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Date: February 22, 2011
Ref: ESH&Q-11-010

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, S.W.
Washington, DC 20585

Dear Ms. Rogers,

Los Alamos National Laboratory appreciates having the opportunity to respond to the Department of Energy's request for information regarding issues related to 10 CFR 850, Chronic Beryllium Disease Prevention Program. Our responses are attached. If you have any questions or require further information please contact:

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We hope our comments will be useful to the Department in determining its course of action for revisions or additions to the chronic beryllium disease prevention program.

Sincerely,

A handwritten signature in blue ink, appearing to read "J. Chris Cantwell".

J. Chris Cantwell
Associate Director
Environment, Safety, Health & Quality

Attachment: a/c

Cy: M. Mallory, PADOPS, A102
C. Casalina, DOE/LASO, A316
C. Blackwell, LC-LESH, A187
G. Beers, IHS-DO, K403
G. Whitney, IHS-DO, K403
B. Hargis, WSR, K491
File

DEPARTMENT OF ENERGY
10 CFR Part 850
[Docket No. HS-RM-10-CBDPP]
RIN 1992-AA39
Chronic Beryllium Disease Prevention Program

Los Alamos National Laboratory (LANL) responses to the Department of Energy request for information regarding possible new requirements in the beryllium rule (10 CFR 850).

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:

The Department should not continue to use the OSHA PEL.

Explanation:

It is generally accepted by the industrial hygiene, occupational medicine, and epidemiology communities that the current OSHA PEL of 2.0 ug/m³, 8 hour time-weighted-average, is not adequate to prevent chronic beryllium disease.

Under the current rule, exceedance of the action level of 0.2 ug/m³, 8 hour time-weighted-average, initiates requirements for respiratory protection (850.28), protective clothing (850.29), hygiene facilities (850.27), exposure monitoring (850.24(c)), establishing regulated areas (850.26), posting warnings (850.38), reporting to the DOE site office (850.24(g)), and developing formal exposure reduction and minimization programs (850.25). For all practical purposes, the action level currently is the effective exposure limit.

Los Alamos National Laboratory (LANL) has taken a more protective, graded approach in its Chronic Beryllium Disease Prevention Program (CBDPP) by establishing requirements and controls for any operation with a reasonable potential for airborne beryllium below the action level (P101-21, 3.14.4). Operations that exceed, or have a reasonable potential to exceed the action level fall under the more stringent requirements of a regulated beryllium area as established under the current rule.

OSHA is in the process of developing a standard for beryllium. It is expected that the standard will establish a PEL that is lower than the current PEL. The development and promulgation of a beryllium standard could take years. The Department should not depend on OSHA to reduce the PEL in any reasonable amount of time.

Question 2 Should the Department use the 2010 ACGIH threshold limit value (TLV) of 0.05 µg/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:

The Department should not implement the 2010 ACGIH threshold limit value (TLV) for beryllium as an allowable exposure limit at this time.

Explanation:

Concerns have been raised on the adequacy and completeness of the data used by the ACGIH in reaching conclusions on the beryllium TLV. LANL will not argue with the ACGIH decision, but rather will discuss some of the issues involved with implementing the TLV as an exposure limit.

- Appropriate use of TLVs
- Analytical Sensitivity and Accuracy
- Statistical Analysis of Data
- Handling, Processing, and Quality Assurance
- Commercial Laboratory Readiness
- Cost of Implementation
- LANL Recommendation

Technical issues concerning the use of inhalable samplers are also discussed in the responses to questions #6 and #7. Until technical issues are resolved and adequate resources are available, the Department should not require an inhalable fraction sampling method. With analytical methods currently available at most DOE sites, beryllium cannot be effectively measured at 0.05 µg/m³.

Appropriate use of TLVs

The ACGIH intends for TLVs to be used as guidelines and not as legal standards. The ACGIH Policy Statement on the Uses of TLVs® and BEIs® contains the following:

“The Threshold Limit Values (TLVs®) and Biological Exposure Indices (BEIs®) are developed as guidelines to assist in the control of health hazards. These recommendations or guidelines are intended for use in the practice of industrial hygiene, to be interpreted and applied only by a person trained in this discipline. They are not developed for use as legal standards and ACGIH® does not advocate their use as such. ”

The ACGIH Statement of Position Regarding the TLVs® and BEIs® (ACGIH 2010) contains the following:

“ACGIH® does not believe that TLVs® and BEIs® should be adopted as standards without full compliance with applicable regulatory procedures including an analysis of other factors necessary to make appropriate risk management decisions.”

And:

“Since ACGIH® TLVs® and BEIs® are based solely on health factors; there is no consideration given to economic or technical feasibility. Regulatory agencies should not assume that it is economically or technically feasible for an industry or employer to meet TLVs® or BEIs®.”

Adopting the beryllium TLV as an enforceable part of the beryllium rule is clearly outside of the use intended by the ACGIH. The ACGIH bases their recommendations for TLVs on their review and interpretation of published literature on exposure and resulting health effects of the substance in question. They do not assume that measuring exposures at TLV levels is economically affordable or even physically possible with current technology. The Department has not yet demonstrated a thorough analysis of the costs, feasibility, and other factors necessary to make risk management decisions regarding the use of the TLV as an exposure limit.

