

**DEPARTMENT OF ENERGY****10 CFR Part 850****[Docket No. AU-RM-11-CBDPP]****RIN 1992-AA39****Chronic Beryllium Disease Prevention Program**

**AGENCY:** Office of Environment, Health, Safety and Security, U.S. Department of Energy.

**ACTION:** Notice of proposed rulemaking and public hearings.

**SUMMARY:** The Department of Energy (DOE or the Department) is proposing to amend its current chronic beryllium disease prevention program regulation. The proposed amendments would improve and strengthen the current provisions and continue to be applicable to DOE Federal and contractor employees who are, were, or potentially were exposed to beryllium at DOE sites.

**DATES:** The comment period for this proposed rule will end on September 6, 2016. Public hearings will be held on:

1. June 28–30, 2016, in Richland, WA, from 9 a.m. to 1 p.m. and 6 p.m. to 9 p.m.;
2. July 12–14, 2016, in Oak Ridge, TN, from 9 a.m. to 1 p.m. and 6 p.m. to 9 p.m.;
3. July 27–28, 2016, in Las Vegas, NV, from 9 a.m. to 1 p.m. and 5 p.m. to 8 p.m.; and
4. August 11, 2016, in Washington, DC, from 9 a.m. to 4 p.m.

Requests to speak at any of the hearings should be made by June 24, 2016, for the Richland, WA hearing; July 8, 2016, for the Oak Ridge, TN hearing; July 25, 2016, for the Las Vegas, NV; and August 10, 2016, for the Washington, DC hearing. Each presentation is limited to 10 minutes.

**ADDRESSES:** You may submit comments, identified by docket number AU-RM-11-CBDPP, and/or Regulation Identification Number (RIN) 1992-AA39 in one of four ways (please choose only one of the ways listed):

1. *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
2. *Email:* [Rulemaking.850@hq.doe.gov](mailto:Rulemaking.850@hq.doe.gov). Include docket number AU-RM-11-CBDPP and/or RIN 1992-AA39 in the subject line of the email. Please include the full body of your comments in the text of the message or as an attachment. If you have additional information such as studies or journal articles and cannot attach them to your electronic submission, please send them on a CD or USB flash drive to the

address below. The additional material must clearly identify your electronic comments by name, date, subject, and docket number AU-RM-11-CBDPP.

3. *Mail:* Address written comments to Jacqueline D. Rogers, U.S. Department of Energy, Office of Environment, Health, Safety and Security, Mailstop AU-11, Docket Number AU-RM-11-CBDPP, 1000 Independence Ave. SW., Washington, DC 20585 (due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt). If possible, please submit all items on a CD or USB flash drive, in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Jacqueline D. Rogers, U.S. Department of Energy, Office of Environment, Health, Safety and Security, 1000 Independence Ave. SW., Washington, DC 20585. Telephone 202-586-4714. If possible, please submit all items on a CD or USB flash drive, in which case it is not necessary to include printed copies.

For detailed instructions on submitting comments and additional information on the rulemaking process, see Section VI of this document (Public Participation).

**Docket:** The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at <http://www.regulations.gov>. All documents in the docket are listed in the [regulations.gov](http://www.regulations.gov) index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available. A link to the docket Web page can be found at: <http://www.energy.gov/ehss/chronic-beryllium-disease-prevention-10-cfr-850>. This Web page contains a link to the docket for this notice on the [regulations.gov](http://www.regulations.gov) site. The [regulations.gov](http://www.regulations.gov) Web page contains instructions on how to access all documents, including public comments, in the docket. See Section VI of this document for further information on how to submit comments through [www.regulations.gov](http://www.regulations.gov).

The public hearings for this rulemaking will be held at the following addresses:

1. Richland, WA: Hammer Federal Training Facility, State Department Room, 2890 Horn Rapids Road, Richland, WA 99354;
2. Oak Ridge, TN: The Pollard Technology Conference Center, 210 Badger Avenue, Oak Ridge, TN 37830;

3. Las Vegas, NV: North Las Vegas Facility, 2621 Losee Road, Building B-03, North Las Vegas, NV 89030-4129; and

4. Washington, DC: U.S. Department of Energy, Forrestal Building, Room 1E-245, 1000 Independence Avenue SW., Washington, DC 20585. Requests to speak at any of the hearings should be telephoned in to Meredith Harris, 301-903-6061. For more information concerning public participation in this rulemaking proceeding, see Section VI of this proposed rulemaking (Public Participation).

**FOR FURTHER INFORMATION CONTACT:**

Jacqueline D. Rogers, U.S. Department of Energy, Office of Environment, Health, Safety and Security, Mailstop AU-11, 1000 Independence Ave. SW., Washington, DC 20585, telephone: (202) 586-4714, or Email: [jackie.rogers@hq.doe.gov](mailto:jackie.rogers@hq.doe.gov).

For information concerning the hearings, requests to speak at the hearings, submittal of written comments, or to obtain copies of materials referenced in this document, contact Jacqueline D. Rogers, 202-586-4714.

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- B. Conduct of the Public Hearing
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### I. Introduction

The U.S. Department of Energy (DOE) has a long history of beryllium use because of the element's broad application to many nuclear operations and processes. Beryllium metal and ceramics are used in nuclear weapons, as nuclear reactor moderators or reflectors, and as nuclear reactor fuel element cladding. At DOE, beryllium operations have historically included foundry (melting and molding), grinding, and machine tooling of parts.

The inhalation and exposure to the skin of beryllium particles may cause beryllium sensitization (BeS) and chronic beryllium disease (CBD). BeS is a condition in which a person's immune system becomes highly responsive (allergic) to the presence of beryllium in the body. CBD is a chronic, often debilitating, and sometimes fatal lung condition. There has long been scientific consensus that exposure to airborne beryllium is the only cause of CBD.

The current worker protection permissible exposure limit (PEL) of 2  $\mu\text{g}/\text{m}^3$ , measured as an 8-hour, time-weighted average (TWA), was adopted by the U.S. Department of Labor's (DOL) Occupational Safety and Health Administration (OSHA) in 1971 and codified in 29 CFR 1910.1000, Tables Z-1 and Z-2, by reference to existing national consensus standards. One of DOE's predecessor agencies, the Atomic Energy Commission, had previously established the same limit of 2  $\mu\text{g}/\text{m}^3$  for application at its facilities in 1949, and that limit has remained in effect at DOE's facilities up to the present. In 1977, the National Institute for Occupational Safety and Health (NIOSH), which is part of the U.S. Department of Health and Human Services, classified beryllium as a potential occupational carcinogen. Between the 1970s and 1984, there was a significant reduction in the incidence rate of CBD in the workplace. Coupled with its long latency period, this led to the assumption that CBD was occurring only among workers who were exposed to high levels of beryllium decades earlier; however, DOE medical screening programs continue to discover cases of CBD among workers employed at DOE facilities. These facilities are expected to maintain worker exposures to beryllium at levels below the OSHA

PEL, as well as operate with an action level of 0.2  $\mu\text{g}/\text{m}^3$  that triggers a number of controls and protective measures designed to protect workers when their exposures are at or above that level.

On December 3, 1998, DOE published a notice of proposed rulemaking (NPR) to establish a Chronic Beryllium Disease Prevention Program (CBDPP) (63 FR 66940). After considering the comments received, DOE published its final rule establishing the CBDPP on December 8, 1999 (64 FR 68854). DOE now has more than 14 years of job, exposure, and health data, as well as experience implementing the rule. New research related to BeS and CBD has been published in the years since 1999. In addition, on December 23, 2010, DOE published a Request for Information (RFI) (75 FR 80734) to request information and comments on issues related to its current CBDPP. DOE is publishing this NPR to propose an update to its CBDPP regulations in light of the information it has obtained since December 1999, when the Final Rule was first published. The proposed amendments would strengthen the current CBDPP under 10 CFR part 850, and the worker protection programs established under 10 CFR part 851, *Worker Safety and Health Program*. Consistent with the requirements established in both rules, this proposal would continue to establish a CBDPP designed to reduce the occurrence of CBD among DOE Federal and contractor workers and any other individuals who perform work at a DOE site. The proposed amendments to the CBDPP would continue to accomplish this disease reduction mission through proposed provisions that: (1) Reduce the number of current workers who are exposed to beryllium by clearly identifying and limiting worker access to areas and operations that contain or utilize beryllium; (2) Minimize the potential for, and levels of, worker exposure to beryllium by implementing engineering and work practice controls that prevent the release of beryllium into the workplace atmosphere and/or capture and contain airborne beryllium particles before worker inhalation; (3) Establish medical surveillance to monitor the health of exposed workers and ensure early detection of disease; (4) Establish continual monitoring of the effectiveness of the program in preventing CBD and implementing program enhancements as appropriate, and (5) Require the collection of data to improve the information available to better understand the cause of CBD. The principle proposed amendments would:

- Revise the definitions of beryllium, beryllium worker, and beryllium

associated worker, and add new definitions for beryllium sensitization and chronic beryllium disease.

- Lower the action level to 0.05  $\mu\text{g}/\text{m}^3$ .
- Allow the use portable laboratories.
- Modify the release criteria of formerly beryllium-contaminated equipment or areas without labeling if they contain beryllium in inaccessible locations or embedded in hard-to-remove substances, provided certain levels are not exceeded.
- Allow releasing beryllium-contaminated equipment, items or areas with removable beryllium above 0.2  $\mu\text{g}/100\text{ cm}^2$  or that have beryllium in material on the surface at levels above the natural level in soil at the point of release.
- Ensure beryllium-associated workers are notified yearly of their right to participate in the medical surveillance program.
- Require mandatory medical and periodic evaluations for beryllium workers.
- Require medical evaluations for beryllium and beryllium-associated workers showing signs and symptoms of beryllium sensitization or chronic beryllium disease when the SOMD determines an evaluation is warranted.
- Require exit medical evaluations for beryllium workers and beryllium-associated workers who voluntarily participated in the medical surveillance program
- Add medical restriction requirements for workers.
- Require mandatory medical removal for workers based on the site occupational medicine director's written opinion.
- Ensure beryllium workers are informed and understand that medical testing is mandatory.
- Revise the training requirements for beryllium-associated workers.
- Revised the wording on beryllium warning signs.
- Require labels for equipment or items containing beryllium in inaccessible locations or embedded in hard-to-remove substances.
- Revised the consent forms for beryllium and beryllium-associated workers.

The proposed rule is estimated to cost from \$13.6 million to \$17.2 million (annualized first year costs plus annual costs in 2014 dollars, using a 7 percent discount rate and a 10 year period lifetime of investment). This includes first year costs of \$41.4 million to \$42.7 million, of which \$7.8 million to \$11.2 million are annually recurring costs. In addition, DOE expects its sites will experience cost-savings attributable to

minor changes and clarifications in the proposed amendments to 10 CFR part 850. As discussed in the Economic Assessment, however, DOE was not able to obtain quantitative estimates of these savings, but anticipates the savings would result from:

- *Reduced controls from currently regulated areas that will no longer be regulated under the proposed definition of beryllium.*

- *Reduced surface sampling for areas that are below 0.05 µg/m<sup>3</sup> (instead of the current requirement to conduct sampling wherever beryllium is present).*

- *Reduced turnaround time for exposure monitoring results as a result of using a portable laboratory;*

- *Relaxed requirements for transferring contaminated equipment to another area in which beryllium work is performed.*

- *Reduced costs, avoided confusion, reduced liability, and avoided disputes with employees over DOE's legal liability due to clarifications in the medical removal surveillance and removal requirements.*

- *Reduced medical evaluation costs due to allowing the SOMD to determine what exams and tests are needed for each worker.*

- *Reduced training requirements for beryllium-associated workers (who currently have the same training requirements as beryllium workers).*

DOE expects its sites, contractors and workers to experience the following benefits from the proposed amendment:

- *Reduced medical costs.*

- *Reduced mortality.*

- *Increased quality of life.*

- *Increased medical surveillance for workers at risk.*

- *Increased work-life for beryllium workers.*

- *Reduced confusion and dispute over legal liability for DOE and DOE contractors.*

- *Reduced restrictions and costs for the release and transfer of equipment or areas with potential beryllium contamination.*

- *Reduced control of areas where contamination is a result of naturally high levels of beryllium in the soil or surrounding environment.*

- *Reduced turnaround time for sample analysis due to the use of portable laboratories.*

- *Reduced medical costs for periodic evaluations due to the Site*

*Occupational Medicine Director's ability to judge that certain medical tests may be unnecessary for some workers.*

#### A. Chemical Identification and Use

Beryllium (atomic number 4) is a silver-gray metallic element with a

density of 1.85 g/cm<sup>3</sup> and a high stiffness. The second lightest of the metals, beryllium also has a high melting point (1,285 °C) and high heat absorption capacity.

Beryllium occurs naturally in the earth's surface in about 30 minerals found in rocks, coal and oil, soil, and volcanic dust. Smith et al. report that the concentration of beryllium in surface soils in the United States ranges from 0.09 to 3.4 parts per million (ppm), with a median of 1.2 ppm. Trace levels are present in food, water, and ambient air (ref. 1).<sup>1</sup> Beryllium for industrial use is extracted from beryl and bertrandite ores as beryllium hydroxide, which is the feedstock for production of beryllium oxide, beryllium metal, and beryllium alloys and composite materials (ref. 2). Naturally occurring beryllium containing silicates are mined, processed into feed material, and cut and polished for sale as gemstones. Aquamarine and emerald are examples of gemstone forms of beryl.

Beryllium was not widely used in industry until the 1940s and 1950s. Beryllium can be used as a pure metal, mixed with other metals to form alloys, processed to salts that dissolve in water, and processed to form oxides and ceramic materials. Beryllium is primarily used to stiffen copper into alloys as strong as steel, but which retain copper's corrosion resistance and electrical and thermal conductivity (ref. 2). Copper alloy strip, rod, and wire containing 0.15 to 2.0 percent beryllium is stamped or machined into complex shapes for electrical connectors, clips, springs and molds for plastics. Copper-beryllium alloys are cast and machined into non-sparking tooling, for applications where fire and explosion are a concern, and into bushings, for bearings in landing gear of commercial and military aircraft. Its corrosion resistance has led to its use as housing for undersea cables. High-strength, light weight beryllium-aluminum alloys and composites are used for structural components in aerospace and defense applications. Nickel-beryllium alloys have niche markets as electrical connectors, in jewelry, and in dental prosthetic. The thermal conductivity and transparency to microwaves of beryllium oxide ceramic has led to its use in electronics, microwave and communication equipment.

Beryllium metal has been produced for various industrial uses, especially in the aerospace and defense industries. Both structural and instrument grade materials are manufactured, including

windshield frames and other structures in high-speed aircraft and space vehicles, aircraft and space shuttles brakes, X-ray windows, neutron moderators or reflectors in nuclear reactors, and nuclear weapons components. Beryllium salts (e.g., sulfate or fluoride) and beryllium hydroxide are intermediates in production processes and small quantities are sold for use as laboratory reagents. Copper-beryllium is a common substrate for gold plated electrical connectors and may be encountered during precious metal recovery. Other beryllium materials include soluble beryllium salts and oxides. Beryllium soluble salts such as beryllium fluoride, chloride and sulfate, are used in nuclear reactors, in glass manufacturer, and as catalysts for certain chemical reactions. Beryllium oxide is used to make ceramics for electronics, and other electrical equipment. Beneficial properties of beryllium oxide include hardness, strength, excellent heat conductivity, and good electrical insulation.

Beryllium is also found as a trace metal in materials such as aluminum ore, abrasive blasting grit, and coal fly ash. Abrasive blasting grits such as coal slag and copper slag contain varying concentrations of beryllium, usually less than 0.1% by weight. The burning of bituminous and sub-bituminous coal for power generation causes the naturally occurring beryllium in coal to accumulate in the coal fly ash byproduct. Scrap and waste metal for smelting and refining may also contain beryllium (ref. 3).

Occupational exposure to beryllium can occur from inhalation of dusts, fumes, and mists. Beryllium dusts are created during operations where beryllium is cut, machined, crushed, ground, or otherwise mechanically sheared. Mists can also form during operations that use machining fluids. Beryllium fumes can form while welding with or on beryllium components, and from hot processes such as those found in metal foundries.

Occupational exposure to beryllium can also occur from skin, eye, and mucous membrane contact with beryllium particulates or solutions.

#### B. Health Effects

Beryllium exposure is associated with a wide range of health effects such as acute beryllium disease, immune system response and sensitization (BeS), CBD, lung cancer, and other possible systemic effects. The National Toxicology Program, the International Agency for Research on Cancer (IARC) and the American Conference for Governmental

<sup>1</sup> A listing of references is included as appendix A to this **SUPPLEMENTARY INFORMATION** section.

Industrial Hygienists (ACGIH®) classify beryllium and beryllium compounds as human carcinogens (refs. 4, 5, 6). This section focuses, however, on BeS and CBD because they represent the critical effects for beryllium and beryllium-associated workers at DOE sites and are the focus of the CBDPP regulation and this amendment. As noted in the “Introduction” section of this NOPR “DOE now has more than 14 years of job, exposure, and health data, as well as experience implementing the rule. New research related to BeS and CBD has been published in the years since 1999.” This “Health Effects” section largely highlights these newer studies, particularly epidemiological and experimental studies that provide further insights about BeS and CBD—exposure, early disease detection, and disease progression.

#### 1. Beryllium Sensitization (BeS)

BeS is an immune system response triggered by beryllium exposure (ref. 7). BeS can occur quickly or many years after exposure to beryllium, potentially progressing into disease (ref. 8). Only a subset of workers exposed to beryllium ever become sensitized. Reported prevalence of BeS ranges from less than 1% up to 19% (refs. 6, 7). BeS alone does not cause physical symptoms. However, individuals showing evidence of BeS may develop subclinical and clinical CBD, including disabling forms.

Sensitization to beryllium can result from both inhalation and skin exposure (refs. 5, 6, 7). The 2008 National Academy of Sciences review points to the hypothesis that “penetration of the skin by poorly soluble beryllium particles may be an immunologic route to sensitization, as can occur with skin contact and soluble beryllium salts” (ref. 7). The authors comment that some exposures may make beryllium more bioavailable to the skin (soluble metals and liquids) and others more bioavailable to the lung (respirable particles, mists and vapors). Tinkle, et al. observed that beryllium particles less than 1 micrometer in diameter, can penetrate intact human skin and reach dermal layers where sensitization can occur (ref. 9). Henneberger et al. found a contrast in chronic beryllium disease between long-term and short-term workers but not a contrast in BeS between these workers (ref. 10). The Henneberger study concludes that short-term workers may have developed beryllium sensitization from skin exposure. Day et al. published a review of the published literature, including epidemiologic, immunologic, genetic, and laboratory-based studies of *in vivo* and *in vitro* models concerning skin

exposure to beryllium (ref. 11). The authors hypothesized “that skin exposure to beryllium may be sufficient to cause sensitization, while inhalation is necessary for progression to lung disease.” The ACGIH® and IARC have assigned a skin notation for beryllium and compounds, with the goal of preventing dermal exposure and possible sensitization by this route, possible absorption of beryllium through open cuts or wounds, and secondary inhalation of beryllium via the re-suspension of settled dust (refs. 5, 6).

As mentioned earlier, individuals sensitized to beryllium are asymptomatic and are not physically impaired. Once sensitization has occurred, it is medically prudent to prevent additional exposure to beryllium. Physicians generally recommend removing the sensitized individual from future beryllium exposure to reduce the risk of progression, based on experience with other immunologically mediated diseases and evidence that exposure is a risk factor for developing CBD. No published research studies are available, however, examining whether the general practice of recommending removal is a benefit. Moreover, the National Academy of Sciences points out that designing a study that would randomize workers to continue or avoid exposure “would likely be considered unethical because of the potential severity of CBD” (ref. 7).

The Beryllium-Induced Lymphocyte Proliferation Test (BeLPT) is used as a diagnostic tool, as well as for medical surveillance and screening for BeS. Currently, it is the most commonly available diagnostic tool for identifying BeS.

#### 2. Chronic Beryllium Disease (CBD)

CBD is an immune-mediated, granulomatous lung disease caused by exposure to airborne beryllium particulate (ref. 8). Granulomas are abnormal tissues that form due to a proliferation of immune system cells known as lymphocytes. In the lung, accumulations of granulomas can interfere with gas exchange between the blood and the lungs. The immune response to beryllium in the lung includes inflammation, which, if it persists, forms scar tissue (fibrosis), resulting in permanent lung damage. This beryllium-induced proliferative and granulomatous response is specific to CBD. CBD pathology is similar to sarcoidosis, a more common disease. Sarcoidosis, however, usually resolves during its normal course, whereas clinically evident CBD generally does

not resolve but may reach a steady state condition and may worsen over time.

