliance with the 2010 ACGIH TLV® which includes:

- Particle size distribution
- Analytical detection limit; demonstration of method precision and accuracy
- Operational impacts; sample run time affecting the reporting limit

Typically OSHA drives, through the use of a PEL or AL, additional controls (e.g. respiratory protection) for operations with the potential where airborne levels are anticipated to be exceeded. LLNL institutes additional controls at levels well below the current AL.

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 dry wipes. Should the department require the use of wet wipes?

LLNS Response to Question 4: The Department should require the use of wet wipes for surface monitoring for beryllium. LLNS also notes the importance of the exemption from the use of wet swipes for items where wet swipes would either damage the surface, or result in additional hazards being generated. An amendment with respect to the use of wet wipes is consistent with the OSHA Technical Manual APPENDIX II: 2–1. General Procedure for Collecting Wipe Samples⁷. In light of the RFI statement "In order to achieve greater comparability of results across the DOE complex," LLNS recommends that the Department articulate its goal for surface monitoring and rationale for future comparison across the complex.

Discussion: The methodology associated with measurements of surface deposition of a material is a semi-quantitative assessment utilized by many DOE sites to evaluate work control practices (e.g., housekeeping). In 2005, LLNL noticed large variations (up to 3 orders of magnitude) in surface swipe results were found when swipes were collected dry, wet/water, or wet/alcohol⁸. LLNL also concluded that the surface characteristics and sampling methodology (i.e., inter- and intra-variability) affect the efficiency of material collection. Due to these preliminary findings, surface swipe samples were considered non-quantitative. LLNL does not associate or assess the exposure risk solely based on surface contamination. Information gathered from routine assessments of surfaces is utilized to ensure that cleaning and decontamination efforts are implemented appropriately.

LLNS would recommend, in efforts to ensure consistency in evaluating facility characterization efforts, equipment or material release, or downgrade of beryllium control requirements, that the Department specify the criteria for evaluation (e.g., trending vs absolute value). The DOE sites, based upon operating

⁷ OSHA Technical Manual: Section II: Chapter 2, Section V. Wipe Sampling Methodology, TED 01-00-015 [TED1.0.15A], November 18, 2008.

⁸ Johnson, et al. "Relative Collection Efficiencies of Dry and Wet Surface Sampling for Particular Contamination" Presented at the 2nd Symposium on Beryllium Particulates and their Detection, November 8, 2005.

and programmatic deliverables, should then review literature, including site operating experience, to fill in the gaps in swipe sampling knowledge, and as necessary, update internal policy and procedures to optimize the methods for site implementation.

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?

LLNS Response to Question 5: As there is no established correlation in the scientific literature between surface levels and the potential for airborne exposure, wipe sampling should not be used as part of an exposure assessment without air monitoring data. Wipe sampling remains a valuable method to ensure that work areas are kept clean, and equipment is properly released from controls. See above response to Question 4 regarding the overall goal for a swipe monitoring program.

Question 6: What is the best method for sampling and analyzing inhalable beryllium?

LLNS Response to Question 6: The best method is dependent upon the drivers for sampling, analytical capability, and operational constraints associated with the activity being monitored. LLNL recommends that the Department recognize the sites operational needs and allow sites to choose a validated methodology (e.g. OSHA, NIOSH, ASTM) for sampling and analyzing inhalable beryllium.

Discussion: Sampling and analysis convention depends upon the OEL, particle size distribution, and health effects. Measurement of exposure to total airborne beryllium dust may not be the best predictor of CBD. Particle size, surface area, number of particles, solubility, and the chemical form of beryllium involved may all be relevant to the development of disease.