Analytical Sensitivity and Accuracy

Inhalable samplers must be run at fixed flow rates to meet the inhalable particle size fraction criteria. The most commonly used inhalable sampler (IOM) runs at 2 liters per minute. This collects a 960 liter full shift sample. The commercial analytical laboratory used by LANL has a beryllium reporting limit of 0.023 ug/sample. This sample volume and analytical sensitivity produce a sample detection limit of 0.024 ug/m³. This is only half of the TLV and is far from the tenfold difference between exposure limit and analytical quantification limit that is desired for statistical analysis.

The real world situation is worse. Many beryllium jobs, particularly those with the higher potential for exposure, last for less than a full 8 hour shift. In 2009 at LANL, the median beryllium breathing zone sample time was 238 minutes (1,313 samples). This results in a sample detection limit of 0.048 ug/m³; equal to the exposure limit. There are inhalable samplers available that run at 4 liters per minute, but that would only bring the sample detection limit to half of the exposure limit for the median LANL sample. The current analytical method used at LANL is not adequate for monitoring beryllium exposures at the TLV.

LANL's analytical lab has indicated that switching from the currently used analysis by inductively coupled plasma atomic emission spectroscopy (ICP-AES) to the more sensitive inductively coupled plasma mass spectroscopy (ICP-MS) may provide the required sensitivity, but would approximately double the cost of sample analysis. For DOE sites that analyze their own beryllium samples, it has been reported that the cost of implementing an ICP-MS system can be as high as \$400,000.

The fluorescence method (NIOSH 7704 or ASTM D7202) may be able to provide the required sensitivity at a more reasonable cost, but most DOE sites and commercial analytical laboratories are not accredited by the AIHA for these methods. The rule requires use of an accredited laboratory for exposure monitoring. Acquiring AIHA accreditation may take a year or more to obtain with costs and fees up to \$10,000.

In 850.24(e) the rule requires "...accuracy of not less than plus or minus 25%, with a confidence of 95% for airborne beryllium at the action level." It is assumed that this accuracy requirement would also apply to the TLV. Accuracy and precision of commonly used analytical methods may not be known at the TLV level.

OSHA method ID-125G reports beryllium precision and accuracy for the method using spiked samples ranging from 0.12 to 0.48 ug. The precision and accuracy at 0.05 ug is not indicated. It may not be possible to demonstrate compliance with 850.24(e) until analytical methods are re-

validated. AIHA accreditation may also fall into question when working outside the normal range of the accredited methods.

Statistical Analysis of Data

Industrial hygienists typically desire at least a tenfold difference between the exposure limit and analytical quantification limit. This allows for statistical analysis of the sampling data. The rule requires the use of "...statistically-based monitoring strategies..." [850.24(b)]. Demonstrating compliance with any degree of confidence becomes problematic when the analytical quantification limit is close to the exposure limit. Even when an operation is actually well controlled, a few detectable samples can skew the analysis and cast doubt on the adequacy of controls.

Having an analytical reporting limit very close to the exposure limit does not allow for the evaluation of trends in the data or the detection of slight changes in processes and operations. This could prevent the identification of the improvements needed in controls and/or work practices to further reduce exposure levels.

The beryllium TLV is very close to the analytical quantification limit for the methods currently employed at most DOE sites. Demonstrating compliance with the TLV and following the intent of 850.24(b), may require the collection of a very large number of samples or switching to more costly analytical methods.

Handling, Processing, and Quality Assurance

The disposable 37mm closed face cassette commonly used to collect total particle fraction samples is typically purchased as a pre-loaded unit. The buyer has a reasonable level of assurance that the filters are free of contamination, are properly assembled, and will perform as expected. The cassettes are typically opened for filter removal at the analytical laboratory in a well controlled situation by a trained and experienced technician. They are not generally considered a significant source of error in sample collection and analysis.

The currently available inhalable samplers are not disposable. They require cleaning and re-loading after each use. Some analytical labs want the entire sampler sent to them for processing and analysis. Other labs want to receive only the filter. In the later case the tasks of removing the filter and transferring it to a sample tube would have to be performed by the DOE site. This could be a source of error and sample loss if not done properly and consistently.

The IOM sampler requires any particles clinging to the walls of the internal filter cassette to be included as part of the sample in order to meet the inhalable criteria. Normally this sampler is used for gravimetric analysis so the filter cassette is pre and post weighted for the analysis. For beryllium analysis the particles on the filter cassette walls will need to be wiped or rinsed from the cassette and added to the filter as part of the sample. This is a potential source of considerable error and variability.

Because the TLV is so low, **any** beryllium remaining on the sampler could have a significant effect on the next sample collected. A single particle of beryllium 37um in diameter would equal the TLV. Samplers would have to be cleaned thoroughly using a validated, well controlled procedure.

A percentage of the samplers themselves would have to be sampled to assure the cleaning process is adequate.