Frequently reported symptoms of CBD include one or more of the following: dyspnea (shortness of breath) on exertion, cough, fever, night sweats, chest pain, and, less frequently, arthralgias (neuralgic pain in joints), fatigue, weight loss, and appetite loss. On physical examination, a physician may find signs of CBD, such as rales (changes in lung sounds), cyanosis (lack of oxygen), digital clubbing (thickening or widening of the ends of the fingers or toes), or lymphadenopathy (enlarged lymph nodes). A radiograph (X-ray) of the lungs may show many small scars. Patients may also have abnormal breathing and pulmonary function test results. Examination of the lung tissue under the microscope may show granulomas, which are signs of damage due to the body’s reaction to beryllium. In advanced cases, there may be manifestations of right-sided heart failure, including cor pulmonale (enlarged right ventricle of the heart caused by blockage in the lungs).

Individuals with CBD may experience mild to severe forms of disease. In severe cases, the affected individuals may be permanently and totally disabled. Mortality of the sensitized individuals directly attributable to CBD and its complications is estimated to be 30% (ref. 12). This estimate is based upon historical data reflecting both the higher levels of exposure that occurred in the workplace prior to regulation of workplace exposure to beryllium in the late 1940s and a tracking of the medical history of subjects of CBD over several decades. DOE’s recent experience with improved diagnoses and treatments may result in a lower mortality rate for CBD cases.

The BeLPT is used as a diagnostic tool for patients who present with possible CBD, as well as for medical surveillance and screening for BeS. For individuals with abnormal blood BeLPT screening results, a positive BeLPT conducted on cells washed from a segment of the lung of an individual can help confirm the presence of CBD. In the absence of granulomata or other clinical evidence of CBD, individuals with a positive BeLPT are classified as sensitized to beryllium.

Stange et al. provided estimates of the sensitivity and specificity of the BeLPT for BeS by evaluating paired results from different testing laboratories. The authors examined 20,275 BeLPT results from medical evaluations of 7,820 current and former DOE workers over a 10-year period. The program led to the diagnosis of 117 cases of CBD and the confirmation of 184 cases of BeS

without disease for a combined prevalence of 3.85% (301/7,820) (ref. 13). With borderline BeLPT results included, the sensitivity of the test was estimated to be 68.3% and the specificity was estimated to be 96.9%. In this same population, the percentage of beryllium sensitized individuals found to have CBD by clinical evaluation (positive predictive value) ranged from 71% for 24 sensitized beryllium machinists to 9% for 11 sensitized scientists, with an overall average of 35% for 235 subjects found sensitized by this study (ref. 14).

As noted above, BeS precedes the development of CBD, but the true risk and rate of disease progression is not known based on available study data (refs. 6, 7, 15). Data suggests that CBD can occur at relatively low exposure levels and, in some cases, after relatively brief durations of exposure (ref. 14). However, CBD can take months to years after initial beryllium exposure before signs and symptoms appear (ref. 15).

The clinical course—the latency period, rate of progression, and severity—of CBD is highly variable. A 2008 National Academy of Sciences review states “CBD has a clinical spectrum that can range from evidence of BeS and granulomas of the lung without clinically significant symptoms or deficits in lung function to end-stage lung disease” (ref. 7). Individuals who only have evidence of BeS and granulomas may or may not progress to a disabling form of CBD. Some individuals deteriorate rapidly; most experience long, gradual deterioration. Treatment generally consists of oral corticosteroid therapy. If lung damage is evident, CBD is treated with anti-inflammatory medications based on the course of treatment used for sarcoidosis to try to reduce granulomas, improve lung function, and minimize permanent damage from fibrosis. Individuals with impaired gas exchange may require continuous oxygen administration.

The observed variability in the clinical progression of CBD is possibly due to variation in exposure amount, route and type, and genetic and other host susceptibility factors. The factors that affect progression are not understood well enough to allow physicians to provide patients with specific advice on their likely prognosis. Currently, there is no medical therapy to prevent possible progression of BeS to CBD. Diagnostic evaluations are required to determine whether a BeS individual has progressed to CBD. Workers are counseled to seek medical attention if they develop new or worsening respiratory symptoms.

A number of studies suggest that the rate of progression from BeS to CBD may be related to the level of exposure and the form of beryllium (ref. 16). Newman et al. evaluated a group of patients with BeS but no CBD at two-year intervals (ref. 15). Of the 55 patients, 17 (31%) progressed to CBD within an average of 3.8 years. In this group, machinists had a higher risk of progression to CBD. The group of 55 patients was a subset of patients described in a subsequent publication by Mroz et al., which examined 171 beryllium exposed workers with CBD and 229 with BeS to look at risk factors for, and progression of, surveillance-identified CBD over a 20 year period (ref. 16). In addition to being machinists, those diagnosed with CBD, as opposed to BeS only, were more likely to have been exposed in the ceramics industry and less likely to have only bystander exposures, suggesting that the form and dose of beryllium may contribute to development of CBD. It was reported that 8.8% of all workers initially identified as having BeS only developed CBD over the course of the study. The study noted that physiologic changes can occur from within one month of first exposure to beyond 30 years from first exposure. However, the authors note that clinical follow-up was incomplete for this larger cohort.

Rosenman et al. studied 577 former workers from a beryllium processing plant whose first exposure, on average, began in the 1960s (ref. 17). This study involved testing subjects more than 20 years after their last exposure to beryllium. The authors identified 7.6% to have definite or probable CBD and another 7.0% with BeS at the time of the study. Those with BeS had a shorter duration of exposure to airborne beryllium, began work later, worked with beryllium longer ago, had lower measures of cumulative and peak exposure to airborne beryllium, and had lower non-soluble beryllium exposures than those with CBD, again suggesting that exposure variables may affect progression from BeS to CBD.

Two other studies have also reported that individuals with positive blood BeLPTs were less likely to have CBD at the time of their initial evaluation if they had jobs and worked in industries with low airborne beryllium exposures. Welch et al. report a total of 75,000 construction workers potentially available for screening, of which 4,458 were initially screened. Of those, 3,842 completed beryllium testing (BeLPT) (ref. 18). The authors reported that 53 (1.4%) of those tested had two or more abnormal BeLPT results. Of the 33

workers who were clinically evaluated, 5 (15%) were diagnosed with CBD. Arjomandi et al. reported similar results among current and former workers at Lawrence Livermore National Laboratory (LLNL) (ref. 19). Among the 1,875 participants tested, 59 (3.1%) were found with BeS. Of these, 50 accepted the offer of a clinical evaluation and 40 consented to bronchoscopy and bronchoalveolar lavage. Five of the 40 (12.5%) were diagnosed with CBD. The authors compared workroom air monitoring results from LLNL and the DOE Rocky Flats Plant and found the results from LLNL were much lower than those from the DOE Rocky Flats Plant. In addition, the incidence of CBD in workers identified as being sensitized was lower at LLNL (12.5%) than Rocky Flats where 38% of BeS cases were diagnosed with CBD. Therefore, there appears to be a correlation between the level of exposure to airborne beryllium and the incidence of disease.

Studies have shown that some people who are diagnosed with CBD have never been occupationally exposed to beryllium. For example, under the direction of Dr. Thomas Mancuso, 16 cases of CBD were diagnosed by X-ray examination among 20,000 residents living in Lorain, Ohio (ref. 20). Likewise, a 1949 report described 11 patients with CBD who lived near a beryllium extraction plant (ref. 21). Ten of the 11 lived within  $\frac{3}{4}$  of a mile of the plant and exposure from the plant discharges into the air was the suggested cause of their CBD. Measurements of air concentrations of beryllium at various distances from the plant provided the basis for the Environmental Protection Agency's (EPA's) community permissible exposure limit (24-hour ambient air limit of 0.01 microgram of beryllium per cubic meter of air).

In addition, CBD has been reported among family members of beryllium workers who were presumably exposed to contaminated work clothing during the 1940s and 1950s (refs. 22, 23). The virtual disappearance of CBD caused by air pollution or household exposure has been attributed to more stringent control of air emissions and improved work practices, such as mandatory work clothing exchange. However, in 1989, a woman previously diagnosed with sarcoidosis was diagnosed with CBD. The woman had no occupational exposure to beryllium, but her husband was a beryllium production worker. This was the first new case of non-occupational CBD reported in 30 years (ref. 24).

*C. Beryllium Exposure at DOE Facilities*

The Department's medical screening programs discovered cases of CBD among workers who were first exposed after 1970, when DOE facilities were expected to maintain workers' exposure to beryllium below the OSHA PEL. As of September 30, 2014, the DOE Former Worker Medical Screening Program has provided BeLPTs to 64,645 former DOE and DOE contractor employees at least once. Of those, 823 (1.3%) had one abnormal BeLPT; 650 (1.0%) had two abnormal BeLPTs; and 223 (0.03%) had one abnormal and one+ borderline BeLPT result (one+ borderline BeLPT means the individual had more than one borderline BeLPT). Of the 64,645 former DOE and DOE contractor employees initially screened, 19,496 were

rescreened. Of those rescreened, 139 (0.7%) had one abnormal BeLPT, 163 (0.8%) had two abnormal BeLPTs, and 71 (0.4%) had one abnormal and one+ borderline BeLPT.

The final rule, issued in 1999, established a Beryllium-Associated Worker Registry (the Beryllium Registry) to gather beryllium task, exposure, and health data for use in identifying trends that inform DOE in how best to continuously improve the Department's CBDPP. In 2002, employers began submitting data to the Beryllium Registry. As of December 2013, a total of 29,869 current beryllium and beryllium-associated workers are listed in the Beryllium Registry. Of those beryllium and beryllium-associated workers, 21,921 (71%) had been screened using BeLPT and 8,416 (28%)

were not screened. Of the workers screened, 20,900 (97%) had normal results while 553 (3%) had abnormal results. Of the 553 workers with abnormal results, 407 (74%) had BeS and 146 (26%) had CBD.

Table 1 shows the BeS and CBD rates at DOE sites. Genetic factors have been reported to be a risk factor in determining who will progress from BeS to CBD (ref. 25). This makes a few percent of exposed individuals more sensitive to exposure to beryllium (ref. 26). DOE assumes that the proportion of workers with a genetic predisposition to contract BeS and CBD is essentially the same among the different sites and, therefore, differences in the prevalence of sensitization and disease among the sites are due to differences in exposure levels.

TABLE 1—PREVALENCE OF SENSITIZATION (BES) AND CHRONIC BERYLLIUM DISEASE (CBD) BY DOE SITE THROUGH 2013

Site	Employees with BeLPT results	Sensitized employees (no CBD)		CBD Employees	
Advance Mixed Waste Treatment Project .....	21	0	0%	0	0%
Ames Laboratory .....	34	2	5.9%	0	0%
Argonne National Laboratory .....	142	3	2.1%	0	0%
Brookhaven National Laboratory .....	25	1	4.0%	0	0%
DOE Oak Ridge Office .....	93	1	1.1%	0	0%
East Tennessee Technology Plant .....	399	6	1.5%	4	1.0%
Fermi National Accelerator Laboratory .....	20	0	0%	0	0%
Hanford Site .....	7,480	91	1.2%	34	0.5%
Idaho National Laboratory .....	355	3	0.8%	0	0%
Kansas City Plant .....	1,208	41	3.4%	14	1.2%
Knolls Atomic Power Laboratory .....	29	0	0%	0	0%
LATA Environmental Services of Kentucky, LLC (PAD LATAKY) ..	112	2	1.8%	0	0%
Lawrence Berkeley National Laboratory .....	26	1	3.8%	0	0%
Lawrence Livermore National Laboratory (LLNL) .....	1,337	41	3.1%	3	0.2%
LLNL-Clean Harbors Environmental Services .....	13	0	0%	0	0%
Los Alamos National Laboratory .....	2,474	21	0.8%	3	0.1%
National Strategic Protective Security Services .....	10	0	0%	0	0%
Nevada National Security Site .....	1,028	23	2.2%	4	0.4%
Oak Ridge National Laboratory .....	639	14	2.2%	0	0%
Pacific Northwest National Laboratory .....	151	0	0%	0	0%
Pantex .....	1,756	27	1.5%	15	0.9%
Sandia National Laboratory .....	604	1	0.2%	0	0%
Savannah River Site .....	713	15	2.1%	6	0.8%
Stanford Linear Accelerator Center .....	47	0	0%	1	2.1%
Y-12 .....	2,691	114	4.2%	62	2.3%
Y-12 Navarro-Gem Joint Venture .....	18	0	0%	0	0%
Y-12 URS Corporation .....	28	0	0%	0	0%
Totals .....	21,453	407	1.9%	146	0.7%

**Note:** "Sensitized" indicates the number of individuals found sensitized from two or more peripheral blood BeLPTs or from a bronchoalveolar lavage BeLPT, and does not include individuals who have been diagnosed as having CBD.

*D. Value of Early Detection*

Early detection of a disease is of value if it leads to reduced exposure, earlier treatment and a better prognosis for the tested individual. Screening for CBD with the BeLPT of peripheral blood can provide less invasive, earlier detection than is possible with other tests. In some cases, this has led to diagnosis and

early treatment of CBD to reduce lung damage that may not have been possible if the CBD remained undiagnosed by other tests. In addition, there is increasing evidence that removal from exposure or reduction in exposure can lower the likelihood of progression from BeS to CBD and disability.

Pappas and Newman compared the lung functions of patients with CBD who had been identified through abnormal chest X-rays or clinical symptoms to those of patients with CBD who had been identified through positive BeLPTs of peripheral blood (ref. 27). Twelve of 21 BeLPT-positive patients were subsequently found to

have lung abnormalities, including reduced exercise tolerance. Fourteen of the 15 patients identified through chest X-rays or clinical symptoms had abnormal lung function, and their abnormalities were more severe than those identified through a positive BeLPT. The authors concluded that screening with the BeLPT of peripheral blood was useful because it permitted detection of CBD earlier in the disease process, when individuals are likely asymptomatic.

Early treatment of CBD may prevent progression of disease to permanent lung damage and disability. Although not providing definitive proof, studies have concluded that the long-standing standard of care for CBD has been shown to reduce the progression of disease in some patients. Marchand-Adams et al. (ref. 28), for example, concluded:

Corticosteroid treatment in patients suffering from serious chronic beryllium disease improved symptoms, pulmonary function tests and radiology by acting on inflammatory granulomas. The control of inflammatory granulomatosis limited the fibrotic evolution as long as doses were monitored under the control of clinical examination, serum angiotensin-converting enzyme and high resolution computed tomography scanning. However, corticosteroids seemed insufficient to stop this poor evolution for some patients.

Though a small study, the observed effectiveness of corticosteroids in suppressing the growth of granulomas and limiting progressive fibrosis in the majority of patients in the study suggests that proactive treatment may prevent the progression of disease to permanent lung damage and disability. BeS identified via BeLPT screening provides the earliest indication that working conditions and work practices are affecting the health of exposed workers. This allows for an earlier opportunity to initiate corrective actions and possibly to prevent cases of CBD.

## II. Legal Authority and Relationship to Other Programs

This proposed rule continues to establish minimum requirements for the protection of beryllium and beryllium-associated workers, and is being promulgated pursuant to DOE's authority under section 161 of the Atomic Energy Act of 1954, as amended (AEA) to prescribe such regulations as it deems necessary to govern any activity authorized by the AEA, specifically including standards for the protection of health and minimization of danger to life or property (42 U.S.C. 2201(i)(3) and (p)). Also, section 3173(a) of the Bob Stump National Defense Authorization

Act for 2003, Public Law 107-314, amended the AEA by adding section 234C, and required DOE to "promulgate regulations for industrial and construction health and safety at Department of Energy facilities that are operated by contractors covered by agreements of indemnification under section 170 d. of the Atomic Energy Act of 1954," and authorized DOE to impose civil or contract penalties for violations of such regulations. Additional authority for the rule insofar as it applies to DOE Federal employees, is found in section 19 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 668) and Executive Order 12196, *Occupational Safety and Health Programs for Federal Employees* (5 U.S.C. 7902 note), which requires Federal agencies to establish comprehensive occupational safety and health programs for their employees. The Department recognizes that OSHA published a proposed rule, *Occupational Exposure to Beryllium and Beryllium Compounds* (80 FR 47565, August 7, 2015), that may differ from the CBDPP established in 10 CFR 850. The Department published its CBDPP in December 1999, after an extensive public review and comment period that included the DOE regulated community and its stakeholders. This notice proposes amendments to the CBDPP rule that would improve and strengthen the current provisions of the rule based on DOE's more than 14 years of experience implementing the rule. DOE believes the proposed amendment represents a balanced, well thought out approach reflecting the perspective of the DOE regulated community and its stakeholders. To avoid potential confusion between the CBDPP and OSHA's proposed beryllium rule, the Department has amended 10 CFR 851, *Worker Safety and Health Program* (80 FR 69564, November 10, 2015), to clarify its intent to only apply OSHA's 8-hour time weighted average permissible exposure limit (TWA PEL) for beryllium, and that DOE and DOE contractors are not subject to any other beryllium-specific OSHA requirements, including the ancillary provisions (e.g., exposure assessment, personal protective clothing and equipment, medical surveillance, medical removal, training, and regulated areas or access control) OSHA has recently proposed to add to its health standard, if adopted by OSHA.

## III. Issues on Which DOE Requests Information and Seeks Comment

### A. Request for Information

The Department is considering additional requirements in other areas covered by the NOPR. It is especially interested in comments supported by technical evidence, rationale, and cost whenever possible, regarding the following areas:

1. *Surface action level.* It appears that not all individuals who become sensitized progress to disease, but individuals with CBD are sensitized, which suggests that sensitization must occur before disease can occur. Preventing sensitization should, therefore, prevent disease.

DOE has found no studies that have determined a threshold of beryllium surface contamination that results in skin contact that, in turn, results in beryllium sensitization although a number of epidemiology studies and reviews of studies suggest that skin contact causes sensitization. DOE, therefore, is relying upon operational experience, rather than a demonstrated relationship between surface levels and health effects, in considering to propose a surface action level which would require employers to implement specified provisions of the rule.

DOE is considering adding in the final rule a surface action level of 1.5 µg/100 cm<sup>2</sup> as a preventive approach to control the beryllium health risk. This level is based on the assumption that surface contamination is a potential source of exposure through re-entrainment from energetic tasks. The Department requests that interested parties submit comments regarding the validity of a 1.5 µg/100 cm<sup>2</sup> surface action level. If an alternate level is suggested, provide the rationale and associated cost implications for choosing the alternate surface action level.

2. *Beryllium restricted areas.* Currently, part 850 provides for "regulated areas", which are areas demarcated by the employer in which the airborne concentration of beryllium is at or above, or can reasonably be expected to be at or above, the action level. However, part 850 contains no provision for demarcating areas designating specified surface levels of beryllium. The Department is considering requiring in the final rule the establishment of beryllium restricted areas where the surface levels of beryllium are at or above a surface action level of 1.5 µg/100 cm<sup>2</sup>, restricting access to authorized persons, and requiring employers to demarcate and control restricted areas from the rest of the workplace in a manner that alerts

workers to the boundaries of such areas. The Department requests that interested parties provide information on the feasibility and effect of requiring such restricted areas.

3. *Medical screening for individuals conditionally hired for beryllium work.* When part 850 was issued in December 1999, DOE viewed the value of medical evaluations for beryllium-induced medical conditions in informing placement decisions to be limited by the fact that sensitization could not occur prior to initial exposure to beryllium. However, DOE has learned from experience that individuals working at DOE sites often have a history of employment at several sites. Their qualifications, such as having security clearances, radiation worker training, and hazardous waste site worker training, make them attractive candidates for positions around the entire DOE complex. As a result, newly hired beryllium workers may have previously been exposed to beryllium at a different DOE site and may have already developed BeS or CBD. It is also possible that newly hired beryllium workers were previously exposed to beryllium while working for other employers.