In 2010, LLNL conducted workplace evaluations comparing personal exposures during beryllium clean-up operations as measured using an IOM sampler and a “total dust” 37 mm sampler. Variability in the IOM/37 mm ratio ranged from 0.064 to 3.7, with an average ratio of 1.1. This variability was likely due to the nature of the tasks (e.g., localized concentration and/or worker movement/sampler position). Though particle size analysis was not conducted, the similarity between the two samples suggests a fine particle size distribution. This study also suggested that, for the type of activities monitored, the “total dust” sampler would perform similarly to an IOM sampler. LLNL notes that ‘total dust’ sampling currently allows for greater operational flexibility to sample multiple operations and tasks that may not be possible through IOM sampling. Economic, operational and technical considerations, e.g. equipment costs and available technology, re-training on IOM sampling strategies, minimization of laboratory worker exposure, needs to be considered individually by each site.

Question 7: How should total fraction exposure data be compared to inhalable fraction exposure measurements?

LLNS Response to Question 7: Total fraction exposure data should not be compared to inhalable fraction exposure measurements without understanding the factors (e.g., particle size, workplace factors) that may influence variations in exposure data. The use of correction factors may be

appropriate for examining data for well-defined activities or exposure groups. This should be determined on a case-by-case basis and not be defined by the Department.

Discussion: Workplace evaluations comparing exposures as measured in terms of inhalable aerosol with exposures as measured in terms of total aerosol have been conducted and indicate that the level of exposure based on inhalable aerosol often exceeds that for total aerosol⁹. These studies have proposed working conversion factors to adjust exposure data to account for the change in exposure assessment rationale. Ratios between inhalable and total fractions have ranged from 1.2 to >3 depending on the level of energy imparted on materials and the resulting particle size distribution of the resulting aerosolizable particulate. Data from other studies indicate this ratio increases as the particulate becomes more coarse¹⁰. Some data¹¹, however, also suggest that when the wall deposits of the “total dust” sampler are analyzed as well as the filter, the ratios between the inhalable and total fractions are closer to unity, thus allowing total fraction to be directly compared to inhalable fraction.

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?

LLNS Response to Question 8: In order to answer this question, LLNL needs clarification as to the actions such an action level would drive. LLNL would strongly disagree with the imposition of regulated beryllium work area requirements on the basis of surface contamination only. LLNL does recommend that the department specify surface criteria for the release of facilities from beryllium controls, and to drive housekeeping in beryllium work areas. LLNL does not recommend setting a low airborne action level to control surface contamination levels.

Discussion: Historically, surface sampling has not been utilized to assess the health risk resulting from the contamination. Rather, it is to ensure that the cleaning and decontamination regimen is being effectively implemented. Establishing a surface contamination limit will depend on the purpose of the control strategies utilized to minimize migration of contamination and decontamination strategies. The mere presence of beryllium activities and/or surface contamination in limited areas in a facility does not automatically constitute a health hazard because there may not be an identified pathway (direct or indirect) to serve as route of exposure.

10CFR850.31 does not identify surface contamination levels for release of facilities, structures or property. As a function of operations, LLNL has established a surface area criterion of 0.2 µg/100 cm² to address areas not covered by the regulation. Exceeding this value requires additional evaluation, review, and, as necessary, clean-up to minimize personnel exposure to beryllium. This surface criterion was not established as a health-based level.

⁹ Werner, et al. “Investigation Into the Impact of Introducing Workplace Aerosol Standards Based on the Inhalable Fraction” September 1996.

¹⁰ Kerr et al, 2002; de Vocht et al., 2006; Tatum et al., 2001; Kenny et al., 1997.

¹¹ Puskar, 1992

Question 8a: If surface area action levels are established, what would be the DOE surface action level?

LLNS Response to Question 8a: LLNS is not in a position to appropriately answer this question, but believes that any such level should have a technical basis that uses commonly accepted re-suspension factors, similar to the approach used for radioactive surface contamination.

Discussion: LLNL recognizes the need for housekeeping and contamination control practices and has, as part of its beryllium safety program, included surface criterion to initiate additional contamination control measures, including notification and cleanup. These practices take into account operational and programmatic needs to account for situations where additional actions is not warranted to control and/or minimize exposure to LLNL workers.