Currently, inhalable samplers are used primarily for gravimetric analysis. With a gravimetric analysis, if some material is left in the filter cassette, it will be compensated for in the pre-weigh and not affect the final result. A few particles carried over from one sample to another are not likely to be significant when the exposure limit is hundreds of micrograms to milligrams. Commercial laboratories using inhalable samplers for gravimetric analysis would not have a motive for thoroughly cleaning the samplers. Inhalable samplers provided by a commercial laboratory may require pre-cleaning and new filters before being used for beryllium sampling at DOE sites.

All of the factors indicated in this section are significant sources of error and variability. The total error and variability introduced by the handling and processing of samplers could introduce error sufficient to exceed the accuracy required by 850.24(e). This will require the development of, and strict adherence to, a quality assurance (QA) procedure. It would be reasonable to expect that the sampling and additional effort required for the QA process would add 10% or more to the total sampling costs.

Commercial Laboratory Readiness

LANL sent letters with questions on the handling and processing of inhalable samplers to 42 commercial analytical laboratories accredited by the American Industrial Hygiene Association (AIHA). Eight laboratories responded (Whitney March 16, 2010). All of the labs reported that there was very little demand for inhalable sampler analysis. Almost all inhalable samples the labs processed were for gravimetric analysis. In general, commercial analytical laboratories are not prepared for large-scale (more than 20) analysis of beryllium samples collected using inhalable samplers. They do not keep an adequate supply of inhalable samplers on hand and are not set up for processing inhalable samplers for metals analysis. DOE sites using commercial laboratories will have to negotiate with their lab regarding processes, procedures, responsibilities and price for inhalable sample analysis. This is expected to result in significant cost increases. Some analytical labs want the entire sampler sent to them. Other labs want to receive only the filter. In either case the costs of handling and processing inhalable samplers will be incurred whether these tasks are performed by a commercial laboratory or by the DOE site.

Cost of Implementation

LANL prepared an estimate of the cost of implementing the use of inhalable samplers (Whitney November 2, 2010). The estimate assumes future sample numbers will be similar to 2009 data and samples will be analyzed by a commercial off-site laboratory. This estimate is based on tangible, direct costs that could be calculated. It does not include indirect costs and overhead. Actual costs are likely to be significantly higher.

The estimated number of samplers required at LANL is approximately equal to the average number of beryllium breathing zone samples collected per month. This assumes that the average weekly use of samplers must be prepared and available; samplers will be in the field one week; samplers will be in the lab one week for analysis and re-loading; and samplers will be used at multiple site locations at the same time. Based on 2009 sampling numbers, LANL would require

100 inhalable samplers. Depending on the sampler selected, initial costs for samplers would be up to \$21,000. Initial costs for support equipment and materials (pump battery upgrades, ultrasonic cleaners, lab supplies, etc.) are estimated at \$13,000. Initial time and effort costs for health and safety professionals developing the inhalable sampler program and procedures are estimated at \$10,000. Initial time and effort costs for technicians to establish a work area and learn techniques are estimated at \$7,000.

Annual time and effort costs for a technician to process, clean, and re-load the samplers are estimated at \$32,000 (20% FTE). Annual time and effort costs for health and safety professional oversight of the program are estimated at \$3,000. Annual costs for consumables, QA sampling, and replacement of samplers/parts are expected to be about \$12,000.

Annual cost for analysis of samples by ICP-AES is approximately \$36,000. This same cost would be incurred if LANL did not switch to an inhalable sampler method, so it will not be included in the totals. If ICP-MS is required to achieve analytical sensitivity, an additional \$40,000 cost would be incurred per year.

First year costs for initial set-up and analysis of 1200 samples using an inhalable particle fraction method is estimated to be \$98,000 (\$138,000 if ICP-MS is required). Processing the same number of samples in subsequent years would cost \$47,000 (\$87,000 if ICP-MS is required). These are costs beyond those incurred for the current total particle fraction method (37 mm closed face cassette, ICP-AES).

The cost to implement the beryllium TLV does not appear to be justified by an exposure limit that may be only slightly, if any, more protective. Considering current flat or declining budgets, these resources would be better spent on improvements to the controls used to minimize exposures from beryllium operations.

LANL Recommendation

LANL believes that the best means to minimize beryllium exposure and prevent beryllium disease is to use the current action level of 0.2 ug/m^3 , 8 hour time-weighted average, total dust particle fraction, as an exposure limit. Implement controls and work practices to minimize all exposures to beryllium. When there is a reasonable potential for airborne beryllium, employ respiratory protection until sampling results demonstrate that the process is adequately controlled. Successful overall performance of the program would be statistically demonstrated when there is 95% confidence that 95% of exposures without respiratory protection are below this limit. This approach is supported by epidemiological research (Madl 2007).

LANL believes that this approach is reasonable, protective of workers, economically feasible, and achievable with the technology and resources currently available at most DOE sites.

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:

The Department should not implement the 2010 ACGIH threshold limit value (TLV) for beryllium as an action level limit at this time. An action level is not necessary.

Explanation:

An email response from DOE (Rogers 2011) clarified that this question is effectively asking: *“Should the TLV be adopted as the action level? If not, what should the action level be?”*

The issues involved with implementing the TLV as an action level are the same as those for adopting the TLV as an exposure limit. These issues are discussed in the responses to questions #2, #6, and #7. Until technical issues are resolved and adequate resources are available, the Department should not require an inhalable fraction sampling method.