DOE believes the early detection, made possible with medical evaluations is essential for ensuring that individuals who have been adversely affected by beryllium are not placed in a job where they will be exposed to beryllium at or above the action level. In addition, given that under this NOPR, current beryllium workers with BeS and CBD will be subject to medical removal, and current beryllium workers with another medical condition for which exposure to beryllium at or above the action level would be contraindicated will be subject to medical restriction, the Department does not believe it is reasonable to place newly hired individuals with such conditions into jobs where the airborne concentration of beryllium is at or above the action level if they too would be subject to removal or restriction once hired. Under Section 161 of the AEA, the Department has broad authority to prescribe such regulations as it deems necessary to govern any activity authorized by the AEA, including standards for the protection of health and minimization of danger to life. Accordingly, DOE is considering including a requirement for mandatory medical screening of individuals conditionally hired for beryllium work to determine if such individuals have a medical condition for which exposure to beryllium at or above the action level is contraindicated. An "individual

conditionally hired for beryllium work" would be an individual who has been offered a job as a beryllium worker (either a new hire or a current worker being transferred into a new job as a beryllium worker), but such offer would be subject to the outcome of a medical evaluation. DOE would require as part of these provisions that the employer inform applicants that any job offer would be conditional pending outcome of a medical evaluation, thus, candidates would have the option of not accepting the conditional offer.

In those cases where the medical screening indicates the individual conditionally hired for beryllium work has CBD, BeS, or another medical condition for which exposure to airborne concentrations of beryllium at or above the action level would be contraindicated, and the employer determines that no reasonable accommodation is available to enable the conditionally hired individual to work in an area where the airborne concentration of beryllium is at or above the action level, the employer would not be permitted to retain the individual as a beryllium worker. Such conditionally hired individuals would not be eligible for medical removal benefits under 10 CFR 850.36. Currently, under 10 CFR part 851, appendix A section 8(g)(2)(i), the occupational medical provider *may* require "[a]t the time of employment entrance or transfer to a job with new functions and hazards, a medical placement evaluation of the individual's general health and physical and psychological capacity to perform work" to "establish a baseline record of physical condition and assure fitness for duty." Therefore, the Department is considering including in § 850.34(b)(1)(iii) a provision that would require employers to use the medical evaluation provided to conditionally hired individuals as the baseline medical evaluation for newly hired beryllium workers.

For consistency in the examinations provided to conditionally hired individuals, the Department is considering adding a provision requiring the identification of the elements of such examinations. In such cases, the Department is considering adding in § 850.34(c) the following:

- Employers would be required to provide individuals conditionally hired for beryllium work the required medical evaluations and procedures at no cost, and at a time and place that is reasonable and convenient for the conditionally hired individual.
- Employers would be required to inform applicants for jobs where exposure to airborne concentration of

beryllium is at or above the action level, that:

- The job involves a beryllium activity at or above the action level, includes a medical qualification, and requires a medical evaluation;
  - Any job offer would be conditional pending the outcome of the medical evaluation;
  - The employer would not be permitted to retain the individual as a beryllium worker if the Site Occupational Medical Director (SOMD) diagnosis indicates the individual has CBD, BeS, or another medical condition for which exposure to beryllium at or above the action level would be contraindicated, and the employer determines that no reasonable accommodation is available to enable the conditionally hired individual to work in a beryllium activity; and
  - Once conditionally hired, no work or training may be performed prior to the worker being cleared by the SOMD for beryllium work.
  - Employers would be prohibited from asking or requiring a conditionally hired individual to have a medical evaluation performed before making the conditional job offer.
  - Employers would be required to ensure both the SOMD and the conditionally hired individual complete the consent form included in an appendix, before any medical evaluations of the conditionally hired individual are performed.
  - Medical evaluations for conditionally hired individuals would be required to include:
    - A detailed medical and work history with emphasis on exposure or potential exposure to beryllium;
    - A respiratory symptoms questionnaire;
    - A physical examination, with special emphasis on the respiratory system, skin, and eyes;
    - A chest radiograph (posterior-anterior, 14 x 17 inches) or a standard digital chest radiographic image, interpreted by a NIOSH B-reader of pneumoconiosis or a board-certified radiologist;
    - Spirometry consisting of forced vital capacity (FVC) and forced expiratory volume at one second (FEV<sub>1</sub>);
    - Two peripheral blood BeLPTs; and
    - Any other tests that would be deemed appropriate by the SOMD for evaluating beryllium-induced medical conditions.
- The Department is considering adding a new § 850.34(d)(3), which would provide the requirements for the medical opinion and determination for individuals conditionally hired for beryllium work. This proposed new

section would require, with respect to a conditionally hired individual, that:

- The SOMD's written opinion to the employer would:
  - Be delivered within 10 working days after the SOMD received the results of the medical evaluation performed pursuant to proposed § 850.34(c)(5); and
  - Contain a determination of whether the conditionally hired individual is sensitized to beryllium, has CBD, or has another medical condition for which exposure to beryllium at or above the action level would be contraindicated.
- The employer would not be permitted to retain the conditionally hired individual as a beryllium worker, if the SOMD determines that the individual conditionally hired for beryllium work has CBD, BeS, or another medical condition for which exposure to beryllium at or above the action level would be contraindicated, and the employer determines that no reasonable accommodation is available to enable the conditionally hired individual to work in a beryllium activity.

The Department is considering including in part 850 an appendix with a new mandatory form for conditionally hired individuals to ensure they receive consistent information on the medical testing required prior to working in a beryllium area. This proposed new form would be similar to the proposed mandatory form in appendix A and entitled: *Conditionally Hired Individual Chronic Beryllium Disease Prevention Program Consent Form*, and include sections for consent, medical evaluation consent, and the physician's review of the medical evaluation results. DOE is aware that the term "informed consent" has a different meaning when used in other contexts (e.g., human subject research). The Department, however, used this term in the original 10 CFR part 850 published in December 1999 to ensure beryllium associated workers were informed of the medical evaluation process before medical evaluations were performed. However, DOE is proposing to not use "informed consent" but would use the term "consent" and expand it to address consent for medical evaluations for conditionally hired individuals. See part A of the proposed mandatory form in appendix A.

The Department is requesting that interested parties provide their comments supported by technical evidence, rationale, and cost information whenever possible, on the feasibility and the effect of mandatory medical qualification for conditionally hired individuals for beryllium work. Alternatively, the Department is

considering allowing conditionally hired individuals and current beryllium workers who are sensitized to beryllium but who do not have CBD to work in a beryllium job after signing an acknowledgment stating the worker has been informed of the risks of continued exposure to beryllium and has voluntarily elected to work in a beryllium job. The Department is also requesting that interested parties provide their comments supported by technical evidence, rationale, and cost information whenever possible, on the feasibility and the effect of allowing workers who are sensitized to beryllium to work in a beryllium job.

4. *Mandatory medical evaluations and removals.* DOE is proposing both mandatory medical evaluations and mandatory medical removal provisions under this proposed amendment based on its commitment to the health and safety of its workers and the understanding that early detection and removal from beryllium exposure is important to prevent harm to workers at risk for developing CBD. Based on these considerations, DOE believes that these provisions are responsible and prudent measures in protecting the health of DOE and contractor workers. DOE recognizes that its proposed lower action level may result in an increased number of activities or work areas that pose the potential for airborne concentrations of beryllium at or above the action level with a corresponding increased number of beryllium workers subject to mandatory medical evaluations and the potential for mandatory medical removals. DOE believes, however, that the additional protections (triggered by the action level) available to workers at a lower action level would result in reduced worker exposures and fewer workers developing BeS or CBD. Since medical removal would be triggered by a BeS or CBD diagnosis, this would result in fewer workers being subject to medical removal.

DOE received several comments concerning whether to continue to require a worker's consent for medical removal, or instead require mandatory medical removal in response to its RFI. The majority of commenters recommended that DOE establish a mandatory medical removal practice (see discussions on proposed § 850.34(c) in the section-by-section analysis). In this NOPR, the Department requests that interested parties provide information on proposing the use of mandatory medical evaluations and medical removal for its beryllium workers, including evidence of their effectiveness, feasibility and

appropriateness relative to voluntary approaches.

5. *Site Occupational Medicine Director's written medical opinion.* DOE is aware of the increased concerns about protection of confidential medical information that have arisen since December 1999, when the current Final Rule was published. DOE is also aware that employers are not necessarily covered entities under the Health Insurance Portability and Accountability Act Privacy Rules, and that the American College of Occupational and Environmental Medicine has stated that "Physicians should disclose their professional opinion to both the employer and the employee when the employee has undergone a medical assessment for fitness to perform a specific job. However, the physician should not provide the employer with specific medical details or diagnoses unless the employee has given his or her permission." In light of this, DOE requests comment on the proposed requirement for Site Occupational Medicine Directors (SOMDs) to provide employers with a written medical opinion that includes any diagnosis of the worker's condition related to exposure to beryllium (i.e., BeS, CBD or any other medical condition for which exposure to beryllium at or above the action level would be contraindicated). See proposed § 850.34, Medical Surveillance.

#### *B. Issues on Which DOE Seeks Comment*

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

1. DOE requests comment on the proposed definitions of beryllium and beryllium-associated workers. See proposed § 850.3.

2. DOE is requesting comments on the proposed definition of beryllium. DOE believes that soluble forms of beryllium are not used at its beryllium sites, and is proposing to exclude soluble forms of beryllium from the definition of beryllium. See proposed § 850.3.

3. DOE requests information on the different forms of beryllium (i.e., soluble and insoluble) and the health effects associated with each form. See the definition of "beryllium" in proposed § 850.3. DOE is requesting comments on and evidence to support the following statement: DOE has learned by experience that common conditions and practices at DOE facilities—such as accumulations of wind-blown dust, abrasive blasting of brick surfaces with coal slag, and drilling into and

demolishing concrete structures—can result in breathing zone and surface levels at or above the proposed action level and release criteria, but with forms of beryllium that are not believed to cause BeS or CBD or with activities with work practices in place that mitigate the risks. See discussion on the definition of “beryllium” in proposed § 850.3.

5. DOE is requesting comment on its proposal to lower the action level which triggers key worker protection measures, from 0.2 µg/m<sup>3</sup> to 0.05 µg/m<sup>3</sup>. See proposed § 850.23.

6. DOE summarized various studies to address the major adverse health effects associated with exposure to beryllium. Are there additional studies or other data DOE should consider in evaluating the health effects of beryllium exposure? What is known or not known about factors influencing disease progression (including continued exposure and varying forms of beryllium) and the reported limitations and challenges in interpreting available study data (e.g., small study sizes, limited exposure data, variability in susceptibility). See Health Effects and References sections of the preamble.

7. DOE recognizes that the potential for developing contact dermatitis,

chronic ulcerations, and conjunctivitis is mainly associated with contact with soluble forms of beryllium compounds. DOE believes that soluble forms of beryllium are not used at its beryllium sites. Is DOE correct in this assumption? If soluble forms of beryllium are used, please indicate so and provide the operations where they are in use. See proposed § 850.29.

8. DOE estimated the compliance costs of the proposed rule by using data from the 1999 Economic Analysis (EA), Beryllium Registry, and an Economic Assessment Questionnaire (EAQ). The EAQ is a questionnaire administered by DOE to its sites potentially affected by the proposed rule in order to solicit the per-site cost of compliance with each provision of the proposed rule. DOE is requesting interested parties to provide comments on the per-site cost data used to prepare the EA for this proposed rule, and to provide alternate estimates where available. See Economic Assessment, section 3.

#### IV. Section-by-Section Analysis

##### Overview of the Proposed Rule

The provisions of the proposed rule are presented in three main subparts: A,

B, and C. Subpart A of the proposed rule would describe the scope and applicability of the proposed rule, defines terms that are critical to the proposed rule's application and implementation, provides its proposed enforcement and dispute resolution provision. Subpart B would establish administrative requirements to develop and maintain a CBDPP and to perform all beryllium-related activities according to the CBDPP. Subpart C would establish requirements for the content and implementation of the CBDPP by focusing on protecting workers from being exposed to airborne beryllium, preventing BeS and CBD and providing benefits for workers with BeS or CBD who are or were removed from work assignments where the exposure to airborne beryllium is or was at or above the action level. Some of the proposed provisions of Subpart C apply only when it is determined that the airborne concentration of beryllium in a specific workplace or operation rises above the specified limit. Table 2 summarizes these provisions and indicates the levels of beryllium at which the provisions would apply.

TABLE 2—LEVELS AT WHICH THE PROPOSED PROVISIONS OF THE CBDPP WOULD APPLY

Proposed provisions	Worker exposure or potential exposure levels (8-Hour TWA)		
	Be operation/ location <sup>a</sup>	≥ Proposed action level (0.05 µg/m <sup>3</sup> )	≥ PEL (8-hr TWA) (2.0 µg/m <sup>3</sup> )
Baseline Inventory (850.20) .....	X	.....	.....
Hazard Assessment and Abatement (850.21) .....	X	.....	.....
Initial Exposure Monitoring (850.24) .....	X	.....	.....
Periodic Exposure Monitoring (850.24) .....	.....	X	.....
Exposure Reduction (850.25) .....	X <sup>b</sup>	X	.....
Beryllium Regulated Areas (850.26) .....	.....	X	.....
Hygiene Facilities and Practices (850.27) .....	.....	X	.....
Respiratory Protection (850.28) .....	.....	X	X <sup>c</sup>
Protective Clothing and Equipment (850.29) .....	X <sup>d</sup>	X	.....
Housekeeping (850.30) .....	X <sup>e</sup>	X	.....
Release and Transfer Criteria (850.31) .....	X <sup>f</sup>	.....	.....
Medical Surveillance (850.34) .....	X <sup>g</sup>	X	.....
Medical Restriction (850.35) .....	X <sup>h</sup>	X	.....
Training and counseling (850.38) .....	X <sup>i</sup>	.....	.....
Warning signs and labels (850.39) .....	.....	X	.....

<sup>a</sup> Would apply to beryllium operations and other locations where there is a potential for beryllium contamination.

<sup>b</sup> Employers would be required to establish a formal hazard prevention and abatement program.

<sup>c</sup> Employers would be required to provide respirators that comply with 10 CFR part 851.

<sup>d</sup> Employers would be required to provide protective clothing and equipment where surface contamination levels are above 3 µg/100 cm<sup>2</sup>.

<sup>e</sup> Housekeeping efforts would be required to maintain removable surface contamination at or below 3 µg/100 cm<sup>2</sup> during non-operational hours.

<sup>f</sup> Would establish contamination criteria for equipment, items, or areas to be removed, released, or transferred from beryllium regulated areas.

<sup>g</sup> Employers would be required to provide medical surveillance to beryllium and beryllium-associated workers.

<sup>h</sup> Employers would be required to medically restrict certain workers from working in area at or above the action level.

<sup>i</sup> Training would be required for all workers who could be potentially exposed. Counseling would be required for beryllium and beryllium-associated workers diagnosed with BeS or CBD.

This section-by-section analysis describes the proposed changes in subparts A, B, C and the appendices that the Department is proposing to make to the current CBDPP regulation (10 CFR part 850) that was published in December 1999.

#### A. Subpart A—General Provisions

##### Proposed § 850.1—Scope

Proposed § 850.1 would continue to establish the CBDPP for DOE employees and DOE contractor employees and clarifies that the CBDPP would also supplement and be an integral part of the worker safety and health program requirements under 10 CFR part 851 for DOE contractor employees. The Department would continue to structure the proposed rule this way to take advantage of existing and effective comprehensive worker protection programs at DOE facilities, and to minimize the burden on DOE contractors by clarifying that contractors need not establish redundant worker protection programs to comply with the proposed rule. Proposed § 850.1 also clarifies that if there is a conflict between the requirements of this part, and part 851, this part controls.

The Department recognizes that, except at the few DOE-operated sites, DOE Federal workers are not usually directly involved in production tasks or other activities in which they would be exposed to airborne beryllium; however, in performing management and oversight duties, DOE Federal workers sometimes must enter areas where beryllium is handled. The health and safety provisions of 29 CFR part 1960, *Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters*, as well as Executive Order 12196, *Occupational Safety and Health Programs for Federal Employees*, protect Federal workers. DOE's intent is to supplement these general worker protection requirements with specific beryllium-related requirements in the limited instances where DOE Federal workers may have the potential for beryllium exposure at or above the action level.

##### Proposed § 850.2—Applicability

Proposed § 850.2(a)(1) and (2) continue to specify that the rule would apply to DOE Federal offices and DOE contractors with responsibility for operations or activities that involve present or past exposure to beryllium at DOE sites. It would also continue to apply to any current DOE employee, DOE contractor employee, or any other current worker at a DOE site who is or

was exposed or potentially exposed to beryllium at a DOE site, regardless of which organization currently employs the worker.

Except at a few DOE-operated sites, DOE Federal workers are not usually directly involved in production tasks or other activities in which they would be exposed to airborne beryllium. However, in performing management and oversight duties, DOE Federal workers may enter sites where beryllium is handled. Federal agencies are required to ensure the protection of Federal workers under the health and safety provisions of 29 CFR part 1960, *Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters*, as well as Executive Order 12196, *Occupational Safety and Health Programs for Federal Employees*. DOE's intent in proposed § 850.2(a)(1) and (2) would be to continue to supplement those general worker protection requirements with specific beryllium-related requirements in the limited instances where DOE Federal workers may have the potential for beryllium exposure.

In the current rule the term "DOE facility" is used instead of DOE sites. DOE is proposing to delete the term "DOE facility" and use in its place "DOE sites" to be consistent with the term used in 10 CFR part 851. A DOE site would continue to mean a DOE-owned or -leased area or location controlled by DOE where activities and operations are performed at one or more facilities or locations by a contractor in furtherance of a DOE mission. This definition is provided in 10 CFR 851 and includes all sites where DOE exercises regulatory control under the AEA, even if DOE does not own or lease the site. Changing the terminology in this proposed amendment does not affect the number of potentially regulated facilities. The Department will still have 22 beryllium sites.

As proposed in the definition of "contractor," found in § 851.3 and in § 850.3 of the proposed rule, DOE's intent is that contractors covered under this rule include any entity, including affiliated entities, such as a parent corporation, under contract with DOE, and any subcontractor at any tier, that has responsibility for performing beryllium work at a DOE site in furtherance of a DOE mission. The requirements of the CBDPP would apply only to contractors and subcontractors who work in areas or on activities in which there is a potential for beryllium exposure at or above the action level.

As with the current rule, the proposed rule would not apply to former DOE

Federal and contractor workers. When workers terminate their employment at a DOE site, they are eligible to have health monitoring through the Former Worker Medical Screening Program. The Former Worker Medical Screening Program was established following the issuance of the Fiscal Year (FY) 1993 National Defense Authorization Act (Pub. L. 102-484), which called for DOE to assist workers with determining whether they had health issues related to their prior work with DOE. Workers eligible for this program include all former DOE Federal, contractor, and subcontractor employees from all DOE sites. In FY 2005, DOE initiated a separate beryllium sensitization screening effort for employees who worked for now defunct DOE beryllium vendors, and who were employed with these companies while the vendor or company was under contract with DOE. These individuals typically have no other access to the beryllium sensitization screening, because their employers are no longer in business. Additional information on the Former Worker Medical Screening Program may be found on the Department's Web site located at: <http://energy.gov/hss/information-center/worker/former-worker-medical-screening-program>. The provisions of this rule would not apply to activities not conducted at a DOE site, such as the off-site laundering of beryllium-contaminated clothing from a DOE site.

DOE is proposing to add § 850.2(a)(3) to clarify that the Site Occupational Medicine Director (SOMD) would be responsible for providing the overall direction and operation of the employer's beryllium medical surveillance program.

Proposed § 850.2(b)(1) and (2) would continue to exempt activities involving beryllium articles and specify the rule would not apply to DOE laboratories that meet the definition of laboratory scale use of hazardous chemicals in OSHA's *Occupational Exposure to Hazardous Chemical in Laboratories* standard, 29 CFR 1910.1450. In § 1910.1450(b) of that standard, OSHA defines a laboratory as a workplace where relatively small quantities of hazardous chemicals are used on a nonproduction basis. Laboratory scale is defined as work with substances in which the containers used for reactions, transfers, and other handling of substances are designed to be easily and safely manipulated by one person. Workplaces whose function is to produce commercial quantities of materials are excluded. Also, the term laboratory scale of hazardous chemical is defined as the handling of such

chemicals where all of the following conditions are met: (1) Chemical manipulations are carried out on a laboratory scale; (2) multiple chemical procedures or chemicals are used; (3) the procedures involved are not part of a production process, nor in any way simulate a production process; and (4) protective laboratory practices and equipment are available and in common use to minimize the potential for employee exposure to hazardous chemicals.