Question 8b: If a low airborne exposure action level should be established in lieu of the surface area action level, what should the airborne action level be?

LLNS Response to Question 8b: LLNS believes that we are not in a position nor has sufficient information been provided to appropriately answer this question.

Discussion: A correlation between surface contamination (e.g., release criteria) and airborne concentration to accurately estimate inhalation dose has not been established in the scientific literature. The literature does not necessarily indicate a 'safe' level to minimize health effects (CBD) associated with beryllium exposure. LLNL personal and area air samples generally indicate airborne results less than the limit of detection when working with contaminated surfaces.

Question 8c: What, if any, additional administrative controls to prevent the buildup on surfaces should be established?

LLNS Response to Question 8c: See LLNS comments to Question 8 above. Additional actions, including administrative controls, are dependent upon operational and programmatic factors with respect to the site's contamination control strategies. Specifying administrative control strategies is not appropriate for all situations.

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?

LLNS Response to Question 9: LLNS does not believe that specific warning labels should be required in such situations, but does recommend that sites' specific equipment release processes address the potential for inaccessible or encapsulated surface contamination. Such processes should take into account the final use and disposition of the equipment, and ensure sufficient conservatism in protection of members of the general public that may take possession of the equipment.

Discussion: Typically, a warning label should be required if there is a health hazard associated with the potential material or item being transferred. LLNL, as a best management practices, utilizes a label to

identify beryllium material and/or surface contamination when identified. This is a good idea but in practice is subject to misuse and misinterpretation depending upon the material or item to be transferred, effectiveness of decontamination techniques, and communication of controls, as necessary, to minimize exposure to beryllium surface contamination.

The mere presence of beryllium surface contamination or beryllium material in equipment does not automatically constitute a health hazard because there may not be an identified pathway (direct or indirect) determined as route of exposure (e.g., encapsulated within a matrix such as paint).

Question 10: Should the Department establish both surface level and aggressive air sampling criteria (modeled after the U.S. Environmental Protection Agency's (EPA'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?

LLNS Response to Question 10: No, the Department should not establish aggressive air sampling as a required method for the clearance of facilities from beryllium controls.

Discussion: A criterion should be established to downgrade beryllium controls and/or release facilities from continued beryllium safety program requirements (e.g., remove them from the site's beryllium inventory). Such a criterion should be based on a statistically-based sampling plan using current swipe techniques, and a quantitative measure of releasable surface contamination. Aggressive air sampling, though established through EPA regulation for clearance of asbestos abatement projects, is not the appropriate approach and may be in direct opposition to DOE's goal of preventing CBD within the DOE complex through minimization of the disability and lost time experienced by workers due to CBD, beryllium sensitization, and associated medical care [10CFR850.11(b)(3)(ii)]. Since there is no surface criterion for asbestos, only airborne, the EPA regulation for aggressive sampling is an appropriate method for asbestos clearance. Aggressive sampling for beryllium, especially due to the terminal settling velocity of such a low density and (often) fine particulate, has the potential to exacerbate airborne exposures for extended periods of time.

Aggressive air sampling may be one of several tools for evaluation of some airborne contaminants but should not be required for those with a surface criterion, especially for beryllium. Visible debris may cause the area to fail clearance, the area would then have to be re-cleaned and resurveyed. Many particulates may be re-entrained during aggressive air sampling and cause a greater hazard potential. With respect to EPA's aggressive air sampling criteria, the specifics for final air sampling are not identified in American Society for Testing and Materials (ASTM) E 1368 and litigation has occurred with respect to the asbestos clearance criterion.

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?

LLNS Response to Question 11: The Department should continue to require the worker's consent for medical removal for several reasons, including the following:

- **Mandatory removal is potentially unlawful under disability statutes**
- **Adverse impact on participation in surveillance programs**
- **Lack of clarity surrounding the term "medical removal"**

Discussion: The proposed change is ill advised as a blanket mandatory removal requirement would likely be unlawful under both federal and state disability statutes.