An action level is not necessary. OSHA defines an action level as: *“Action level means a concentration designated in 29 CFR part 1910 for a specific substance, calculated as an eight (8)-hour time-weighted average, which initiates certain required activities such as exposure monitoring and medical surveillance.”* (29 CFR 1910.1450(b)). Under the current beryllium rule exposure monitoring, medical surveillance, and training are all required when there is **any** beryllium exposure or reasonable potential for exposure. The requirements typically initiated by an action level are already in place; therefore, the purpose that an action level normally serves is met. An action level exposure does not have to be reached invoke these requirements. Having an exposure limit becomes meaningless if all requirements take effect at an action level. In the current rule the action level is actually an exposure limit for all practical purposes.

LANL believes that the best means to minimize beryllium exposure and prevent beryllium disease is to use the current action level of 0.2 ug/m³, 8 hour time-weighted average, total dust particle fraction, as an exposure limit. Implement controls and work practices to minimize all exposures to beryllium. When there is a reasonable potential for airborne beryllium, employ respiratory protection until sampling results demonstrate that the process is adequately controlled. Successful overall performance of the program would be statistically demonstrated when there is 95% confidence that 95% of exposures without respiratory protection are below this limit. This approach is supported by epidemiological research (Madl 2007).

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:

It would be reasonable for the Department to require the use of wet wipes for specific stated purposes and require the use of a validated method published by a recognized agency (e.g. ASTM, OSHA, NIOSH, EPA, ISO, etc.) for surface sampling.

Explanation:

Studies have shown that wet wiping methods collect surface contaminants more efficiently than dry methods (Kerr 2004, Dufay 2006). However, there are some surfaces that cannot be contacted with wet wipe media due to restrictions imposed by design specifications. In some rare situations, water reactive surfaces may have to be sampled. Surface monitoring involving both radioactive materials and beryllium will typically require a dry method to allow for counting of the wipe media before release for beryllium analysis. There are validated dry surface sampling methods available (e.g. ASTM D7296). As noted in the question, any changes to the rule would have to recognize that there are some surface sampling situations where a wet wipe is not appropriate and allow sites the flexibility to select a suitable method.

The rule would have to specify the specific situations where the use of a wet method would be required, such as release of equipment; clearance of facilities and workspaces; or demonstrating compliance with housekeeping limits. These would be situations where the sampling result was being compared to some regulatory limit or technical standard criteria.

The use of a validated method published by a recognized agency (e.g. ASTM, OSHA, NIOSH, EPA, ISO, etc.) may be the best approach to "*achieve greater comparability of results across the DOE complex*" for surface sampling. Due to the inherent lack of precision in surface sample collection methods; the broad range of beryllium operations performed; and the variability in workplace conditions between sites; the Department should not expect anything more than a qualitative comparability of results at best.

In situations where the sampling result is not being compared to regulatory or technical criteria (e.g. process monitoring, research, diagnostic, qualitative testing), sites should be able to select the surface sampling method (e.g. wet wipe, dry wipe, vacuum, or bulk) most suitable to their situation. There are validated alternative surface sampling methods available (e.g. ASTM D7144 micro-vacuum sampling).

Sites must be able to choose a method that their analytical laboratory is accredited to perform and a media their laboratory is capable of digesting and processing with the required sensitivity. While the rule does not currently require American Industrial Hygiene Association (AIHA) accredited labs for analysis of surface samples, some site CBDPPs (e.g. LANL's P101-21) require that surface samples collected for purposes of release be analyzed by an accredited laboratory.

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:

Surface contamination levels determined by wipe sampling are only one factor among the many used by health and safety professionals when evaluating the potential for exposure and determining the controls required to protect beryllium workers.

Due to the many variables in sample collection, surface wipe samples should be considered a semi-quantitative measure of surface contamination.

Explanation:

Wipe samples may be collected for a variety of reasons:

- Hazard Assessment
- Housekeeping
- Evaluation of Controls
- Release of Facilities
- Identifying Legacy Contamination
- Release of Equipment and Materials
- Preparation for D&D
- Research

Industrial hygienists and other health and safety professionals use surface contamination levels as **one** point of information in evaluating the potential for exposure and determining the controls and procedures required to protect beryllium workers. Many other factors must be taken into consideration in the overall exposure assessment (e.g. type of work, tools and equipment used, controls available, nature of surfaces, potential for re-entrainment, proximity to contamination, etc.). While it is a valuable tool for the industrial hygienist, surface contamination level in and of itself cannot be used as a measure of exposure or risk. Some professional judgment and interpretation needs to be applied based on the specific situation.

Surface contamination level is not a direct indication of worker exposure (Caplan 1993). There are a large number of variables involved in the collection of surface samples that affect the overall accuracy and precision of the technique and render its use as an assessment of exposure or regulatory criteria questionable (Mitchell 1966, Lichtenwalner 1992, Klingner 1994).

Surface wipe samples should be considered a semi-quantitative measure of surface contamination. A number of variable factors affect the reliability and accuracy of current sampling and analytical methods for beryllium wipe samples. Consideration should be given to these factors when comparing results between sites or to standards and guidelines.