The Department continues to believe OSHA's regulation is adequate to protect workers from beryllium exposures in facilities that meet the definition of laboratory use of hazardous chemicals. The requirements set forth in OSHA's regulation are made applicable to DOE contractors performing work on a DOE site in § 851.23(a)(3).

The exemption of laboratory use of hazardous chemicals would continue to apply only in instances where relatively small quantities of beryllium are used in a non-production activity. In addition, OSHA's laboratory standard has specific provisions to ensure protective laboratory practices are followed. Many of the provisions in OSHA's laboratory standard are the same as, or similar to, those in this proposed rule. For instance, OSHA's laboratory standard establishes provisions for identifying the presence of hazardous chemicals (baseline inventory), establishing a chemical hygiene plan (hazard assessment), performing periodic monitoring at the action level, implementing exposure reduction measures at the PEL, training employees on related hazards, and providing employees with the opportunity for medical consultation and examination. In part because each of these aspects of the proposed beryllium rule is already included in the OSHA laboratory standard, DOE is retaining the laboratory operations exemption.

#### Proposed § 850.3—Definitions

Proposed § 850.3(a) would continue to apply traditional industrial hygiene terminology to define key terms used throughout the proposed rule. The following discussion explains the definitions in the proposed rule.

*Action level* would mean the airborne concentration of beryllium at which, or above which, the implementation of certain provisions of the proposed rule would be required. Using an action level to trigger certain provisions of the proposed rule ensures additional appropriate workplace precautions are taken and training and medical evaluations are provided, in situations where worker exposures could

significantly increase the risk of workers developing CBD. Additional information on the application of the action level is presented in the discussion on proposed § 850.23, *Action level*, and in the discussions of other provisions that would continue to be triggered by airborne concentration of beryllium being at or above the proposed action level. Note that several provisions of the proposed rule would continue to apply independent of the action level. Specifically, the CBDPP requirement (10 CFR 850.10), the inventory requirement (10 CFR 850.20), the voluntary protective clothing and equipment requirement (10 CFR 850.29(a)(3)), the housekeeping requirements related to the cleaning of surfaces with removable beryllium (10 CFR 850.30(b) through (d)), the release or transfer requirements (10 CFR 850.31(c)), the waste disposal requirements (10 CFR 851.32), the beryllium emergencies requirement (10 CFR 850.33), the medical surveillance and restriction requirements as they relate to beryllium associated workers (10 CFR 850.34 and 850.35), the training and counseling requirements (10 CFR 850.38), the warning labels requirements (10 CFR 850.39(b)), and the recordkeeping and use of information requirements (10 CFR 850.40).

*Authorized person* would continue to mean any person required by their work duties to be in a beryllium regulated area. Authorized individuals would be required to be trained and experienced in the hazards of beryllium, and the means of protecting themselves and those around them against such hazards. Proposed training requirements are specified in § 850.38 of this proposed rule. The concept of authorized person continues to be consistent with OSHA standards and with contractor practice at many DOE sites, and is intended to ensure that the population of potentially exposed individuals is reduced to the lowest possible number and that workers who are granted access to beryllium regulated areas have the knowledge they need to protect themselves and other workers.

*Beryllium* would be revised to mean elemental beryllium, beryllium oxide, and alloys containing 0.1 percent or greater beryllium by weight that may be released as an airborne particulate. Though uncertainty exists, studies investigating the health effects of exposures to elemental beryllium, beryllium oxide, and beryllium alloy suggest no compelling evidence that BeS or CBD is caused by exposure to particulates that contain beryllium in forms other than elemental, oxide and

alloys. An important consequence of this proposed change is to exclude mineral forms of beryllium from the definition of beryllium. The American Conference of Governmental Industrial Hygienists (ACGIH®) (ref. 29) reports, for example, that: "Beryllium occurs naturally as the silicate, bertrandite, and the aluminosilicate, beryl. Exposure to bertrandite and beryl dust occurs during ore crushing and grinding; however, the ores are not considered sources of beryllium sensitization." While mineral forms of beryllium do not appear to be linked with BeS or CBD, these forms can be at or above the action level when samples are analyzed by currently available methodologies. This occurs because materials containing mineral forms of beryllium—such as clays, and concrete—are ubiquitous on many DOE sites, and the most common currently used analysis methods analyze all the beryllium in a sample without distinguishing the different forms of beryllium. DOE has learned by experience that common conditions and practices at DOE facilities—such as accumulations of wind-blown dust, abrasive blasting of brick surfaces with coal slag, and drilling into and demolishing concrete structures—frequently result in breathing zone levels at or above the proposed action level and release criteria, but with forms of beryllium that are not believed to cause BeS or CBD. Studies by Stefaniak *et al.* of dissolution rates of beryllium in various beryllium containing materials in airway and phagolysosomal fluids suggest that dissolution rates of beryllium metal and oxide in lungs are in a range that is relatively slow in lung airways fluid to prevent removal by dissolution and is sufficiently fast in phagolysosomal fluid to compete with removal by phagocytosis. The range of dissolution rates of beryllium-containing minerals (*e.g.*, beryl ore) are slow in phagolysosomal fluid, indicating the persistence of these particles until removed by mechanical clearance which may alter its capacity to influence development of CBD (ref. 30). DOE's proposal to eliminate beryllium-containing minerals from the definition of beryllium would greatly reduce the burden on its missions without diminishing worker safety and health protection.

The definition would continue to exclude soluble forms of beryllium, such as beryllium salts, from the definition of beryllium. High exposures to soluble beryllium compounds cause acute beryllium disease (*i.e.*, inflammation of the upper and lower respiratory tract), but this exposure

essentially has been eliminated by compliance with OSHA's PEL.

Cummings *et al.* reported in 2009 on two cases of production plant employees who in the 1980s were exposed to both highly and poorly soluble forms of beryllium and developed skin conditions, acute beryllium disease, and eventually CBD. The exposure monitoring results associated with these cases indicate levels were well above the OSHA PEL. Included in this article is the following statement: "More recently, insoluble beryllium metal and oxide have been shown to have dissolution lifetimes of hundreds of days to years in lung airway epithelial lung fluid and alveolar macrophage phagolysosomal fluid (ref. 31, 32). Autopsy studies have confirmed that beryllium particles are identifiable in granulomas formed in the lungs of individuals with CBD years after exposure ceased (Butnor *et al.* 2003; Sawyer *et al.* 2005; Williams and Wallach 1989). Thus, Stefaniak *et al.* (2003, 2008) hypothesized that exposure aerosol physical properties, chemical properties, and physicochemical properties control development of beryllium lung burdens, and that the ongoing presence of a lung reservoir of beryllium may be necessary for the development of CBD" (ref. 33). Moreover, ACGIH® states, "Exposure to soluble beryllium salts (sulfate, ammonium carbonate, beryllium carbonate, and to a lesser extent, beryllium hydroxide) may occur during extraction of the metals from the ore (Deubner *et al.*, 2001). These salts are considered the main source of beryllium sensitization during beryllium extraction" (ref. 29).

DOE recognizes that inhalation and skin exposure to soluble beryllium compounds may create risk for BeS, however, DOE believes that soluble forms of beryllium are not used at its beryllium sites and, therefore, do not warrant regulation under this rule.

*Distinguishing the forms of beryllium.* DOE believes it is feasible to distinguish the forms of beryllium specified in DOE's proposed definition of beryllium. The Department recognizes that the most common analytical techniques for determining the beryllium content of a sample begin with digesting all the beryllium into ions in solution. These techniques do not distinguish the form the beryllium was in before the digestion step. However, DOE believes Qualified Individuals (as defined in § 850.3 of this proposed rule) can make the determination that the beryllium at a DOE site is in a metal, oxide, or alloy form based on knowledge of the processes conducted at that site and

matching the composition of certain constituents of air and surface samples with the composition of possible source materials. Another approach for distinguishing the form of beryllium is to demonstrate that the source of beryllium contamination is in infiltrated background soil. One technique that has been used successfully at DOE sites to determine if the beryllium in indoor settled particulates consists of beryllium that has infiltrated indoors, as a constituent of background soil, is to demonstrate that the concentration of beryllium in the accumulated indoor "dust" is not higher than the concentration in the outside background soil. Another technique is based on demonstrating that the ratio of atoms of beryllium to the atoms of a constituent of soil is the same in background soil and indoor dust. Other techniques may be available to determine whether beryllium is in an elemental, oxide, or alloy form. DOE believes the methods its sites use to determine the form of beryllium are technically defensible, which is important when the site determines that the source is a form of beryllium, such as background soil or coal fly ash, not included in the proposed definition of beryllium.

*Beryllium activity* would mean an activity taken for or by DOE at a DOE site that can expose workers to airborne concentrations of beryllium at or above the action level, including any activity involving the disturbance of legacy beryllium-containing dust.

*Beryllium article* would be revised to mean a "commercially available, off-the-shelf" item composed of beryllium that is formed to a specific shape or design during manufacture, has end-use functions that depend in whole or in part on its shape or design during end use, and does not release airborne beryllium at or above the action level under normal conditions of use. The proposed definition would revise the current definition from stating that it "does not release beryllium" to stating that it "does not release particulate beryllium at or above the action level under conditions of normal use."

DOE is modifying this definition since some of its sites have found surface contamination associated with items that met the definition of "articles" but were part of the weapons systems. The identification of surface contamination on "articles" or manufactured products is not new. While the risk of airborne exposure is negligible, there have been Occurrence Reporting and Processing System reports and/or Lessons Learned, which highlight the need to reexamine the article definition and use around the DOE complex.

DOE recognizes the existence of weapon components that are categorized as articles, and they are exempt from the requirements of the beryllium program. Several weapons programs include operations involving beryllium-containing components classified as articles. The components are processed during weapon assembly, dismantlement, stockpile maintenance, and other operations. The operations involve routine handling, and may include light wiping of the components with a dry disposable wipe or a disposable wipe moistened with a solvent. These operations involving those alloy components do not result in measurable concentrations of airborne beryllium and are exempted from the requirements of this rule. However, the article exemption does not apply to these parts if they are processed in a more aggressive manner that might lead to the release of beryllium from the component.

*Beryllium-associated worker* would be clarified to mean a current worker who was exposed or potentially exposed to airborne concentrations of beryllium at a DOE site. DOE is proposing to clarify the definition of beryllium-associated worker by removing the term "beryllium workers" (*i.e.*, workers who are currently exposed or potentially exposed to beryllium at or above the action level). DOE has learned from experience in implementing this part, as issued in 1999, that including "beryllium worker" in the definition caused confusion and different interpretations of the term by individuals responsible for implementing this provision.

The term "beryllium-associated worker" would continue to apply to current workers whose work history showed they may have been exposed to airborne concentrations of beryllium at a DOE site; or a worker who exhibits signs and symptoms of beryllium exposure. The definition clarifies that current workers who have been removed from beryllium exposure as part of the medical removal process and are receiving medical removal benefits are beryllium-associated workers under the proposed rule, but they are not "beryllium workers" (see definition of "beryllium worker"). Beryllium-associated workers may be DOE Federal or contractor workers, or employees of subcontractors to DOE contractors who perform work at DOE sites in furtherance of a DOE mission.

*Beryllium emergency* would continue to mean any occurrence such as, but not limited to, equipment failure, container rupture, or failure of control equipment or operations that results in an

unexpected and significant release of beryllium at a DOE site. This definition is particularly important when determining appropriate emergency response procedures that fall within the scope of OSHA's *Hazardous Waste Operations and Emergency Response* standard, 29 CFR 1910.120. This definition continues to be based on OSHA's use of the term "emergency" as applied in 29 CFR 1910.120 and refers to any event, such as a major spill of powdered beryllium or an unexpected upset, that results in a significant release of beryllium into the workplace atmosphere.

*Beryllium-Induced Lymphocyte Proliferation Test (BeLPT)* would remain unchanged from its current definition as an in vitro measure of the beryllium antigen-specific, cell-mediated immune response to beryllium. However, the Department is adding language to clarify that a split sample BeLPT (where one blood draw is split and sent to two different testing facilities) would constitute two tests for purposes of diagnosing BeS.

This test measures the extent to which lymphocytes, a class of white blood cells, respond to the presence of beryllium. Medical personnel use the blood Be-LPT to identify workers who have become sensitized to beryllium through their occupational exposure.

*Beryllium-induced medical condition* would be added to provide a term in the rule that refers to CBD and BeS. Other diseases may resemble CBD, but are not attributable to beryllium. Medical tests, such as the lung lavage BeLPT, can help a physician decide if a person has CBD or another disease.

*Beryllium Registry* would be added as a new term and refers to the DOE Beryllium-Associated Worker Registry, which is a collection of health and exposure information of individuals potentially at risk for CBD due to their work at DOE-owned or leased sites. The data from the Beryllium Registry is analyzed to better understand CBD and to identify those at risk. Reported data are cumulative through calendar year and are located at: <http://energy.gov/ehss/beryllium-associated-worker-registry>. The Beryllium Registry is also a risk management tool for sites to use in managing their CBDPP and other risk management operations. Sites are encouraged to use their Beryllium Registry data to evaluate beryllium exposure risks.

*Beryllium regulated area currently known as "regulated area,"* would be clarified to mean an area established, demarcated, and managed by the employer where the airborne concentration of beryllium is at or

above, or can reasonably be expected to be at or above, the action level. Employees working in beryllium regulated areas would be authorized by their employer to work in the area, and trained, and equipped with protective clothing and equipment. The purpose of such areas is to limit exposure to beryllium to as few workers as possible. The use of these "regulated areas" is consistent with OSHA's expanded health standards for toxic particulates.

*Beryllium sensitization or sensitivity (BeS)* would be added as a new term to ensure consistency within the Department in how BeS is diagnosed. BeS would mean a condition diagnosed by the SOMD based on any of the following: (1) Two abnormal blood BeLPT results; (2) One abnormal and one borderline blood BeLPT; or (3) One abnormal BeLPT test of alveolar lung lavage cells. This definition would also make clear that it is the SOMD who makes the diagnosis of BeS.

The Department recognizes that OSHA has proposed slightly different criteria for BeS diagnosis in its proposed rule, *Occupational Exposure to Beryllium and Beryllium Compounds*. Specifically, OSHA proposed a BeS diagnosis based on two abnormal tests performed after two separate blood draws. DOE does not believe this slight difference in proposed approaches will create confusion because the Department would only be subject to the permissible exposure limit established in the current OSHA beryllium standard and any new OSHA beryllium standard when promulgated, and would not be subject to the ancillary provisions (e.g., definitions, exposure assessment, personal protective clothing and equipment, medical surveillance, medical removal, training, and regulated areas or access control) of the new rule. Therefore, DOE workplaces will only be subject to the DOE provisions. The Department expects DOE and DOE contractors to continue to implement the provisions of 10 CFR part 850 at DOE sites.

*Beryllium worker* would be revised to mean a current worker exposed or potentially exposed to airborne concentrations of beryllium that are at or above the action level in the course of the worker's employment in a DOE beryllium activity. Incorporation of the action level is necessary, as beryllium is ubiquitous in small amounts, and DOE's experience has been that "potentially exposed" has been misunderstood to refer to all workers on a site regardless of whether they were exposed to levels of beryllium of any consequence to their health.

This definition would also clarify potential confusion over what it means to be "regularly employed in a DOE beryllium activity" and to include those persons who are exposed to airborne concentrations of beryllium at or above the action level as part of their employment, such as supervisors or others who are authorized to enter beryllium regulated areas. The employer would be required under this proposed rule to provide the SOMD with a list of all beryllium workers, as well as beryllium-associated workers. Former workers would not be included in the definition of beryllium workers. The Department established the Former Worker Medical Screening Program and offers medical examinations to former (retired and separated) workers who are at risk for developing CBD due to their work at a DOE site.

*Breathing zone* would continue to mean the hemisphere forward of the shoulders, centered on the mouth and nose, with a radius of 6 to 9 inches. This definition applies specifically to proposed § 850.24, *Exposure Monitoring*, which requires employers to determine the worker's exposures to beryllium by monitoring for the presence of contaminants in the worker's personal breathing zone. This definition is consistent with sound and accepted industrial hygiene practices, and ensures that samples collected for personal exposure monitoring represent the air inhaled by workers while performing their duties in their work areas.

*Chronic beryllium disease (CBD)* would be added as a new term to ensure consistency within the Department in how CBD is diagnosed. CBD would mean a condition diagnosed by the SOMD based on the worker having the following: (1) BeS as defined in this section; and (2) a lung biopsy showing non-caseating granulomas or a lymphocytic process consistent with CBD, or radiographic (including computed tomographic (CT) scans) and pulmonary function testing results consistent with pulmonary granulomas.

*Cognizant Secretarial Officer (CSO)* would be added as a new term by adopting the definition from 10 CFR part 851, *Worker Safety and Health Program*. The definition would clarify that the CSO would mean, with respect to a particular situation, the Assistant Secretary, Deputy Administrator, Program Office Director, or equivalent DOE official who has primary line management responsibility for a contractor, or any other official to whom the CSO delegates in writing a particular function under this part.

*Contractor* would be revised from the current term “DOE contractor” by adopting the definition from 10 CFR part 851, *Worker Safety and Health Program*, but specifying that the definition applies to contractors performing beryllium work. This change would reflect DOE’s intent that contractors covered under this rule includes any entity, including affiliated entities, such as parent corporation, under contract with DOE, and any subcontractor at any tier, that has responsibilities for performing beryllium work at a DOE site in furtherance of a DOE mission.

*DOE* would continue to mean the United States Department of Energy, including the National Nuclear Security Administration.

*DOE site* would be added as a new term by adopting the definition from 10 CFR part 851, and the current term “DOE facility”, would be deleted. The definition would clarify that a DOE site would mean a DOE-owned or -leased area or location or other location controlled by DOE where activities and operations are performed at one or more facilities or places by a contractor in furtherance of a DOE mission. This definition would include all locations where DOE exercises regulatory control under the Atomic Energy Act of 1954, as amended (AEA), even if DOE does not own or lease the site.

*Employer* would replace the term “responsible employer” because DOE recognizes that “responsible” is self-evident in the context of this part. Therefore, an employer would be, (1) for DOE contractor employees, the DOE contractor that is directly responsible for the safety and health of employees while performing a beryllium activity or other activity at a DOE site; (2) for DOE employees, the DOE office that is directly responsible for the safety and health of DOE Federal employees while performing a beryllium activity or other activity at a DOE site; or (3) any person acting directly or indirectly for the contractor or DOE office with respect to terms and conditions of employment of beryllium workers and beryllium-associated workers.

*Final medical determination* would be added to the definitions section and would mean the final written medical determination of the SOMD as to whether the beryllium worker should be permanently removed because of BeS or CBD. The final medical determination to permanently remove a worker must be made by the SOMD based on a diagnosis of BeS or CBD as defined in this section. If the worker is eligible, and has elected the multiple physician review or alternate physician’s determination, the

SOMD must issue the final medical determination at the conclusion of such process.

The current rule provides in § 850.35(a)(1)(i) that “final medical determination” is the “outcome of the multiple physician review process or the alternate medical determination process,” and thus temporary removal is only available pending this independent review. This proposed rule would be intended to permit the SOMD to determine that a worker should be put on temporary medical removal based on tests, recommendations, or any other symptoms that the SOMD deems medically sufficient, pending the SOMD’s final medical determination as to whether the worker should be permanently removed. For example, if a SOMD evaluates a worker and believes the worker needs to undergo additional testing before a final determination can be made, the SOMD may determine that the worker should be temporarily removed pending the outcome of that testing. In instances where the worker does not request multiple physician review or alternate physician determination, the SOMD’s initial determination may also be the final determination.

*Head of DOE Field Element* would be revised by adopting the definition from 10 CFR part 851. This change would reflect DOE’s intent that the Head of DOE Field Element is the individual who is the manager or head of the DOE operations office or field office.

*High-efficiency particulate air (HEPA) filter* would continue to mean a filter capable of trapping and retaining at least 99.97% of 0.3 micrometer mono-dispersed particles.