A mandatory removal requirement based on a positive Lymphocyte Proliferation Test (LPT) test would presumably be based on an assumption that a beryllium worker who has already been sensitized to beryllium would incur a higher degree of risk to his or her health if there were further accidental exposure to beryllium. Although there may be a recommendation that sensitized individuals be removed from working with beryllium or around 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.

To qualify as a disability there must be a physical or mental condition that substantially impairs a major life activity. A major life activity can be working. Merely being sensitized does not impair the ability to work, even in a beryllium-related job. Mere BeS by itself is not necessarily a disability, much as under the Equal Employment Opportunity Commission (EEOC) regulations an allergy or asthma are not by themselves a disability because they don't necessarily substantially impair the ability to work. However, a mandatory removal requirement would likely bring the sensitized individual under the "regarded as having a disability" protections of the Americans with Disabilities Act (ADA) and other disability statutes because the individual would be regarded as having an impairment that prevents him or her from working in a class of jobs involving beryllium.

Assuming for the sake of argument that a sensitized individual has a disability or is regarded as having a disability, the only lawful basis for mandatory removal from a job would be the "direct threat" defense allowed employers under the EEOC regulations. However, those regulations, and the case law interpreting the regulations, do not allow a simple blanket determination that all individuals with a certain medical condition must be precluded from performing a job that may present a risk to them. Rather, an individualized assessment must be performed based on reasonable medical judgment that relies on the most current medical knowledge and/or on the best available objective evidence. The factors to be considered include: 1) duration of the risk; 2) nature and severity of potential harm; 3) likelihood of potential harm; and 4) imminence of potential harm. This would include an evaluation not only of the individual by an expert in the field, but also an evaluation of the work site to determine what the actual risks of exposure are. Given that there is insufficient evidence regarding the prediction of risk to beryllium affected workers who continue to perform beryllium work, the direct threat criteria could be difficult to satisfy. Furthermore, even if it were determined that there was an increased risk from further exposure, a determination would have to be made that the work site itself would present an unacceptable risk of exposure which could not be mitigated, and that the exposure itself would result in likely and imminent harm. In fact, the level of risk of CBD from very low levels of exposure, such as those present in some research and development settings, is uncertain. In June of 2010, research conducted by the Department of Medicine at the University of California San Francisco (UCSF)¹² suggest

¹² Arjomandi et al, J Occup Environ Med. 2010 Jun; 52(6):647-52.

that because of lower average levels of beryllium exposure, a smaller proportion of sensitized workers at LLNL, may go onto to develop CBD when compared to other workers with higher exposures.

The potential impacts of implementing mandated removal will vary significantly depending on where the “acceptable exposure bar” is set in terms of impacts to career advancement and employment security. Mandatory medical removal would result in an adverse impact on participation in the program, ultimately affecting the health of beryllium workers that chose not to participate. If mandatory removal is implemented (without mandating participation), there would likely be significant reduction in participation in the surveillance program due to concern for career advancement and employment security. The role of medical surveillance in monitoring adequacy of the work control process would be significantly diminished. Workers are already worried about loss of their jobs once the two-year protection ends by agreeing to voluntary removal. Such a provision could result in employees simply abstaining from any testing or surveillance.”

If the Regulation were changed to require “mandatory removal,” the current Regulation does not provide specific guidance on what constitutes removal. This has led to varying interpretations in the DOE Complex ranging from requiring that a sensitized worker have **no** beryllium exposure risk to allowing a sensitized worker in work areas that may have less than the AL. What is the “acceptable exposure bar” for the medical removal of sensitized workers? This issue should be addressed prior to (or concurrent with) consideration of whether to mandate removal. In addition, if mandated removal occurs without clear definition of removal, inconsistent implementation will continue across the complex that might present some legal liabilities.