The reliability and accuracy of the analytical portion of beryllium wipe sample methods has been fairly well defined:

- The accuracy and precision of the analytical method used for wipe samples is determined during the validation process by the agency publishing the method (e.g. NIOSH 1994, Manual of Analytical Methods, Chapter E, Development and Evaluation of Methods).

- The AIHA evaluates the quality assurance procedures used by analytical laboratories in the accreditation process. Standards and spiked samples are routinely employed as quality assurance controls.
- Laboratories participating in the AIHA's Beryllium Proficiency Analytical Testing (BePAT) Program are sent blind, spiked samples for analysis on a tri-annual basis.

The use of validated methods published by a recognized agency (e.g. ASTM, OSHA, NIOSH, EPA, ISO, etc.) and AIHA accredited laboratories, or laboratories meeting equivalent quality assurance standards, should ensure adequate accuracy for the analysis of wipe samples.

Even when using validated methods and accredited laboratories, interferences within the samples can adversely affect accuracy and sensitivity. The collection of excessive dust on the wipe media may require a larger volume of acid to digest the sample, reducing sensitivity. Interfering materials collected from the surfaces can reduce sensitivity or provide falsely high values for beryllium.

The accuracy and precision of current beryllium surface sample collection methods, as applied in the field, has not been well demonstrated. A limited number of laboratory studies have looked at collection efficiencies (e.g. Kerr 2004, Dufay 2006, Verkouteren 2008), but these studies are often very artificial (e.g. drops of beryllium solution on a glass plate) and may be best suited for comparing wipe media and wetting agents. The study by Kerr attempted to simulate "real-world" conditions by using a painted test surface with an oily metal working fluid residue. This was perhaps the best attempt at estimating accuracy and precision that might be seen in the field, but the controlled conditions in the lab are still far from what is present in an actual workplace.

The accuracy and precision of the collection of wipe samples is expected to be highly dependent on the skill, training, and work practices of the persons collecting the samples. It is expected that there will be a high level of variability within and between the individuals collecting the samples.

The condition of the surface (smooth, rough, porous, tacky, etc.); the nature of the material on the surface (fine particulate, coarse dust or chip, "diluting" materials like household and process dust, etc.); the wipe media selected (total mass, "digestibility", tear strength, particle holding capacity, etc.); and wetting agent (water alcohol, solvents, surfactants, etc.) all can impact the reliability and accuracy of beryllium wipe samples. Methods, media, and wetting agents must be selected that are appropriate for the surfaces sampled.

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:

A “best” method sampling and analyzing inhalable beryllium has not been demonstrated. Until technical issues are resolved and adequate resources are available, the Department should not require an inhalable fraction sampling method.

Methods for selective particle size sampling in general should be evaluated by the Department and a guideline or technical standard developed to identify recommended methods to help ensure appropriate, accurate sampling and achieve greater consistency and comparability across the complex.

Explanation:

Three inhalable samplers are readily available in the United States: the IOM sampler (SKC Inc., Eighty Four, PA), the button sampler (SKC Inc.) and the CIS (BGI Inc., Waltham, MA). There are a number of lab and field studies comparing inhalable samplers to each other and to other methods (Werner 1996, Katchen 1998, Li 2000, Predicala 2003, Vincent 2007, Dufresne 2009).

In general, these studies indicate that inhalable samplers tend to collect more material than total particulate samplers, but the results are variable, depending on the particle size range present and conditions such as wind speed and direction. Some of the issues regarding inhalable samplers are also addressed in the response to questions #2 and #7.

There are a number of concerns with implementing the use of inhalable samplers. LANL performed some evaluations of the IOM, CIS, button, and 37mm closed face cassette (CFC) samplers (Whitney March 16, 2010). LANL found that the pump pressure required for the button and IOM samplers, which use a 25mm filter, can be considerably higher than that for the CFC (button 42 cm H₂O, IOM 52 cm H₂O, CFC 18 cm H₂O). The pump pressure requirement forces the use of higher capacity sampling pumps equipped with lithium ion batteries. This can result in considerable expense if sampling pumps must be replaced.

The IOM and the CIS samplers had serious problems during calibration. The IOM calibration adaptor leaked, causing errors when measuring flow rate. The CIS sampler does not have a calibration adaptor. The user must try to hold a piece of tubing at the sampler orifice when measuring air flow. These problems could result in significant errors in sampling results.

The IOM is intended as a gravimetric method. The sample must include the filter cassette wall deposits. No validated methods for wiping or rinsing the IOM filter cassette walls for inclusion in sample digestion appear to have been published. Sampler wall loss can be a significant source of error and variability. Some studies have measured wall losses when comparing samplers (Li 2000). Other studies ignored wall loss and only measured material collected on the filter (Dufresne 2009). Sampler wall loss in general (Brisson 2009) is an issue the Department needs to address and include in any guidelines or technical standards for sampling that are developed.

The issue of collecting an inhalable particle size fraction is not just related to beryllium. The ACGIH will eventually specify particle size fractions for all TLVs for airborne particulate matter. LANL recommends that the Department conduct (or sponsor) a thorough critical review of the literature and perform a study to determine technically acceptable and economically feasible particle size selective sampling methods for use in the DOE complex.