*Medical removal benefits* (currently medical removal protection benefits) is being revised to mean the employment benefits that would be established by § 850.36 of this proposed rule for beryllium workers temporarily or permanently removed from beryllium activities in which the workers can be exposed to airborne concentrations of beryllium at or above the action level following a recommendation by the SOMD. This proposed definition would clarify that only beryllium workers are eligible for medical removal benefits. Medical removal provisions give contractors an incentive to make reasonable efforts to find and offer alternate employment to beryllium workers who have suffered negative health effects due to exposure to beryllium. The proposed definition of medical removal benefits and the proposed requirements in proposed § 850.36 would ensure that permanently removed beryllium workers would

suffer no reductions in total earnings, or other worker rights and benefits for up to two years after permanent medical removal, and up to one year for temporary removal. During this time the contractor would be required to make reasonable efforts to find alternate employment for a removed beryllium worker. Alternative employment may also be found through job retraining and out-placement programs operated by many sites during this two-year period. For workers who are removed, medical removal benefits would continue for the designated period, even where the employee has, during that period of removal, received a notice of and is subsequently laid-off.

*Medical restriction* would be added and refer to the outcome of the process under § 850.35 in which the worker is not suffering from CBD or has not been sensitized to beryllium, but the SOMD determines that exposure to beryllium is nonetheless contraindicated due to other medical conditions of the worker and thus, the SOMD recommends that the worker be restricted from a job that involves an exposure to beryllium at or above the action level. For beryllium workers with BeS or CBD, this proposed rule would require medical removal—not medical restriction—if the SOMD determines that a beryllium worker should be removed from a beryllium job.

*Qualified Individual* would be added and defined to mean an individual, designated by the employer, who possesses the knowledge, skills, and abilities needed to implement an industrial hygiene program (i.e., an individual who is either a certified industrial hygienist or has a college degree in industrial hygiene or a related scientific, engineering, or technical degree); who has completed special studies and training in industrial hygiene; and who has at least five years of full-time employment in the professional practice of industrial hygiene.

*Site Occupational Medical Director (SOMD)* would continue to mean the licensed physician responsible for the overall direction and operation of the site occupational medicine program. However, DOE believes the physician should be qualified to diagnose beryllium-induced medical conditions. Specifically, DOE expects the medical evaluations and procedures required to diagnose CBD will be performed or validated by a specialist in pulmonary medicine or occupational medicine, or by another physician familiar with the specialized equipment and examination protocols required to definitively

differentiate between CBD and other lung diseases.

*Surface levels of beryllium* would replace the term “removable contamination,” and the definition would be revised by deleting the words “nondestructive” and “washing.” The word “nondestructive” gives the erroneous impression that actions to remove contamination can be very aggressive as long as the surface is not damaged. Washing is inconsistent with casual contact. The intent of the definition of “surface levels of beryllium” would be to describe the material that could be transferred to an individual by casual contact, such as brushing by the contaminated surface.

*Unique identifier* would continue to mean the part of a paired set of labels used in records that contain confidential information that does not identify individuals except by using the matching label.

*Worker* would be revised to mean an employee of DOE or a DOE contractor, or subcontractor, at any tier, who performs work in furtherance of a DOE mission at a DOE site.

*Terms and definitions deleted and not explained above.* The definitions of “DOE facility,” “immune response,” “operational area,” and “worker exposure” would be deleted, as these terms are either not used in this proposed notice or are fully explained as established in § 850.24 (Exposure monitoring).

Proposed § 850.3(b) would be amended to provide that undefined terms shall have the same meanings as used in the AEA and 10 CFR part 851, *Worker Safety and Health Program*.

#### § 850.4—Enforcement

Proposed § 850.4 would continue to preserve the section as amended on February 9, 2006 (71 FR 6858, 6931). That amendment provides that DOE may take appropriate steps pursuant to 10 CFR part 851, *Worker Safety and Health Program*, to enforce compliance by contractors with this part, and any DOE-approved contractor’s CBDPP. This provision would continue to allow DOE to employ contractual mechanisms such as a reduction in fees, or to assess a civil penalty when a contractor fails to comply with the provisions of the proposed rule.

#### § 850.5—Dispute Resolution

Proposed § 850.5 would continue to establish that any adversely affected worker may refer a dispute regarding compliance with the rule to the Office of Hearings and Appeals (OHA) for resolution; however, employees who are represented by a labor organization are

required first to exhaust any grievance-arbitration procedure that is available for resolving disputes over terms and conditions of employment. The rule would continue to provide that a worker will be deemed to have exhausted all applicable grievance-arbitration procedures if 150 days have passed after the filing of a grievance and a final decision on it has not been issued. This provision is consistent with 10 CFR part 708, *DOE Contractor Employee Protection Program*, at § 708.13(a)(2). Proposed § 850.5(b) would permit OHA to “elect not to accept a petition from a worker unless the worker had requested that the employer correct the violation,” rather than prohibit the petition from being accepted by OHA unless the worker had requested his employer correct the violation.

#### § 850.6—Interpretations, Binding Interpretive Rulings and Requests for Information

Proposed § 850.6 would be added to establish and clarify that requests for legal interpretations under this proposed rule would be in accordance with 10 CFR 851.6, *Petitions for generally applicable rulemaking*, requests for binding interpretive rulings would be in accordance with § 851.7, *Requests for a binding interpretative ruling*, and informal requests for information would be made pursuant to 10 CFR 851.8, *Informal requests for information*. Informal requests for information and inquiries regarding technical requirements in this proposed rule would be directed to the Office of Environment, Health, Safety and Security (AU). The responses given by AU would be advisory only and would not be binding on DOE. In addition, to assist the DOE community in understanding the technical meaning or application of a specific requirement in this proposed rule, AU would continue to operate the DOE Response Line (1–800–292–8061) to provide information to DOE, DOE contractor and DOE subcontractor employees.

#### B. Subpart B—Administrative Requirements

Subpart B of the proposed rule would establish general and administrative requirements to develop, implement, and maintain a CBDPP and to perform all beryllium related activities according to the CBDPP.

#### Proposed § 850.10—Development and Approval of the CBDPP

Proposed § 850.10 would continue to establish the requirements for development and approval of the CBDPP. Proposed § 850.10(a)(1) would

continue to require each employer engaged in beryllium activities at a DOE site to prepare and submit a CBDPP for review and approval as indicated in proposed § 850.10(b). DOE would expect its employers to perform the beryllium inventory and hazard assessment as would be required by proposed §§ 850.20 and 850.21 and then prepare and submit for approval a CBDPP that is warranted by the results of the beryllium inventory and hazard assessment.

Proposed § 850.10(a)(1) would also establish a 90 day timeframe from the effective date of the final rule for employers’ submissions of the CBDPP. DOE is aware of the burden of documentation that can be generated by new programs. However, most employers have already developed CBDPPs in response to the current rule. DOE expects the additional effort required to refine the existing CBDPPs to meet the requirements of the proposed rule will be minimal.

Proposed § 850.10(a)(2) would require employers that employ beryllium-associated workers at a DOE site, but which are not engaged in beryllium activities, to submit a CBDPP with the provisions appropriate for its workers [e.g., medical surveillance (§ 840.34), training and counseling (§ 840.38), and recordkeeping (§ 840.40)] for review and approval. This section clarifies that DOE does not expect employers to prepare and submit a CBDPP that includes all the provisions of this proposed rule if they do not employ beryllium workers. This proposed section would establish a 90-day timeframe from the effective date of the final rule for the employers’ submission of a CBDPP to the appropriate Head of DOE Field Element. 10 CFR 851.26, *Recordkeeping and reporting*, requires documentation of all hazard inventory and hazard assessment results, so employers would be required to have records to support the conclusion that a CBDPP would not be required.

Proposed § 850.10(a)(3) would continue to require a single CBDPP be submitted to encompass all beryllium-related activities at a site, as currently provided in § 850.10(a)(2). Because DOE recognizes that one site may encompass multiple contractors and numerous work activities, this proposed sections would continue to clarify that the CBDPP for a given site may include specific sections for individual contractors or work tasks. DOE believes that this allowance for a segmented CBDPP structure would minimize the burden associated with the CBDPP update and approval requirements because it allows individual contractors

to update and submit for approval only the section of the CBDPP pertaining to their specific activities. If multiple contractors are involved, the DOE contractor designated by the Head of the DOE Field Element must take the lead in compiling the overall CBDPP and coordinating the input from various contractors, subcontractors, or work activities. This proposed section further clarifies that in such cases the designated contractor would be required to review the sections of the CBDPPs prepared by the other contractors engaged at the site before a consolidated CBDPP could be submitted to the Head of DOE Field Element for final review and approval.

Proposed § 850.10(a)(4) would require multiple employers at a DOE site to share relevant assessment information gathered under proposed § 850.41(a) of this proposed rule, to ensure the safety and health of their workers.

Proposed § 850.10(b)(1) would continue to require the Heads of DOE Field Elements to review and provide approval or rejection of the CBDPPs. However, the proposed section would amend the current rule by requiring that approvals or rejections of the CBDPP be provided in writing. DOE believes that its review and approval of CBDPPs is necessary to ensure that each contractor's CBDPP is consistent with the requirements and objectives of the rule. The Head of DOE Field Element is not only responsible for operations within his or her jurisdiction, but also is familiar with the operations and any related special circumstances or unique situations that may affect implementation or effectiveness of the CBDPP. Thus, DOE believes the Head of DOE Field Element is the most appropriate DOE approval authority for CBDPPs. This proposed section would establish a 90 working day period for DOE to review and either approve or reject the CBDPP or any updates to the CBDPP. During its review, DOE may direct the contractors to modify the CBDPP. DOE established this 90 working day period to facilitate timely implementation of program elements by employers and to ensure that Heads of DOE Field Elements respond to employers' submissions.

Proposed § 850.10(b)(2) would require the appropriate CSO to review and provide a written approval or rejection of the CBDPPs or any updates to the CBDPP for DOE Federal offices with beryllium workers or beryllium-associated workers. This proposed section would establish a 90 working day period for the CSO to review and either approve or reject the CBDPP. During its review, the CSO may direct

the DOE Federal office to modify the CBDPP.

Proposed § 850.10(b)(3) clarifies that the CBDPP is would be deemed approved 90 working days after submission to the Head of DOE Field Element or the CSO if it has not been approved or rejected earlier.

Proposed § 850.10(b)(4) would amend § 850.10(b)(2) to require employers to give a copy of the approved CBDPP, upon request, to the Office of Environment, Health, Safety and Security, DOE program offices, affected workers, and their designated worker representatives. This section ensures that workers and their representatives have access to information related to the protection of their health.

Proposed § 850.10(c) would continue to require employers to update the written CBDPP for review and approval within 30 working days in two circumstances: (1) Whenever a significant change or addition to the CBDPP is made or warranted, and (2) whenever a contractor changes. DOE believes that such updates are appropriate to ensure that the CBDPP accurately reflects workplace conditions and addresses specific workplace beryllium exposure hazards. This section would also require the Head of DOE Field Elements, or appropriate CSO, if applicable, to review CBDPPs at least annually and, if appropriate, require the employers to update CBDPPs. DOE considers the annual review cycle to be appropriate and necessary to ensure that CBDPPs remain up-to-date and that they accurately reflect workplace conditions and required control procedures.

Proposed § 850.10(d) would continue to require employers to notify any associated labor organization of the development and implementation of the CBDPP plan and updates, and upon request, bargain with the labor organization on implementation of part 850 in a manner that is consistent with Federal labor laws and this part. This section continues to ensure that CBDPPs are developed and implemented consistently with the requirements imposed by the National Labor Relations Act (NLRA), 29 U.S.C. 151–169, and that they do not create obligations in excess of those that would be found in such circumstances under the NLRA.

#### Proposed § 850.11—General CBDPP Requirements

Proposed § 850.11 would continue to establish the general requirements of the CBDPP. Proposed § 850.11(a) would continue to specify that the CBDPP would be expected to address the

existing and planned beryllium activities. Also, proposed § 850.11(b) continues to require employers to tailor the scope and content of the CBDPP to the specific hazards associated with the beryllium activities being performed, but would no longer require that the CBDPP augment or be integrated into existing Worker Safety and Health Programs. The existing provision is considered unnecessary because § 850.1, *Scope*, already provides that the CBDPP supplements, and is deemed an integral part of, the worker safety and health program under 10 CFR part 851, for DOE contractor employees. In addition, proposed § 850.11(b)(1) would require that the CBDPP include formal plans outlining how the employer would ensure that beryllium exposures are maintained below the level prescribed in proposed § 850.22 of this part. Proposed § 850.11(b)(2) would make clear that the plans must, at a minimum, satisfy each requirement in subpart C of the rule (*Specific Program Requirements*). Proposed § 850.11(b)(3) would clarify that the CBDPP provisions must contain provisions for minimizing the number of workers exposed to airborne levels of beryllium at or above the action level, and the instances in which workers are exposed to beryllium.

DOE proposes to delete the requirement in the existing rule at § 850.11(b)(3)(iii) to minimize the disability and lost work time of workers due to beryllium-induced medical conditions and associated medical care, because DOE recognizes that this specific requirement has no practical effect and its intent is met by the other requirements in the CBDPP regulations.

DOE also proposes to delete the requirements in the existing rule at § 850.11(b)(3)(iv), which require the CBDPP to include specific exposure reduction and minimization goals to further reduce exposures below the PEL prescribed in proposed § 850.22, *Permissible exposure limit*, DOE is proposing this change because its experience in implementing this part indicates that the open-ended expression “further reduce exposures” is problematic to implement because beryllium is ubiquitous in small amounts. In addition, DOE believes the actions required when workers are exposed to airborne levels of beryllium at or above the proposed action level are protective and expects that few workers will develop CBD from future exposures.

#### Proposed § 850.12—Implementation

Proposed § 850.12(a) would require employers to manage and control

beryllium activities consistent with the approved CBDPP. Proposed § 850.12(b) [currently § 850.12(c)] would provide that tasks involving potential exposure to airborne levels of beryllium at or above the action level, that are not covered under the CBDPP may only proceed with the written approval from the Heads of DOE Field Elements, or appropriate CSO, as applicable.

Proposed § 850.12(c) [currently § 850.12(b)], would continue to establish that no person employed by DOE or a DOE contractor may take or cause any action that is inconsistent with the requirements specified in this part, an approved CBDPP, or any other applicable Federal statute or regulation concerning the exposure of workers to levels of beryllium at a DOE site. This section clarifies that DOE and contractor personnel would be required to follow applicable requirements of the rules as well as applicable requirements in other applicable Federal statutes and regulations concerning exposure of workers to beryllium.

As with the existing § 850.12(d), proposed § 850.12(d) would continue to recognize that, depending on the circumstance of the work, employers may choose to take additional actions to protect their workers. In implementing this part of the rule, the Department has learned that in certain instances, some sites took actions they felt were more protective of workers, but which in fact conflicted with the requirements of the rule. This provision makes it clear that while employers may take additional actions to protect their workers, employers would be required to first comply with the requirements of this part. DOE recognizes that individuals responsible for implementing CBDPP activities must use their professional judgment in protecting the safety and health of workers. Proposed § 850.12(e) would continue to provide that nothing in the rule is intended to diminish the responsibilities of DOE officials under 29 CFR part 1960 and related requirements for Federal workers.

#### Proposed § 850.13—Compliance

Proposed § 850.13(a) would revise existing § 850.13(a) to allow contractors or DOE offices, as applicable, who already have CBDPPs that have been approved by a Head of DOE Field Element, or appropriate CSO, as applicable, to continue to use them for one year after the effective date of the final rule. Thereafter, proposed § 850.13(b) would mandate that employers conduct beryllium activities in compliance with their approved CBDPP under this proposed rule.

Proposed § 850.13(c) would continue to require contractor employers responsible for a beryllium activity to be responsible for complying with the proposed rule. When no contractor is responsible for the beryllium activity and Federal employees perform the activity, this proposed section would require DOE to be responsible for compliance.

#### C. Subpart C—Specific Program Requirements

Subpart C of the proposed rule would continue to establish performance-based requirements for the CBDPP. These proposed requirements would focus on preventing CBD by requiring specified protective actions, reducing the number of workers exposed to beryllium, and continuous monitoring to ensure that workplace controls are sufficiently protective. DOE would expect implementation of the rule to continue to increase its understanding of the development, course and prevention of CBD.

#### Proposed § 850.20—Beryllium Inventory

Proposed § 850.20 would continue to require employers to take specific actions in order to develop a beryllium inventory, and would also provide that employers must update the inventory at least annually and when significant changes to beryllium activities occur.

DOE intended that the current version of § 850.20 include the requirement to maintain an up-to-date inventory. Proposed § 850.20(a)(1) through (4) would require employers to develop their beryllium inventory by reviewing current and historical records, interviewing workers, conducting air, surface and bulk sampling as appropriate to characterize the beryllium and its locations and documenting the locations of beryllium at or above the action level at a site. Characterizing the beryllium and identifying the locations of beryllium are necessary to assess and control beryllium workplace hazards. Employers should conduct the sampling that is appropriate for the specific workplace conditions and the suspected types and locations of beryllium contamination. Sampling techniques could include collecting area and wipe samples and collecting personal breathing zone samples.

By maintaining a beryllium inventory, employers will accomplish the following functions that are critical to the success of the CBDPP: (1) Identification of locations and operations that should be physically isolated from other areas to prevent the spread of contamination, (2)

identification of areas in which worker access should be restricted to minimize the number of workers who could be exposed to beryllium at or above the action level, (3) identification of beryllium contamination that must be controlled in areas that are scheduled for decontamination and decommissioning, and (4) identification of beryllium contamination in areas that are being used for non-beryllium activities, to determine the need for cleanup.

Surface level data obtained with dry wipes before the effective date of the final rule will be acceptable for meeting the beryllium inventory requirements for conducting surface sampling in proposed § 850.20(a)(3). However, subject to § 850.20(b), employers that previously used dry wipe sampling would have to convert to wet wipe sampling for new surface exposure monitoring after the effective date of the final rule to comply with the requirements of proposed § 850.24(a)(2)(ii), unless the use of wet wipes would have an undesired effect on the surface being sampled or is not technically feasible.

DOE is proposing to delete from § 850.20(a) the requirement that employers identify workers that were exposed or potentially exposed to beryllium at the inventoried locations. DOE has found that identifying workers is more effectively accomplished by listing the identified locations, using surveys to ask workers about their activities in those locations, and looking at the work histories workers provide when undergoing medical evaluations. Also, proposed § 850.34(a)(3) and (4) would require employers to provide information related to workers' beryllium exposures, to facilitate the SOMD's determination of which workers should receive mandatory medical evaluations and which workers should be offered voluntary medical evaluations.

Proposed § 850.20(b) would permit employers to use inventory results obtained within 12 months prior to the effective date of the final rule to satisfy the requirements set forth in § 850.20(a) if a Qualified Individual determines that conditions represented by the results have not changed in a manner that would warrant changes in the beryllium inventory. While wet wipe data would replace the dry wipe beryllium data in inventories as surfaces are monitored as part of the employer's ongoing CBDPP activities, DOE believes that repeating surface measurements solely for updating the inventory as of the effective date of the final rule would not be cost-effective or justified based on

the amount of reduced risk of beryllium disease that would be realized. Proposed § 850.20(b) would also require employers to update their beryllium inventory at least annually and when significant changes occur to beryllium activities, which is consistent with the common practice at DOE sites.

Proposed § 850.20(c) would continue to require the employer to ensure that the beryllium inventory is managed by a Qualified Individual. DOE believes this provision is necessary to ensure that the inventory is accurate and complete.

#### Proposed § 850.21—Hazard Assessment and Abatement

Because the identification of the possible presence of beryllium in a workplace does not, in and of itself, suffice to determine whether a hazard exists or whether and, if so, what control measures must be employed, proposed § 850.21(a) would continue to require employers to conduct a beryllium hazard assessment if the inventory establishes the presence of beryllium. This section, as proposed, would limit the requirement to conduct hazard assessments to areas where the airborne concentration of beryllium is potentially at or above the action level. This requirement allows each site the flexibility to determine the appropriate risk-based approach for assessing beryllium-related hazards in its worksites. Flexibility is important because operations, conditions, and the potential for exposure may vary greatly from operation to operation and site to site.

Proposed § 850.21(b) would require employers to conduct the beryllium hazard assessment in accordance with the requirements in 10 CFR 851.21, *Hazard Identification and Assessment*. 10 CFR 851.21 establishes the employer's duty to enact procedures for identifying the hazards and assessing the related risk in the workplace. This section lists the activities employers would perform as part of their hazard and risk assessment procedures (e.g., conducting workplace monitoring, evaluating operations).

Proposed § 850.21(c) would be added to require employers to abate beryllium hazards in accordance with the requirements in 10 CFR 851.22, *Hazard Prevention and Abatement*. This section requires employers to develop and implement a process for preventing, prioritizing and abating beryllium hazards using the hierarchy of controls, starting with elimination (or substitution of the hazard, if appropriate and feasible) and ending with personal protective equipment.

Proposed § 850.21(d) would be added to provide that employers ensure paragraphs (a) through (c) of this section, are managed by a Qualified Individual as defined in this proposed rule.

#### Proposed § 850.22—Permissible Exposure Limit

DOE received several comments in response to its Request for Information (RFI) concerning the adoption of the OSHA PEL for beryllium. Approximately two-thirds of the commenters favored DOE no longer adopting the OSHA PEL and pointed out that even OSHA recognizes that the current OSHA PEL may not be adequate to prevent the occurrence of CBD (ref. 34).

In response to the Department's RFI concerning whether DOE should adopt the 2010 ACGIH® threshold limit value (TLV®) of 0.05 µg/m³ (ref. 6) as its PEL, approximately two-thirds of the commenters rejected its adoption. Several commenters pointed out that TLVs® are not developed with technical or economic feasibility in mind and that TLVs®, quoting from the ACGIH®, “are not developed for use as legal standards and ACGIH® does not advocate their use as such.” Others suggested DOE adopt the 2010 ACGIH® TLV® as its PEL because it is the most protective and conservative published level.

Proposed § 850.22(a) would continue to retain OSHA's 8-hour TWA PEL for airborne exposure to beryllium (2 µg/m³), as measured in the worker's breathing zone by personal monitoring, but allows for the adoption of a stricter standard should OSHA establish one through its rulemaking process. As in the current rule, the PEL would supplement the action level by establishing an absolute 8-hour TWA level above which, no worker may be exposed. Engineering or work practice controls would be required to bring exposures to at or below the PEL.

OSHA has published the beryllium PELs in Tables Z-1 and Z-2 of 29 CFR 1910.1000. The values in Table Z-2 were American National Standards Institute (ANSI) standards that existed when OSHA was created and were adopted by OSHA. Tables Z-1 and Z-2 both list 2 µg/m³ as an 8-hour TWA. In addition, Table Z-2 lists 5 µg/m³ as an “acceptable ceiling concentration” and 25 µg/m³ as an “acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift”, where workers may be exposed above 5 µg/m³ (but never above 25 µg/m³) for a maximum cumulative period of 30-minutes during an eight hour shift (ref. 35).

The proposed requirement in § 850.22(b) would provide that when OSHA promulgates a lower PEL, DOE would notify its contractors through a notice in the **Federal Register**.

While DOE is proposing to continue to adopt the OSHA PEL, the Department believes that provisions to minimize worker exposure to beryllium in DOE facilities by lowering the action level (proposed § 850.23) and to encourage and require regular medical monitoring of workers (proposed § 850.34) will ensure an adequate level of protection for workers engaged in beryllium activities.

DOE considered adopting a short term exposure limit (STEL) of 10 µg/m³, averaged over a 15-minute sampling period (the ACGIH STEL at the time) in its original rule in 1999, however, because the STEL of 10 µg/m³ would not provide any added protection for the worker given that the action level of 0.2 µg/m³ would be exceeded in less than 15 minutes where exposure levels are at 10 µg/m³, the Department elected not to establish a STEL. The ACGIH dropped its STEL in 2009 when it lowered its 8-hour TWA TLV to 0.05 µg/m³.

DOE recognizes that OSHA has included a STEL of 2 µg/m³ in its proposed rule, *Occupational Exposure to Beryllium and Beryllium Compounds* (80 FR 47565, August 7, 2015), however, similar to the 1999 comparisons (between the DOE action level and ACGIH STEL), DOE's proposed action level of 0.05 µg/m³ would be exceeded in less than 15 minutes where exposure levels are at 2 µg/m³. Accordingly, the Department has elected to continue to not propose a STEL in this amendment.

#### Proposed § 850.23—Action Level

Proposed § 850.23(a) would continue to require employers to include in their CBDPPs an 8 hour time weighted average action level for beryllium and would change the action level from 0.2 µg/m³ to 0.05 µg/m³ (8-hour TWA of 0.05 microgram of beryllium, per cubic meter of air), as measured in the worker's breathing zone by personal monitoring. Due to the number of workers who have been identified as being sensitized to beryllium or having CBD, the Department feels that it is prudent to lower the action level. The 0.05 µg/m³ action level was chosen based on the Department's review of epidemiological studies and the ACGIH® TLV® (refs. 6–28). Lowering the action level to 0.05 µg/m³ would result in greater protection for the affected work force because it would lower the trigger that requires the use of controls and protective measures designed to prevent worker exposure to

beryllium. DOE does not anticipate that the lower action level will require the use of new or different types of equipment; it will just require implementation of the controls at a lower level.

*Benefits of lowering the action level.*

As specified in this proposed rule, being at or above the action level triggers the requirements to use a number of controls and protective measures designed to protect employees from exposures to beryllium. Employers at DOE sites where exposure levels are at or above the action level would be required to implement these controls at DOE's proposed lower action level.

Lowering the action level would increase the number of workers afforded the protective measures. DOE believes there are still a number of workers exposed to concentrations of beryllium between 0.05  $\mu\text{g}/\text{m}^3$  and 0.2  $\mu\text{g}/\text{m}^3$ , but who are never exposed to levels above 0.2  $\mu\text{g}/\text{m}^3$ . Under an action level of 0.2  $\mu\text{g}/\text{m}^3$ , these workers would not be provided the protective measures triggered by that action level. Under an action level of 0.05  $\mu\text{g}/\text{m}^3$ , however, these workers would be provided the additional protective measures specified in proposed § 850.23(b). These additional protective measures would potentially reduce the exposures experienced by these workers, leading to a reduction in their risk of developing a beryllium-induced medical condition.

As stated earlier, several provisions of the proposed rule would continue to apply independent of the action level. Specifically, these are the CBDPP requirement (10 CFR 850.10), the inventory requirement (10 CFR 850.20), the voluntary protective clothing and equipment requirement (10 CFR 850.29(a)(3)), the housekeeping requirements related to the cleaning of surfaces with removable beryllium (10 CFR 850.30(b) through (d)), the release or transfer requirements (10 CFR 850.31(c)), the waste disposal requirements (10 CFR 851.32), the beryllium emergencies requirement (10 CFR 850.33), the medical surveillance and restriction requirements as they relate to beryllium associated workers (10 CFR 850.34 and 850.35), the training and counseling requirements (10 CFR 850.38), the warning labels requirements (10 CFR 850.39(b)), and the recordkeeping and use of information requirements (10 CFR 850.40).

Proposed § 850.23(b) would continue to require employers to implement a number of protective measures designed to protect workers from beryllium exposures when the levels are at or above the action level, including:

- Periodic exposure monitoring (10 CFR 850.24(c));
- Additional exposure monitoring (10 CFR 850.24(d));
- Exposure reduction (10 CFR 850.25);
- Beryllium regulated areas (10 CFR 850.26);
- Hygiene facilities and practices (10 CFR 850.27);
- Respiratory protection (10 CFR 850.28);
- Protective clothing and equipment (10 CFR 850.29);
- Housekeeping (10 CFR 850.30); and
- Warning signs and labels (10 CFR 850.39).

Thus, DOE sites where exposure levels are at or above the action level would be required to implement these protective measures to provide further protection to workers exposed at or above the action level. These additional protections would reduce the exposure levels experienced by these workers, potentially reducing their risk of developing a beryllium-induced medical condition.

**Proposed § 850.24—Exposure Monitoring**

Proposed § 850.24 would continue to establish the worker exposure monitoring requirements of the CBDPP. The exposure monitoring provisions in this section are necessary to determine the extent of exposure at the worksite; prevent worker overexposure; identify the sources of exposure to beryllium; collect exposure data so that the employer can select the proper control methods to be used; evaluate the effectiveness of selected protective measures; and provide continual feedback on the effectiveness of the program in controlling exposures.

Exposure monitoring is important not only to determine the level of beryllium to which workers are exposed and the frequency at which workers should be monitored, but also to determine whether other protective provisions of the rule need to be implemented. The employer's obligation to provide protective clothing and equipment, for example, is triggered by monitoring results showing that a worker is exposed to airborne concentrations of beryllium at or above the action level.

Proposed § 850.24(a)(1) would continue to require employers to ensure that exposure monitoring be managed by a qualified individual, and add the requirement for monitoring to be conducted in accordance with the approved CBDPP. Proposed § 850.24(a)(2) would require employers to determine the beryllium exposure of workers by collecting personal breathing

zone samples that reflect a worker's exposure to airborne concentrations of total beryllium averaged over an 8-hour period. This is a measurement of the exposure that would occur if the worker was not using respiratory protection equipment. Breathing zone is defined in § 850.3(a) as “a hemisphere forward of the shoulders, centered on the mouth and nose, with a radius of 6 to 9 inches.” Thus, a breathing zone sample should be taken as close as practical to the nose and mouth of the worker and must be taken within a 6 to 9 inch radius.

*Surface level monitoring.* DOE received several comments in response to its RFI concerning how current wipe sampling protocols aid exposure assessments and protect beryllium workers. The commenters' general view is that wipe sampling is effective at determining the presence of beryllium and can be used to define contaminated spaces, and that wipe sampling remains a valuable method to ensure that work areas are kept clean and equipment is properly released from controls. In addition, wipe samples aid in the identification of beryllium that could potentially become airborne and are therefore an important tool that should be used when assessing potential beryllium hazards. A few commenters suggested that measuring surface levels is not sufficiently exact and that surface levels do not correlate with health effects. Those commenters suggested that surface sampling should not be used to measure worker exposure or demonstrate regulatory compliance; that workers and the media have inappropriately focused attention on wipe sampling results as the indicator of what is “safe”; that DOE facilities have come under scrutiny for surface sampling results that do not accurately represent the potential for BeS or development of CBD; and that surface sampling is prohibitively expensive when used for the release of equipment.

DOE also received several comments in response to its RFI concerning how reliable and accurate current sampling and analytical methods are for beryllium wipe samples. Commenters pointed out that there is a high level of variability in measured surface loadings within and between individuals collecting wipe samples from the same surface. Studies have shown that a number of factors affect the reliability and accuracy of current wipe sampling methods, and recovery of material from surfaces is highly dependent on the skill, training, and work practices of the individual collecting the samples. Concerning analysis of wipe samples, however, commenters suggested that the

issues associated with the reliability and accuracy of analytical methods used for beryllium wipe samples are no different from those encountered in obtaining good results for airborne samples, and the current sampling and analytical protocols are reliable and accurate.

DOE has considered the commenters' suggestions, along with other available information, and proposes to amend this section by including requirements for monitoring the levels of beryllium on surfaces. Monitoring surface levels is necessary for implementing requirements applying to surfaces that have a potential for exceeding the release criteria established in proposed § 850.31.

DOE received several comments in response to its RFI concerning whether the Department should require the use of wet wipes for surface monitoring. Many of the commenters supported DOE requiring the use of wet wipes but also recommended allowing the use of dry wipes where necessary. These commenters also recommended that DOE specifically identify the standard wipe test method that employers must use. A few commenters recommended that DOE continue not to specify how surfaces are sampled for beryllium.

In the preamble to the final rule, DOE had encouraged the use of wet wipes rather than dry wipes for surface monitoring, but did not require this in the rule itself. DOE's experience with wipe testing since December 1999, when the final rule was issued, supported by the suggestions of commenters to its RFI, as well as published (ref. 36) and unpublished studies demonstrating that wet wipes recover more of the surface contamination than do dry wipes, leads to proposed § 850.24(a)(2)(ii)(A) and (B). The proposed section would require the use of wet wipes with certain exceptions. This will also allow DOE to achieve greater comparability of results across the DOE complex. DOE intends for wetting agents to be selected such that wipe test results would be representative of removable beryllium (e.g., DOE would not expect employers to use aggressive solvents that would remove beryllium embedded in sticky cutting fluid on machine surfaces).

DOE recognizes that surface wipe sampling using wet wipes could have an undesirable effect on some potentially contaminated surfaces, or surfaces surrounding the target surface, and that it is not technically feasible on some textured surfaces. Proposed § 850.24(a)(2)(ii)(B) would allow dry surface wipe sampling for those situations. DOE recognizes that any type of wipe testing may not be technically

feasible on highly textured surfaces and proposes in § 850.24(a)(2)(ii)(C) to allow vacuum sampling for those situations. DOE also recognizes that surface wipe testing does not recover a high proportion of heavy accumulations of materials on surfaces and is therefore not appropriate for measuring concentrations of beryllium on such surfaces. Proposed § 850.24(a)(2)(ii)(D) would allow bulk sampling for heavy accumulations of materials on surfaces.

Proposed § 850.24(a)(3) would not require surface monitoring in the interior of installed closed systems such as enclosures, glove boxes, chambers, ventilation systems, or normally inaccessible surfaces (e.g., under fixed cabinets, on the tops of overhead structural beams), as beryllium in those locations normally is not accessible to workers. DOE expects that employers will consider the hazards posed by those sources of beryllium exposure in work planning or operating procedures that may involve disturbing the beryllium.

Proposed § 850.24(b)(1) would continue to require employers to perform initial exposure monitoring of workers who perform work in areas that may have airborne concentrations of beryllium, as shown by the inventory and hazard assessment that are at or above the action level, or have the potential to be at or above the action level. However, DOE is proposing to revise this section to make an exception for employers in paragraphs (b)(2) and (3) of this section. In implementing this part, as issued in December 1999, DOE has identified a great many stable situations at its sites in which beryllium has been effectively inventoried, controlled, and conditions have not changed for many years. DOE recognizes that many employers have performed initial exposure monitoring in areas that are accessible to workers and shown by the inventory and hazard assessment as part of their compliance with the current rule. DOE sees no value in repeating exposure monitoring if prior monitoring results are adequate under the proposed rule. Accordingly, proposed § 850.24(b)(2) would allow employers to use the monitoring results obtained within 12 months prior to the effective date of the final rule to satisfy this requirement when a qualified individual has determined that the conditions represented by the results have not changed in a manner that would necessitate changes in beryllium controls.

Proposed § 850.24(b)(3) would be added to clarify that no initial monitoring is required in cases where the employer has relied upon objective

data that demonstrates that beryllium is not capable of being released in airborne concentrations at or above the action level under the expected conditions of processing, use, or handling.

Proposed § 850.24(c)(1)(i) would continue to require employers to conduct periodic exposure monitoring of workers in a manner and at a frequency necessary to represent workers' exposures in locations where the airborne concentration of beryllium is at or above the action level. Periodic monitoring provides employers with the assurance that workers are not experiencing higher exposures that might require the use of additional controls. In addition, periodic monitoring reminds workers and employers of the continued need to protect against the hazards associated with exposure to beryllium. Proposed § 850.24(c)(1)(ii) would require employers to conduct exposure monitoring at least quarterly for the first year of operation.

DOE is proposing to add § 850.24(c)(2) to allow employers, after the first year of conducting periodic monitoring, and subject to paragraph (d) of this section, to reduce or terminate monitoring if the employer can demonstrate for 6 months that the airborne concentration of beryllium is below the action level. Employers would be required to base their decision on an analysis of monitoring results and of any activities, controls, or other conditions that would affect beryllium levels. If the employer cannot demonstrate that the airborne concentration of beryllium is below the action level, then periodic monitoring must continue on a quarterly basis.

Proposed § 850.24(d) would require that employers conduct additional exposure monitoring whenever there has been a production, process, control or other change that may result in an exposure to beryllium at or above the action level. DOE is proposing this requirement to address a condition at several DOE sites in which beryllium controls usually keep exposure levels below the action level, but beryllium sources are still present, or could be present such as in waste streams exhumed from legacy sites—and could result in exposures if the controls fail. DOE would require periodic monitoring on a quarterly basis for those conditions so that monitoring results are available to verify the continued effectiveness of the controls.

Proposed § 850.24(e)(1) would be revised to require that samples that are collected be analyzed in a laboratory that is accredited for beryllium analysis by the American Industrial Hygiene Association's Laboratory Accreditation

Programs, LLC (AIHA-LAP, LLC) or an equivalent organization. Currently, § 850.24(f) requires samples to be analyzed in a laboratory accredited for metals by the AIHA-LAP, LLC or a laboratory that demonstrates quality assurance for metals analysis that is equivalent to AIHA-LAP, LLC accreditation. The proposed language is intended to correct the problem DOE has experienced in which laboratories, currently accredited by AIHA-LAP, LLC for metals, may not be aware that a significant amount of beryllium in samples (in the form of beryllium oxide) may not be recovered in the laboratories' sample preparation processes. DOE anticipates that AIHA-LAP, LLC, and perhaps other accrediting or certifying organizations, will have proficiency testing programs specifically for beryllium oxide and potentially other forms of beryllium-containing materials of interest which are present in field samples, to ensure that a high percentage of those forms of beryllium in the sample are recovered in the sample preparation step and are included in the analysis results. Such proficiency testing programs also would assist laboratories in using some of the strategies for distinguishing forms of beryllium as discussed in this preamble regarding proposed § 850.3.

Proposed § 850.24(e)(2) would require a number of additional changes dealing with the quality assurance of the sample analysis results. DOE proposes to delete the requirement that the method of sample monitoring and analysis has an accuracy of not less than plus or minus 25%, with a confidence level of 95%, because that data quality objective is superseded by requirements of the AIHA laboratory quality assurance program. Also, proposed § 850.24(e)(2)(i) would permit employers to use a field or portable laboratory that is accredited in an AIHA or equivalent quality assurance program, to support increasing the speed with which exposure results are delivered so that employers can more quickly identify and control beryllium hazards. DOE anticipates that this will also increase mission productivity.

Proposed § 850.24(e)(2)(ii) would allow employers to use results that are below laboratory reporting limits, which would enhance the usefulness of these results for determining if specified levels are exceeded.

DOE is proposing to delete existing § 850.24(f) because its subject matter is proposed to be included in § 850.24(e). Proposed § 850.24(f) would amend the requirement in existing § 850.24(g) for notification of results to clarify DOE's intent that the employer notify all the

workers in the same work area of the monitoring results that represent those workers' exposures rather than only notifying the workers that were monitored. This clarification addresses DOE's observation that some DOE sites have interpreted the notification requirement to mean that workers are notified only of their individual airborne monitoring results. When this happens, it means that the group of unmonitored workers in the same work area failed to receive useful feedback regarding potential exposures and the need for various levels of exposure controls. Accordingly, proposed § 850.24(f)(1) would require employers to notify workers of their exposure monitoring results within 10 working days after receipt of the results. Proposed § 850.24(f)(1)(i) and (ii) would require employers to provide notification of exposure monitoring in written or electronic format and posted in locations or in electronic systems that are readily accessible to workers, but not in a manner that would identify an individual or workers. Employers would be required to give directly to individuals that were sampled their results in written or electronic format.

Proposed § 850.24(f)(2)(i) and (ii) would specify the form of notification required for monitoring results at or above the action level. Employers would be required to include in the notification a statement that exposures were at or above the specified action level, a descriptions of the controls being implemented to address those exposures. In addition, proposed § 850.24(f)(3) would continue to require employers to provide a notification to the SOMD, and a notification to the Head of DOE Field Element or their designee. DOE believes that the SOMD should be informed of such exposures in order to refine, as appropriate, the medical surveillance protocol for affected workers to ensure effective monitoring and early detection of beryllium-related health effects.

#### Proposed § 850.25—Exposure Reduction

Proposed § 850.25 would continue to establish the exposure reduction and minimization provisions of the CBDPP that reflect DOE's goal of achieving aggressive reduction and minimization of worker exposures to airborne beryllium. However, this section would be revised to require employers, where exposures and the action level, to establish a formal exposure reduction program in accordance with 10 CFR 851.22, *Hazard Prevention and Abatement*, to reduce exposure levels to below the action level.

DOE is proposing to delete the requirement to continue reducing and minimizing exposures that already are below the action level because DOE believes that the measures required at or above the proposed action level are protective. DOE would also delete the specific exposure reduction actions that are required of responsible employers in the current version of 10 CFR 850.25 because DOE expects employers to understand how to establish a formal exposure reduction program, and listing certain specific steps could constrain employers in unproductive ways.