The Department should develop a guideline or technical standard identifying recommended methods and procedures to help ensure appropriate, accurate sampling and achieve greater consistency and comparability across the complex. Use of the inhalable particle fraction should be considered by the DOE, but should not be required until some of the technical issues have been resolved and the Department has developed the guideline or technical standard.

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:

Total fraction exposure data should not be compared to inhalable fraction exposure measurements. It would be inappropriate to retrospectively adjust sampling data to compare to a regulatory standard or attempt to adjust sampling results to a different sampler type to determine compliance.

Explanation:

Total fraction samples are collected using a 37mm closed face cassette. Inhalable samples are collected using one of several available samplers (Li 2000, Vincent 2007). The inhalable samplers collect larger particles (i.e. > 30 um aerodynamic diameter) more efficiently (Werner 1996, Li 2000, Vincent 2007). Differences between the measurements made using the two types of samplers are dependent on the underlying particle size distribution in the workplace where the samples are collected.

In workplace situations where small particles are expected (e.g. welding fume) the two sampler types could be expected to produce similar results. In situations where particles are relatively large and/or significant energy is applied to the particles (e.g. grinding or blasting), the inhalable sampler would be expected to produce a significantly larger result. This has been demonstrated in lab and field studies (Werner 1996, Kenny 1997, Kerr 2002, de Vocht 2006).

When comparing results from 37 mm closed face cassette samplers (total fraction) to IOM samplers (inhalable fraction), Werner suggested a range of conversion factors from 1.0 to 2.5, based on the type of operation. No simple correction factor can be applied to compare total fraction to inhalable fraction measurements for all workplace situations.

For some operations there may be little difference between total fraction and inhalable sampler results. Large beryllium particles tend to settle out fairly quickly. A 100 um diameter beryllium particle (the median cut point for inhalable samplers) would be expected to settle out at a rate of approximately 96 feet per minute (fpm); a 50 um particle at 23 fpm; and a 25 um particle at 6 fpm. The larger particles that the inhalable samplers collect more efficiently will settle out within a few minutes unless continuing forces are applied. Applying a correction factor to the total fraction sampling results would over-estimate the exposure. (Settling velocity calculated using simplified Stokes equation: $V = 0.0052 \times (SG) \times d^2$; where V = velocity in fpm, SG = specific gravity, and d = diameter.)

A number of factors further compound any attempts to compare measurements between the two sampler types. Different inhalable samplers have been shown to produce different results under the same laboratory conditions (Li 2000). The specific inhalable sampler selected could affect any comparisons to total fraction measurements. Inhalable samplers have been shown to significantly oversample in certain situations dependant on wind direction (Li 2000, Vincent 2007).

In some cases use of a correction factor might be appropriate, but only for situations such as comparing large bodies of sampling data for epidemiological studies, or when examining data for well defined similar exposure groups.

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:

DOE should not attempt to control surface contamination via a low airborne action level.

The Department should not specify a surface area action level, but rather should require each site's CBDPP to address surface contamination and contain appropriate responses specific to the site's operations and conditions. The Department should consider adopting 0.2 ug/100 cm² as a housekeeping *guideline* (not absolute limit) for non-beryllium areas.

The Department should consider requirements for packaging and storage of beryllium or beryllium contaminated items as an administrative control to prevent buildup on surfaces.

The Department must recognize that naturally occurring beryllium in local soils can significantly contribute to measured surface contamination levels.

Explanation:

Airborne beryllium levels are kept low to prevent worker exposure. A side benefit of low airborne levels is the prevention of long-term build-up of surface contamination. However, legacy contamination from past operations and point-to-point contamination spread from beryllium parts or contaminated items are the major surface contamination concerns at most sites. Neither would be affected by attempting to control contamination by a low airborne action level.

The generally accepted (but not currently required) housekeeping level of 0.2 ug/100 cm² for non-beryllium areas does not represent a health hazard boundary. Surface contamination is not a direct indication of worker exposure (Caplan 1993). Possible sensitization through dermal contact is a growing concern (Curtis 1951, Tinkle 2003, Day 2006, Day 2007), but this has not been proven and there is no evidence to indicate the amount of dermal exposure that would present a sensitization hazard.

The LANL CBDPP (P101-21, section 3.12) takes a graded approach in actions required in response to surface contamination levels in both beryllium and non-beryllium areas. Higher levels of contamination trigger more aggressive required actions. Trigger levels are lower in non-beryllium areas.

DOE should specify requirements and surface contamination limits for the release of facilities and equipment; but each site's CBDPP should cover a graded approach to workplace surface contamination levels and required responses. All CBDPPs must be approved by the responsible DOE site office so there would be a control mechanism in place to ensure that the site's responses to surface contamination are appropriate to the situation and adequate to prevent

worker exposure and contamination spread. The Department should consider adopting 0.2 ug/100 cm² as a housekeeping guideline for non-beryllium areas.