#### Proposed § 850.26—Beryllium Regulated Areas

Beryllium regulated areas typically are areas in which activities that involve beryllium are conducted. Proposed § 850.26 would continue to establish beryllium regulated areas at DOE sites. Accordingly, proposed § 850.26(a) would continue to require employers to establish beryllium regulated areas in facilities at DOE sites where the airborne concentration of beryllium is at or above the action level.

Proposed § 850.26(b)(1) would require employers to demarcate beryllium regulated areas from the other workplace areas in a manner that alerts workers to the boundaries of such areas. This would allow employers the flexibility to determine the most appropriate means of identifying each beryllium regulated area based on specific worksite conditions.

Proposed § 850.26(b)(2) would continue to require employers to limit access to beryllium regulated areas to authorized persons only. DOE intends that only individuals who are essential to the performance of work in the beryllium regulated area will be authorized to enter beryllium regulated areas. Employers will have to evaluate the affected operation and determine which personnel (including managers, supervisor, and workers) are necessary for the performance of the work and authorized to enter. Methods for preventing unauthorized persons from entering a regulated area may include posting a sign indicating that only authorized persons may enter, using locked access doors, and employing other security measures, as required by worksite conditions. DOE believes that employers are best equipped to determine whether any access control methods are needed in addition to warning signs specified in proposed § 850.39 of this part.

Proposed § 850.26(b)(3) would continue to require employers to keep record of all individuals who enter beryllium regulated areas. The record

must include the name of the person who entered, the date of entry, the time in and time out, and the type of work performed. DOE believes that recordkeeping must be adequate to permit DOE to monitor the effectiveness of each employer's compliance activities and to provide information regarding each worker's history of potential exposures. This information will assist the employer's occupational medicine staff in establishing appropriate medical evaluations and will aid in DOE's efforts to establish links between working conditions and potential health outcomes.

#### Proposed § 850.27—Hygiene Facilities and Practices

Proposed § 850.27 would continue to provide requirements regarding hygiene facilities and practices of the CBDPP. Accordingly, proposed § 850.27(a)(1) and (2) would continue to require employers to ensure that beryllium workers observe prohibitions on the use of cosmetics and tobacco products, and consumption of food and beverages in beryllium regulated areas. Proposed § 850.27(a)(3) would require employers to prevent beryllium workers from exiting areas that contain beryllium with contamination on their bodies or their personal clothing. DOE believes these provisions would promote sound workplace hygiene practices that may protect workers from exposure to other substances present in the workplace as well as beryllium.

Proposed § 850.27(b)(1) would continue to require employers to provide a separate changing room or area for workers to change into and store personal clothing and clean protective clothing and equipment. DOE believes that such provisions are necessary to prevent cross-contamination between work and personal clothing and the subsequent spread of beryllium into clean areas of the site and workers' private automobiles and homes. These provisions also address the need to prevent contamination of clean protective clothing and equipment, ensuring that protective clothing and equipment actually protect workers rather than contribute to their exposure.

Proposed § 850.27(b)(2) would continue to require that the changing-rooms used to remove beryllium-contaminated clothing and protective equipment be maintained under negative pressure, or be located in a manner or area that prevents dispersion of beryllium contamination into clean areas. DOE believes that providing changing rooms for workers who work in beryllium-regulated areas is the most effective method for preventing workers

from carrying beryllium contamination on their work clothes and bodies from beryllium regulated areas to other areas of the DOE site, and to their private automobiles and homes.

Consistent with the goal of preventing the spread of contamination into adjacent work areas and into workers' homes and automobiles, proposed § 850.27(c) continues to require employers to provide handwashing and shower facilities for workers in beryllium regulated areas. In addition to controlling the spread of contamination, showering also reduces the worker's period of exposure to beryllium by removing any beryllium that may have accumulated on the skin and hair. Requiring workers to change out of work clothes that are segregated from their street clothes, leave work clothing at the workplace (see § 850.29), and shower before leaving the plant, significantly reduces the movement of beryllium from the workplace. These steps ensure that the duration of beryllium exposure does not extend beyond the work shift and, thus, protect workers and their families from off-site exposures.

Proposed § 850.27(d) would continue to require employers to provide beryllium workers working in beryllium regulated areas with readily accessible lunchroom facilities. Employers must also ensure that workers in beryllium regulated areas do not enter the lunchroom wearing protective clothing unless the clothing is cleaned beforehand. Employers have discretion to choose the method for removing surface beryllium from the clothing, including HEPA vacuuming, so long as the method does not disperse the dust into the air.

Proposed § 850.27(e) would continue to require change rooms or areas, showers and handwashing facilities, and lunchroom facilities to comply with 29 CFR 1910.141, *Sanitation*.

#### Proposed § 850.28—Respiratory Protection

Proposed § 850.28 would continue to establish the respiratory protection provisions of the CBDPP. However, proposed § 850.28(a) would be revised for consistency with part 851 to require employers to establish a respiratory program in accordance with 10 CFR 851.23, *Safety and Health Standards*, and appendix A, section 6, *Industrial Hygiene*, for workers exposed, or potentially exposed to airborne concentrations of beryllium at or above the action level. The standards listed in 10 CFR 851.23 include 29 CFR 1910.134 "Respiratory Protection" and ANSI Z88.2 "American National Standard for Respiratory Protection (1992). The

requirements in appendix A, section 6, *Industrial Hygiene*, cover the DOE Respirator Acceptance Program. Note that the requirements established in 10 CFR 851.23 are set forth as minimum requirements. DOE contractors may elect to implement alternative provisions (e.g., newer versions of consensus standards such as ANSI/ASSE Z88.2–2015) if they determine the alternative provisions are more appropriate and provide an equivalent or improved level of protection, and if the provisions are included in their CBDPP that has been approved by DOE.

#### Proposed § 850.29—Protective Clothing and Equipment

Proposed § 850.29 would continue to establish the protective clothing and equipment provisions (other than respirator use) of the CBDPP. The objectives of this section would be to provide clothing and equipment that protects workers against the hazards of skin and eye contact with dispersible forms of beryllium and to prevent the spread of contamination outside work areas that could occur from the improper handling of beryllium-contaminated clothing and equipment. In addition, the requirement for handling protective clothing and equipment used for protecting workers from beryllium exposure in beryllium regulated areas would be clarified.

The proposed rule would continue to require employers to provide protective clothing and equipment where skin or eye contact with dispersible forms of beryllium is possible. Proposed § 850.29(a) would continue to require employers to provide protective clothing and equipment to beryllium workers where dispersible forms of beryllium may contact workers skin, enter openings in workers' skin or contact workers' eyes.

An opening in workers' skin could include fissures, cuts, and abrasions. DOE recognizes that the potential for the development of contact dermatitis, chronic ulcerations, and conjunctivitis is mainly associated with contact with soluble forms of beryllium compounds that are not included in the definition of "beryllium" in this proposed rule because DOE believes that soluble forms of beryllium are not used at its beryllium sites. Insoluble beryllium, however, has also been shown to cause chronic ulcerations if introduced into or below the skin via cuts or abrasions (ref. 37). DOE believes that it is prudent practice to avoid skin or eye contact with a material that causes chronic ulcerations and, therefore, continues to include the protection of workers' skin and eyes from contact with insoluble

beryllium in proposed § 850.29(a). The protective equipment required by this proposed section could include coveralls, overalls, jackets, footwear, headwear, face shields, goggles, gloves, and gauntlets, depending on the nature of operations and the related skin and eye exposure hazard.

Proposed § 850.29(a) would continue to require employers to provide protective clothing and equipment and ensure its appropriate use and maintenance by workers where dispersible forms of beryllium may contact workers' skin or eyes or may enter openings in which workers' skin, including where:

- Exposure monitoring has established that the airborne concentration of beryllium is at or above the action level [proposed § 850.29(a)(1)];
- Surface contamination levels measured or presumed prior to initiating work are at or above the level prescribed in proposed § 850.30 of this part [proposed § 850.29(a)(2)];
- Surface contamination level results obtained to confirm housekeeping efforts are above the level prescribed in proposed § 850.30 of this part [proposed § 850.29(a)(3)]; and where;
- A worker requests the use of personal protective clothing and equipment for protection against airborne beryllium, regardless of the measured exposure level [proposed § 850.29(a)(4)].

Proposed § 850.29(b) would continue to require employers to comply with 29 CFR 1910.132, *Personal Protective Equipment General Requirements*, when workers use personal protective clothing and equipment. This requirement to comply with 29 CFR 1910.132 is consistent with the general worker protection provisions of 10 CFR part 851.

Proposed § 850.29(c) would continue to require employers to establish procedures for donning, doffing, handling, and storing protective clothing and equipment that prevent beryllium workers from exiting beryllium regulated areas with contamination on their bodies or personal clothing [proposed § 850.29(c)(1)]. Proposed § 850.29(c)(2) would require these procedures include a requirement that workers exchange their personal clothing for full-body protective clothing and footwear (work shoes or booties) before beginning work in beryllium regulated areas. This change from personal clothes into protective work clothing must occur in a changing room that protects the worker's personal clothes and clean protective clothing from beryllium

contamination. DOE believes the use of full-body protective clothing in lieu of personal clothes in beryllium regulated areas is necessary to prevent the spread of beryllium contamination into adjacent work areas and to preclude the possible transport of beryllium onto workers' private property.

Proposed § 850.29(d) would require employers to ensure that workers do not remove beryllium-contaminated protective clothing and equipment from beryllium regulated areas, except for workers authorized to launder, clean, maintain or dispose of the clothing and equipment.

Proposed § 850.29(e) would require employers to prohibit the removal of beryllium from protective clothing and equipment by blowing, shaking, or other means that might disperse beryllium particulates into the air. Although DOE generally believes that employers should have the flexibility to determine the most appropriate methods to clean contaminated clothes based on their own specific worksite conditions, DOE continues to include this well-recognized and accepted industrial hygiene control to prevent the dispersion of beryllium particles into the workplace atmosphere.

Proposed § 850.29(f) would continue to require employers to ensure that protective clothing and equipment is cleaned, laundered, repaired, or replaced as needed to maintain effectiveness. This section allows employers flexibility in determining the required frequency for laundering protective clothing based on specific work conditions and the potential for contamination.

Proposed § 850.29(f)(1) would continue to require employers to ensure that protective clothing and equipment removed for laundering, cleaning, maintenance, or disposal are placed in containers that prevent the dispersion of beryllium particulates and that these containers are labeled in accordance with proposed § 850.39(b)(1). These warning labels would help ensure appropriate subsequent handling of materials contaminated with beryllium and may prevent inadvertent exposures that could result if laundry, maintenance, or disposal personnel are not aware of the contamination and the prescribed methods to prevent the release of airborne beryllium.

Proposed § 850.29(f)(2) would continue to require employers to ensure that organizations that launder or clean DOE beryllium-contaminated clothing or equipment are informed that exposure to beryllium is harmful, and that clothing and equipment should be laundered or cleaned in a manner

preventing the dispersion of beryllium. This section would require informing onsite cleaning and laundry services, as well as off-site cleaning and laundry vendors because employees performing the work may not know about the presence and hazards of beryllium on the clothing and equipment unless the employer informs them.

#### Proposed § 850.30—Housekeeping

Proposed § 850.30 would continue to establish the housekeeping provisions of the CBDPP. Good housekeeping practices are necessary to prevent the accumulation of beryllium contamination on surfaces in operational areas where beryllium is used or handled. Such accumulations, if not controlled, may lead to the spread of beryllium contamination on surfaces and the re-suspension of beryllium particles into the air, both in the area where beryllium dust was originally generated and in other work areas. In addition, monitoring surface contamination levels is an indispensable tool for ensuring that beryllium emissions from operations are under control. The uncontrolled accumulation of beryllium-contamination on equipment in the workplace increases the potential for worker exposure to beryllium during the performance of equipment maintenance, handling, and disposal tasks. Accordingly, proposed § 850.30(a) would continue to establish that the removable contamination housekeeping level on surfaces must not exceed  $3 \mu\text{g}/0;100 \text{ cm}^2$  during non-operational periods to reduce the potential for beryllium to become re-suspended in the workplace or spread to non-controlled areas. Employers must conduct routine surface sampling to determine if operational work areas are compliant with the rule. Sampling should not be carried out during a normal work shift, but rather it should be undertaken after normal clean-up and during non-operational periods. As with the current § 850.30(a), the sampling requirement would not include the interior of installed closed systems such as enclosures, glove boxes, chambers, or ventilation systems.

The performance of housekeeping tasks can, in and of itself, lead to worker exposures to beryllium-contaminated dust. Therefore, this section would continue to seek to prevent the spread and re-suspension of dust during housekeeping activities.

Proposed § 850.30(b) would continue to require vacuuming using HEPA filters, wet methods, or other cleaning methods that avoid the dispersion of dust, and prohibits the use of

compressed air or dry methods that may disperse beryllium particulates. The use of wet methods for reducing or minimizing the dispersal of dust during general housekeeping tasks is a common industrial hygiene practice. The purpose of using these methods is to reduce or eliminate the potential for re-suspension of beryllium dust into the air and breathing zone of the worker.

Proposed § 850.30(c) would require the use of HEPA filters in all vacuuming operations used to clean beryllium-contaminated surfaces, and further requires filter replacement, as needed, to maintain the capture efficiency of the vacuum system. HEPA filters must be used to prevent the spread of dust by effectively gathering the dust that is collected by vacuum systems. Employers should adhere to procedures for cleaning or replacing filters that ensure minimum employee exposure to beryllium dust.

The movement of contaminated equipment from a regulated area to a non-regulated area may result in the spread of beryllium contamination to the non-regulated area. To prevent the potential spread of contamination from performing housekeeping activities, proposed § 850.30(d) would continue to require that cleaning equipment used in areas where surfaces are contaminated with beryllium be labeled, controlled, and not used for other non-hazardous materials. These procedures are similar to those required under OSHA's asbestos standard for equipment used during cleanup or removal of asbestos from buildings.

#### Proposed § 850.31—Release and Transfer Criteria

Proposed § 850.31 would continue to establish beryllium contamination levels and other requirements that must be met before equipment and other items used in beryllium regulated areas may be released or transferred. However, DOE is proposing to amend the criteria for the release and transfer of beryllium-contaminated equipment and items, and add provisions for the release and transfer of “areas” (*i.e.*, real property, an area of a building, or a work area) at or above the specified level to this section. DOE's experience with managing beryllium-contaminated areas, as well as recent literature suggesting that surface contamination is a risk factor for BeS, motivated DOE to include release and transfer criteria for beryllium-contaminated areas.

This part, as issued in December 1999, included requirements to label decontaminated equipment and items and obtain a commitment from their recipients to implement safety controls

to prevent exposure to beryllium. At that time, DOE's focus was on the typical machine shop equipment on which work with beryllium was reported to have caused cases of BeS and CBD. The machines in these shops contain many areas that were not accessible for decontamination and, therefore, considered potential sources of exposure to downstream users of the machines. DOE's wording in this part did not make allowances for equipment and items of simple construction that can be conclusively demonstrated to have all surfaces adequately decontaminated, or for equipment and items suspected but subsequently determined to not have been contaminated with beryllium, and that do not pose a risk to downstream users. Very few potentially interested parties were willing to accept equipment, items, or areas that were decontaminated, or found not to have been contaminated in the first place, that came with a warning label and required the commitment to implement controls.

DOE's proposed amendments would allow for the release without restriction of equipment, items, and areas that are demonstrably decontaminated at or below specified levels or were suspected but subsequently shown not to have been contaminated. DOE expects that potential downstream users will be more willing to accept decontaminated equipment, items, and areas that do not include these unwarranted warnings.

In this proposed section, the term “items” would be intended to cover tools, supplies, documents, etc., and any personal property in beryllium regulated areas that may not be encompassed by the term equipment. The terms “equipment” and “items” do not include real property or buildings. However, the term “area” would be intended to include real property, buildings or work areas.

Proposed § 850.31(a) would amend the requirements for releasing from beryllium regulated areas equipment, items, and areas contaminated at or below the levels specified in this subsection.

Proposed § 850.31(a)(1) would amend the existing regulation to require that, prior to the general release or transfer of equipment and items, or areas, employers ensure that for formerly beryllium-contaminated equipment and items, or areas (except those that only contain beryllium in normally inaccessible locations or embedded in hard-to-remove substances), the removable contamination level of beryllium is at or below  $0.2 \mu\text{g}/100 \text{ cm}^2$ .

Beryllium inventories of older sites that uncover records or other information indicating past beryllium activities are required by existing § 850.20(b)(4) and would be required by proposed § 850.20(a)(3) to be surveyed to determine if legacy contamination is present. Such surveys would include sampling accumulated material on the surfaces of infrequently cleaned equipment and items, and in areas that may contain beryllium because of the trace quantities in soils and building materials (*i.e.*, below 0.1% beryllium pursuant to the definition of beryllium in this proposed rule). For example, concentrations of beryllium range from 0.09 to 3.4 parts per million (ppm) in U.S. soils (ref. 18). Proposed § 850.31(a)(2) recognizes that concentrations of beryllium in accumulated indoor material that is not greater than the concentration of beryllium in surrounding soil provides convincing evidence that the area is not contaminated. A variety of approaches may be used to compare beryllium concentrations in soil collected from a reference area to the concentration in settled dust in such reference area. The National Institute for Science and Technology Engineering Statistics Handbook provides methods used to demonstrate that the difference between two sets of samples is significant (ref. 38).

In response to its RFI, DOE received several comments concerning whether the Department should establish both surface level and aggressive air sampling criteria (modeled after Environmental Protection Agency (EPA)'s aggressive air sampling criteria to clear an area after asbestos abatement) for releasing areas in a facility, or instead whether the Department should consider establishing only the aggressive air sampling criteria. Commenters' suggestions varied considerably in response to this question, with some recommending only surface sampling, some recommending only aggressive air sampling, and some recommending use of both for the area considered for release. Some commenters suggested that aggressive sampling in buildings that previously had known areas of beryllium use was not able to remove beryllium from structural beams, even though multiple fans were blowing large volumes of air. In addition, these commenters indicated that there is no need to assign a lower airborne level (*i.e.*, lower than the action level) if the surface level is below  $0.2 \mu\text{g}/100 \text{ cm}^2$ . Others suggested use of aggressive air sampling as a means to release an area

where beryllium is suspected in hard to reach places, and that aggressive air sampling would be more representative than surface sampling for a worker's airborne exposure, which is the route of exposure of greater concern.

DOE has considerable experience with repeat cycles of cleaning and verifying that decontaminated equipment, items, and areas have achieved either the 0.2  $\mu\text{g}/100\text{ cm}^2$  or 3  $\mu\text{g}/100\text{ cm}^2$  release criteria by wipe testing alone. DOE's experience includes decontaminating areas, even though there were no provisions regarding the release of such areas in the final rule, as issued in December 1999. The use of wipe testing to demonstrate completeness of decontamination often is very time consuming and costly, with diminishing reduction in health risk as the cycles are repeated, especially for surfaces that are many-faceted, rough, highly textured, or difficult to access (e.g., around many-faceted and complex utility surfaces). DOE's objective in this part is to establish an effective method for assuring that decontaminated surfaces no longer present a beryllium health risk of concern.

Proposed § 850.31(a)(3) would establish that the airborne concentration of beryllium in an enclosure of the smallest practical size surrounding the equipment or item, or in an isolating enclosure of the area could not exceed 0.01  $\mu\text{g}/\text{m}^3$ . In such cases, DOE is not requiring, but believes its contractors would be able to demonstrate achieving this level by borrowing from EPA's 40 CFR part 763, subpart E, *Asbestos-Containing Materials in Schools*, approach to clearing an area after asbestos abatement. This approach involves enclosing the equipment or item, or creating an enclosure of the area, and demonstrating by aggressive air sampling that air levels in the enclosure do not exceed a specified level. Aggressive air sampling refers to the method of using leaf blower-equivalents and large fans to dislodge and keep suspended particles that were on a surface, and then sampling the air for the suspended particles. In proposed § 850.31(a)(3), DOE selected 0.01  $\mu\text{g}/\text{m}^3$  as the clearance level because it is the same as EPA's limit for beryllium emissions, as specified in "*National Emission Standards for Hazardous Air Pollutants*," 40 CFR part 61. EPA's limit is a 30-day average in ambient air and is an around-the-clock exposure; therefore, applying that level to workers' hours of potential exposure provides a significant safety factor. Aggressive air sampling maximizes the amount of surface material entrained in the air and consequently, the amount of airborne

material captured in the sample as well. Aggressive sampling, therefore, creates a "worst-case" contamination condition and a "best-case" for measuring the cleanliness of the equipment, item, or area.