Surface contamination housekeeping guidelines should not be considered absolute limits. Some professional judgment and interpretation needs to be applied based on the specific situation. For example, the oiled ways on a lathe may have beryllium contamination many times the housekeeping guideline, but not present an exposure concern. Conversely, detectable beryllium on the surface of a desk in a clean office area may not be considered acceptable even if it is below housekeeping guidelines or release limits. Keeping surface contamination trigger levels (other than for release) and responses within the site's CBDPP allows for the use of this situation specific judgment.

Experience at LANL has shown that the highest surface contamination levels encountered are due to direct contact with beryllium parts or beryllium contaminated items. In response to surface contamination events, LANL established requirements for beryllium storage areas (P101-21, section 3.14.1) and strengthened requirements for packaging of beryllium and beryllium contaminated items (P101-21, section 3.26). The Department should consider requirements for the packaging and storage of beryllium as an administrative control to prevent contamination buildup and spread.

Naturally occurring beryllium in local soils can easily exceed current release limits. This is recognized in the current beryllium rule [850.31(b)(1)]. An excessively low surface action level could result in a significant waste of time and resources responding to non-hazardous accumulations of wind-blown soil on workplace surfaces. The presence of naturally occurring beryllium is another reason for keeping housekeeping levels as guidelines rather than absolute limits.

Geologists at LANL have identified the naturally occurring concentration of beryllium and other elements in the local soils (Longmire 1996). When soil is suspected as a source of beryllium contamination at LANL, bulk samples are collected on the surfaces in question and the beryllium concentration and the ratio of beryllium to iron in the sample are compared to the levels occurring naturally in local soils. This can demonstrate that the sample beryllium concentration is consistent with that occurring naturally in the soil. This can also be used to determine that the source is anthropogenic if the sample is outside the tolerance limits of the local soil.

The use of trace elements found in soils, but not associated with site operations, has been investigated as a marker to help distinguish beryllium from legacy operations from natural background for both ambient air (Lochamy 2002) and surface samples (Gran 2010).

The Department must recognize in any revisions to the rule that naturally occurring beryllium in local soils can contribute to measured surface contamination levels. The Department must identify acceptable methods by which sites may determine if beryllium contamination on surfaces is from natural sources. The Department should consider funding research to develop better methods for determining the contribution of natural sources in beryllium surface contamination.

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:

Warning labels, or other means of informing recipient, should be required for items which may contain inaccessible or sealed beryllium contamination unless there is no reasonable potential for exposure to the beryllium without applying destructive methods.

Explanation:

Best practices would indicate that beryllium contaminated items should not be released to the general public and items released to another DOE entity should be accompanied with clear information regarding any beryllium contamination. However, it is recognized that banning release to the general public is not economically feasible in many cases.

The beryllium rule currently requires labeling of released items that are contaminated with beryllium (850.31 and 850.38). The surface of these items must be below the release criteria of $0.2 \text{ ug}/100 \text{ cm}^2$ and the recipient must implement controls to prevent foreseeable beryllium exposure due to hidden or entrapped contamination. It is reasonable that the item be labeled to warn the recipient of any beryllium contamination that could result in an exposure.

The question becomes one of determining if an item that contains or is contaminated with beryllium, when used as intended, could reasonably result in exposure or contamination spread. A lathe or milling machine that had been used for years to process beryllium would be expected to have contamination on its many internal parts and surfaces; even if external surfaces were decontaminated and shown to be free of beryllium. When used as intended, it is expected that such a machine would be dismantled occasionally for maintenance or repair. This could expose the workers performing these tasks to beryllium. Such an item would require a warning notifying the recipient of the internal contamination.

However, if beryllium contamination were sealed internally in such a manner that it would not be accessible unless extreme destructive methods were applied; and if there were no open passageways to the contamination (e.g. holes or vents); then it is reasonable that a warning label would not be necessary in some situations. When used, maintained, serviced, or modified as intended there would be no exposure potential.

This approach would be consistent with the idea of a beryllium article. An article is a manufactured item containing beryllium, that when used as intended does not present an exposure potential. A desktop computer might be an example. Computers often contain beryllium copper contact points and electronic components with beryllium oxide ceramics. Both of these materials contain greater than 0.1% beryllium; defining them as beryllium under the rule (850.3).

Beryllium sensitization and disease have been observed in workers producing and processing beryllium copper and beryllium oxide ceramics (Schuler 2005, Kreiss 1996). Beryllium

sensitization and disease has also been observed in workers involved in the re-processing of materials recovered from scrapped electronic equipment (Volker 2007). However, no BeS or CBD has been associated with normal use of a computer. Warning labels notifying users of the beryllium content of computers are not needed and not required under any regulation.

It might be considered reasonable that items containing beryllium material or contamination would not require warning labels provided that the beryllium is sealed or contained in a manner that prevents any reasonable exposure potential when the item is used, maintained, serviced, or modified as intended (i.e. no pathway to the contamination; no destructive forces applied). Effectiveness of sealing in contamination with paint or some other sealant would have to be demonstrated by the site releasing the item or by published studies regarding specific sealants and methods of application. Reasonable limits may have to be placed on the level of contamination that could be contained using this method.

A different approach would be required for facilities, buildings, and structures. It would be reasonable to expect that walls, floors, and painted surfaces of facilities would undergo destructive actions during normal expected use (e.g. penetrations, remodeling, peeling and weathering, preparation for re-painting, etc.). Release of facilities having beryllium contamination sealed beneath paint, within walls, or behind building materials would require a warning notifying the recipient of the internal contamination.

LANL wishes to stress that best practices would indicate that beryllium contaminated items should not be released to the general public and items released to another DOE entity should be accompanied with clear information (label or otherwise) regarding any beryllium contamination (internal, sealed, or otherwise). LANL does, however, recognize that there may be situations at DOE sites where the release of well contained beryllium material or contamination without warning labels would be acceptable.

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:

Aggressive air sampling should not be required for releasing areas in a facility that had been used for beryllium operations or had legacy beryllium contamination concerns. Rather, the Department should develop a technical standard and/or guideline on acceptable criteria for releasing facilities based on statistically valid surface sampling strategies.

Explanation:

While aggressive air sampling has been used extensively for asbestos, there is only limited experience with using this method for beryllium (Project 1703 Report, 2010). Although the Kansas City Plant demonstration project provided useful information and some lessons-learned on the application of aggressive air sampling to beryllium, this was only one location with one specific set of conditions. Application of this technique without further verification via published studies under a variety of workplace conditions is not likely to be well accepted by the DOE community, the general public, or the organizations who may be receiving the facilities in question.

If not carefully applied, and only used in the appropriate situations, aggressive air sampling could place workers at risk of exposure and contribute to the spread of beryllium contamination. Entrainment of even a few milligrams of beryllium particulate on a surface could result in airborne beryllium concentrations that exceed the assigned protection factor of respirators used during aggressive air sampling. Aggressive air sampling could actually spread a small localized pocket of beryllium contamination through-out the area being studied.

Aggressive air sampling may not adequately entrain beryllium particulate on oily or tacky surfaces. Such surfaces are likely to exist in locations that housed operations such as machining, plating, or parts treatment and cleaning. Residual beryllium contamination missed by aggressive air sampling could result in release of areas with contamination on accessible surfaces. Although not proven, sensitization through dermal contact is a growing concern (Curtis 1951, Tinkle 2003, Day 2006, Day 2007).

Aggressive air sampling methods may have some application where sampling and workplace history indicate the surface contamination in general is relatively low and there is no reasonable expectation for high level pockets of legacy contamination. Aggressive air sampling methods and guidance should be established as an optional tool for sites to use for evaluation and characterization of the potential for entrainment of residual beryllium contamination on surfaces.

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:

The Department should leave section 850.35 of the rule unchanged and continue to require worker consent for medical removal from beryllium work.

Explanation:

There are a number of reasons for continuing to require worker consent for medical removal:

- Participation in beryllium medical surveillance is currently voluntary. Workers often state that the reason for declining participation is fear that they will be removed from their job if they become sensitized to beryllium. If the rule is changed to require removal from beryllium work for any worker who becomes sensitized, this could result in significant reduction in the number of workers who are willing to participate in the medical testing.
- Medical removal protection benefits last a maximum of two years. Unemployment or job changes (or fear thereof) can have a very negative impact on workers' lives. Workers are likely to refuse to participate in LPT testing; not report exposure concerns; hide work history; and/or be reluctant to report medical symptoms of concern if they believe they might be forced from their jobs.
- Beryllium sensitization in itself is not a disease condition. The Department issued a clarification (Cook 2002) indicating that OSHA did not consider beryllium sensitization an occupational illness. Sensitization to beryllium may indicate an increased risk, but does not always progress to Chronic Beryllium Disease (CBD). Follow up studies have observed that from 10 to 30 percent of beryllium sensitized workers have progressed to CBD (Arjomandi 2010; Newman 2005; Mroz 2009).
- The physical symptoms of CBD range from sub-clinical (no symptoms noticed by the worker) to severe. Therefore a diagnosis of CBD does not automatically result in an adverse impact on the life of the worker (Mroz 2009). Many cases remain fully functional with only mild or no symptoms. These unimpaired workers should be allowed the choice of continued employment.
- With current level of personal protective equipment and hazard controls there is no basis for removing sensitized individuals from performing many types of beryllium work. The worker may be removed from beryllium work for other health reasons if he/she develops physical symptoms that impact his/her ability to meet certification criteria. For example, if a security guard cannot run due to decreased respiratory function the guard cannot be certified; if a worker can no longer be certified to wear a respirator due to decreased respiratory function, the worker could no longer perform work requiring a respirator. Both of these mandatory medical removals could result in removal from beryllium work.

LANL wishes to stress the importance of informed consent. As is required in the current rule, the affected worker must receive appropriate advice and counseling on: medical test results; medical removal recommendations; medical treatment options; risks of continued exposure;

medical removal protection; and worker rights and responsibilities under the beryllium rule and workers compensation laws.

If the SOMD determines it is medically appropriate to remove a worker from further exposure to airborne beryllium, employers should make all reasonable efforts to minimize or eliminate beryllium exposures for that worker, but the worker should retain the right to consent to medical removal and continue to work with beryllium if the worker chooses to do so.

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