DOE included in this proposal the provision that the enclosure surrounding equipment or items must have as small a size as practical to prevent the use of unnecessarily large enclosures that would facilitate meeting the 0.01  $\mu\text{g}/\text{m}^3$  criteria simply by dilution. DOE believes clearance for release of equipment and items, and areas by aggressive air sampling would ensure that surfaces are not sufficiently contaminated to present a risk of BeS. This belief is based on the assumption that, under all realistic conditions, removable beryllium levels sufficient to present a risk of BeS would be entrained in the air and shown by the clearance air samples to exceed 0.01  $\mu\text{g}/\text{m}^3$ . This approach would also more directly demonstrate that removable surface beryllium does not present an inhalation hazard, as opposed to making an assumption about a possible inhalation risk caused by the re-suspension of surface contamination. Finally, this approach would allow for a potentially more cost-effective process than wipe testing for demonstrating completeness of decontamination for clearance of release of some types of surfaces.

Proposed § 850.31(b) would allow the release or transfer of equipment, items, or areas in which surface contamination is inaccessible or has been sealed with hard-to-remove substances (e.g., paint), and the requirements in paragraphs (a)(1) through (3) of this section are met. In this case, the employer would be required to ensure that the labeling requirements in 850.39(b)(2) are met as specified in proposed § 850.31(b)(1). Proposed § 850.31(b)(2) would require the employer to condition the release of equipment, item, or area based on the recipients' commitment to implement controls to ensure that exposure does not occur. Such a commitment should be based on the nature and possible use of the equipment or item, the nature of the beryllium contamination, and whether exposure to beryllium is foreseeable.

Proposed § 850.31(c) would be amended to allow for conditional release or transfer of equipment, items, or areas with levels that exceed 0.2  $\mu\text{g}/100\text{ cm}^2$ . For equipment, items, or areas that have removable beryllium above 0.2  $\mu\text{g}/100\text{ cm}^2$ , or that have beryllium in material on the surface at levels above the levels in soil at the point of release, the employer would be required to:

- Provide the recipient with a copy of this part [proposed § 850.31(c)(1)];
- Condition the release of the equipment, item, or area on the recipient's commitment to control foreseeable beryllium exposures from the equipment, item, or area considering its future use [proposed § 850.31(c)(2)];
- Label, or post signs on, as applicable, the equipment, item, or area in accordance with proposed § 850.39(a) or (b)(1) of this part to warn recipients of potential beryllium hazards [proposed § 850.31(c)(3)];
- Place equipment or items in sealed, impermeable bags or containers, or have a sealant applied to prevent the release of beryllium during handling and transporting [proposed § 850.31(c)(4)]; and
- Ensure that the beryllium that remains removable on the surfaces in areas that are being released do not exceed the 3  $\mu\text{g}/100\text{ cm}^2$  surface contamination level [proposed § 850.31(c)(5)].

#### Proposed § 850.32—Waste Disposal

Proposed § 850.32 would continue to establish the waste disposal provisions of the CBDPP. Like many of the provisions of the rule (e.g., beryllium regulated areas, protective clothing and equipment, housekeeping), the waste disposal provisions are designed to minimize the spread of beryllium contamination on the site or beyond the site boundaries.

Proposed § 850.32(a)(1) would require employers to dispose of beryllium waste in sealed, impermeable bags, containers, or enclosures to prevent the release of beryllium during handling and transportation.

Proposed § 850.32(a)(2) would require employers to label the bags, containers, or enclosures for disposal in accordance with § 850.39(b)(1) of this part.

DOE is proposing to delete existing § 850.32(a), which is the requirement for employers to control the generation of beryllium-containing waste, beryllium-contaminated equipment, and other items through the application of waste minimization principles, because waste minimization is outside the scope of this part and is addressed in the Department's environmental policy documents.

#### Proposed § 850.33—Beryllium Emergencies

Proposed § 850.33 would continue to establish the beryllium-related emergency provisions of the CBDPP. Such provisions continue to be particularly important in light of the possibility that a single high-level beryllium exposure may be the cause of

CBD among workers thought to have had no previous exposure or only incidental low-level exposure to beryllium. However, proposed § 850.33(a) would be revised for consistency with part 851 to require employers to establish provisions for beryllium-related emergencies in accordance with 10 CFR 851.23, *Safety and Health Standards*. The standards listed in 10 CFR 851.23 include 29 CFR 1910.120(l) for emergency response activities related to hazardous waste cleanup operations, and 29 CFR 1910.120(q) for emergency response activities related to all other operations.

#### Proposed § 850.34—Medical Surveillance

Proposed § 850.34 would continue to establish the medical surveillance provisions for the CBDPP. Accordingly, proposed § 850.34(a) would continue to require employers to establish and implement a medical surveillance program for beryllium and beryllium-associated workers. However, DOE proposes to make the surveillance program mandatory for beryllium workers and voluntary for beryllium-associated workers.

*a. Public policy and legal issues related to mandatory medical evaluations, mandatory restrictions and mandatory removal.* The Department proposes several changes in part 850 that make certain actions mandatory rather than voluntary. These include the following:

- Proposed § 850.34(a) and (b)(1)(i) would require that medical evaluations be mandatory rather than voluntary for beryllium workers. In the final rule, as issued in 1999, § 850.34(b) required employers to provide medical evaluations to beryllium-associated workers (which included beryllium workers); however, the final rule did not make participation in the medical surveillance program mandatory for those workers.

- Proposed § 850.36(a)(3) would require the SOMD to recommend temporary removal of a beryllium worker pending the outcome of the medical evaluations conducted pursuant to § 850.34(b), or pending the outcome of the multiple physician review process pursuant to § 850.34(e) or the alternate physician review process pursuant to proposed § 850.34(f), if the beryllium worker is showing signs or symptoms of BeS or CBD, and the SOMD believes that further exposure to beryllium may be harmful to the worker's health. Similarly, proposed § 850.36(a)(4) requires the SOMD to recommend permanent removal of a beryllium

worker if the SOMD makes a final medical determination that the worker should be permanently removed from exposure to beryllium at or above the action level, based on a diagnosis of BeS or CBD. The SOMD may not recommend medical restriction instead of medical removal if the SOMD determines that the beryllium worker should not work in an area where the airborne concentration of beryllium is at or above the action level, due to BeS or CBD. While both medical restriction and medical removal are means to ensure a worker is not exposed further to a work environment which would be harmful to the worker's health, medical removal under part 850 was conceived as a form of medical restriction specifically for those working with beryllium and provides additional protection and benefits to such workers. Medical restriction, however, is for workers with medical conditions (other than BeS or CBD) for which, exposure to beryllium would be contraindicated and, as indicated in 10 CFR 851, appendix A, section 8(h), is intended as a provision to facilitate a workers rehabilitation and return to work. Medical restrictions would be lifted by the SOMD when determined appropriate; medical removal, however, would be temporary pending final diagnosis, or permanent upon final diagnosis of BeS or CBD. The final rule, as issued in 1999, was silent on the issue of medical restriction. As a result, the Department has learned that there was some confusion about whether the SOMD could place beryllium workers on medical restriction instead of medical removal when the SOMD determined that the beryllium worker should not work in an area where the airborne concentration of beryllium is at or above the action level. The Department would clarify in the proposed rule that medical removal must be recommended if the SOMD determines that the beryllium worker with BeS or CBD should not work in an area where the airborne concentration of beryllium is at or above the action level.

- Proposed § 850.36(c) would require an employer to remove a beryllium worker from a job that involves an activity where the airborne concentration of beryllium is at or above the action level within 15 working days after receiving the SOMD's written opinion pursuant to § 850.36(b)(2) stating that it is medically appropriate to remove the worker. Section 850.35(a) of the final rule, as issued in 1999, required the responsible employer to offer a beryllium-associated worker removal from exposure to beryllium if the SOMD determined in a written

medical opinion that the worker should be removed from exposure to beryllium, but did not require the worker to be removed.

The changes in the requirements above are based on the Department's commitment to the health and safety of its workers, and the understanding that early detection and removal from beryllium is important to prevent harm to workers at risk for developing CBD. These proposed changes are consistent with the Department's authorities under the AEA to prescribe such regulations as it deems necessary to govern any activity authorized by the AEA, including standards for the protection of health and minimization of danger to life.

*b. Overview of the medical surveillance program.* DOE continues to believe the medical surveillance program is important for: (1) Identifying workers at higher risk of adverse health effects from exposure to beryllium; (2) linking health outcomes to the beryllium tasks; and (3) making possible the early treatment of beryllium-induced medical conditions.

The medical surveillance program is designed to ensure the prompt identification, and make possible the proper treatment and prevention of future exposures, of workers who become sensitized to beryllium or develop CBD. In addition to determining the incidence of CBD in the workforce, the medical surveillance program continues to fulfill a critical information development function, including identifying the risk factors associated with the development of CBD and beryllium sensitization. This proposed rule continues to require that medical surveillance be provided to the workers who are at the greatest risk from continued exposure. The determination that a worker should be included in the medical surveillance program should be made on the basis of the air monitoring results, the SOMD's recommendation, and any other relevant information the employer may possess, such as past medical or air monitoring records, workers' past job duties and work history, etc.

Proposed § 850.34(a)(1) would continue to require employers to designate an SOMD who will be responsible for administering the medical surveillance program.

Proposed § 850.34(a)(2) would require employers to ensure that medical evaluations and procedures are performed by, or under the supervision of, a licensed physician who is qualified to diagnose beryllium-induced medical conditions. Although a licensed physician is the appropriate person to

supervise and evaluate a medical evaluation, proposed § 850.34(a)(2) would continue to permit certain required elements of the evaluation to be performed by another appropriately qualified person under the supervision of the physician. The licensed physician is required to be qualified to diagnose beryllium-induced medical conditions. DOE expects the medical evaluations and procedures required to diagnose CBD will be performed or validated by a specialist in pulmonary medicine or occupational medicine, or by another physician familiar with the specialized equipment and examination protocols required to definitively differentiate between CBD and other lung diseases. DOE believes that this is necessary due to the unusual nature of CBD and the fact that not all physicians are familiar with the evaluation of patients exposed to beryllium in their workplace.

Proposed § 850.34(a)(3) would require employers to establish and maintain a list of all beryllium and beryllium-associated workers. The list should be based on the hazard assessments, exposure records, and any other information that will identify such workers.

Proposed § 850.34(a)(4)(i)–(vii) would require employers to provide the SOMD with the information needed to administer the medical surveillance program. This information includes the list of workers required by proposed § 850.34(a)(3); hazard assessment and exposure monitoring data; the identity and nature of the activities that are covered in the CBDPP; a description of the workers' duties as they pertain to exposures to beryllium that are at or above the action level; records of the workers' beryllium exposures; a description of the personal and respiratory protective equipment used by the workers; and a copy of the final rule. DOE believes that this information is necessary to ensure that the SOMD can make informed decisions regarding the required content of the medical evaluation and the subsequent development of recommendations related to each beryllium and beryllium-associated worker.

Proposed § 850.34(a)(5) would be added to clarify that employers are required to ensure that the SOMD and beryllium or beryllium-associated workers complete the consent form in appendix A or appendix B of this part, before performing any medical evaluations for beryllium or beryllium-associated workers.

DOE has learned from implementing the rule as issued in December 1999, there was confusion regarding how often the employer should offer

participation in the medical surveillance program to beryllium-associated workers, and when a worker would be eligible to participate in the program if he or she initially decline the offer. To clarify the confusion, DOE would propose to add § 850.34(a)(6) to require employers to notify beryllium-associated workers yearly of their right to participate in the medical surveillance program. If the beryllium-associated worker declines at that time, he or she may elect to participate at any time during the year, but the worker is required to notify the employer in writing of the intent to participate in the program.

Proposed § 850.34(b) would continue to require employers to provide, without cost to the worker, all of the medical evaluations and procedures required under this section. The proposed rule would add a requirement that the procedures be provided to workers without loss of pay. It is necessary that examinations and procedures be performed at a place convenient to the employee, and without loss of pay, which means the employee should not be required to use vacation or sick leave, in order to maximize the likelihood that beryllium and beryllium-associated workers will participate in the medical evaluations. This proposed provision is consistent with OSHA's health standards [*e.g.*, Asbestos, 29 CFR 1910.1001(l)(1)(ii)(A); Arsenic, 29 CFR 1910.1018(n)(1)(ii); and Cadmium 29 CFR 1910.1027(l)(1)(iii)].

#### *c. Mandatory medical evaluations.*

The purposes of baseline medical evaluations are to: (1) Establish the current health status of the worker and determine whether it is appropriate to assign the worker to a job where the worker will be exposed to airborne concentrations of beryllium at or above the action level; (2) initially determine what level of medical surveillance the employer must provide to the workers; and (3) establish essential baseline data for the worker which is used to assess subsequent health changes attributable to beryllium exposure.

DOE recognizes the potential negative consequences that medical evaluations for beryllium disease may have with respect to a worker's employability and insurability; work restrictions; and risk of complications from the medical evaluation. Nonetheless, it is DOE's considered determination that the early detection possible with medical evaluations is essential for removing workers at risk for CBD from further exposure to beryllium, thereby potentially reducing risk of symptomatic beryllium disease and the magnitude of symptoms that may

occur—as well as for providing early opportunities for effective treatment. In 2008, researchers in France published results of a study of corticosteroid therapy in CBD cases and confirmed that the long-standing standard of care for CBD—corticosteroid therapies—was beneficial in treating CBD (*ref.* 28). Corticosteroids were effective in suppressing granulomatous lesions in all cases and in stopping the evolution to pulmonary fibrosis in six of eight patients.

Physicians who diagnose a worker with BeS or CBD generally recommend that their patients stop working with beryllium. The National Academy of Sciences recently published a study for the U.S. Air Force (*ref.* 7) that contains the following recommendations for physicians conducting diagnostic evaluations:

Workers with CBD should discontinue work in areas that have beryllium exposure because of concern about worsening the disease. Although the effect of continuing exposure to beryllium at relatively low concentrations has not been clearly shown, the potential for CBD to become serious suggests that, given the current state of knowledge, it is prudent to avoid further beryllium exposure. Workers with CBD should continue to receive regular medical followup. Workers with CBD who discontinue work with beryllium should receive medical removal protection.

The prudent practice to have workers with BeS or CBD avoid additional exposure is based on the knowledge that, as is the case of other immune-system mediated diseases, continued exposure to the antigen may worsen the outcome. Observation that the rate of conversion from BeS to CBD appears to vary in a consistent manner with workers' exposures supports avoidance of additional exposure. Sensitized workers with low exposures appear to have relatively low rates of conversion, and sensitized workers with high exposures appear to have relatively high rates of conversion. A study published in 2004 of DOE construction workers thought to have intermittent and presumed low exposures, provides an example of a low rate of conversion. In this study, 15% of the workers with sensitization who underwent clinical evaluations were found to have CBD (*ref.* 18). Examples of medium rates of conversion of workers with presumed medium exposures are provided by the findings of two studies at DOE plants. First, a DOE plant that fabricated beryllium metal components reported that of 301 sensitized workers evaluated, 117 (39%) had CBD (*ref.* 13). Second, a DOE plant that fabricated beryllium ceramic components reported

that 23 of 56 (41%) sensitized workers had CBD (ref. 39). Examples of high rates of conversion of workers with presumed high exposures are provided by a study of former workers at beryllium production plants in Pennsylvania in which 19 of 29 (66%) of sensitized workers were diagnosed as having CBD, and by a study of former workers at a Colorado ceramics fabrication plant in which 100% of seven sensitized workers were diagnosed with CBD (refs. 40, 41).

The importance of early detection of beryllium sensitization in workers cannot be ignored in light of the fact that the existing studies provide support for the importance of early detection of beryllium sensitization. Proposed § 850.34(b)(1)(i)(A) would require employers to make baseline medical evaluations mandatory rather than voluntary for beryllium workers. Proposed § 850.34(b)(1)(i)(B) provides that baseline medical evaluations for beryllium-associated workers are voluntary. DOE believes that participation in the medical evaluation program should not be mandatory for beryllium-associated workers because these workers are not currently performing work in beryllium regulated areas. This approach would continue to ensure the early identification of those workers most at risk for health effects from exposure to beryllium, provide the greatest protection of worker health, and provide a more complete documentation of beryllium exposures.

Proposed § 850.34(b)(1)(ii)(A) through (G) is intended to ensure consistency among baseline medical evaluations in order to detect, at an early stage, any pathological changes that could lead to CBD or be aggravated by beryllium exposure. By detecting abnormalities early, workers may be medically removed to prevent further beryllium exposure. Therefore, each baseline medical evaluation would be required to include the following:

- A detailed medical and work history, particularly emphasizing exposures to levels of beryllium [proposed § 850.34(b)(1)(ii)(A)];
- A respiratory symptoms questionnaire [proposed § 850.34(b)(1)(ii)(B)];
- A physical examination with special emphasis on the respiratory system, skin and eyes [proposed § 850.34(b)(1)(ii)(C)];
- A chest radiograph (posterior-anterior, 14 x 17 inches) or a standard digital chest radiographic image interpreted by a NIOSH B-reader of pneumoconiosis or a board-certified radiologist, unless there is an existing baseline chest radiograph that may be

used to meet this requirement. The use of a digital radiographic image is new, and reflects the development of technology [proposed § 850.34(b)(1)(ii)(D)];

- Spirometry consisting of forced vital capacity (FVC) and forced expiratory volume (FEV<sub>1</sub>) at one second [proposed § 850.34(b)(1)(ii)(E)];
- Two peripheral blood BeLPTs [proposed § 850.34(b)(1)(ii)(F)];
- Any other tests deemed appropriate by the SOMD for evaluating beryllium-induced medical conditions [proposed § 850.34(b)(1)(ii)(G)]. DOE believes it is important that the SOMD have such discretion because individuals may exhibit different responses to beryllium exposures.

For purposes of the medical evaluations in this part (baseline, periodic and exit), two peripheral blood BeLPTs would be required. In the final rule, as issued in December 1999, only one BeLPT is required for the baseline and periodic evaluations. The reason for this change is that in the proposed rule, a diagnosis of BeS requires either: Two abnormal blood BeLPT results; or one abnormal and one borderline blood BeLPT; or one abnormal BeLPT of alveolar lung lavage cells. Employers are required to provide two peripheral blood BeLPTs to the worker in order to permit a proper diagnosis to be made by the SOMD. As set forth in the definition of BeLPT, a split sample BeLPT (where one blood draw is split and sent to two different testing facilities) would constitute two peripheral blood BeLPTs. If the SOMD determines that additional BeLPTs or other tests are required in order to diagnosis a worker, then the SOMD may order additional tests as part of the medical evaluation.

*d. Use of Beryllium-induced Lymphocyte Proliferation Test (BeLPT).* DOE concludes there is a general consensus that medical surveillance that includes screening with the BeLPT on peripheral blood cells provides an opportunity for timely worker removal from exposure which may reduce the chances of progression of BeS to CBD, and from sub-clinical CBD to significant lung damage and disability. In addition, positive BeLPT results lead to increased medical monitoring and therapy. This may also reduce an individual's chance of progressing to more severe disease.

The peripheral blood BeLPT was included as a component of medical evaluations in this part of the final rule, as issued in December 1999. DOE is aware that concerns have been expressed over shortcomings of the peripheral blood BeLPT, but DOE continues to consider the test to be an

effective tool for screening individuals for BeS (refs. 42, 43, 44).

A published evaluation of the commonly used blood BeLPT method used for 12,194 current and former workers at 18 DOE sites found the test to have a positive predictive value that is comparable to other widely accepted medical tests and that it was, therefore, effective in the medical surveillance of beryllium-exposed workers (ref. 13). Epidemiology researchers commonly rely on peripheral blood BeLPT results in workforce medical surveillance data as an indicator of beryllium disease risk, as exemplified by Mroz, et al.: "This longitudinal study demonstrated that workforce medical surveillance with the blood BeLPT identifies individuals at significant risk of disease progression and future impairment with sufficient time since first exposure" (ref. 16). A National Academy of Sciences' study concluded, "Despite some issues regarding the reproducibility, sensitivity, and specificity of the BeLPT, the committee judged it to be an adequate assay for use in a surveillance program" (ref. 7). The authors note that BeS is "a valuable indicator" in a medical surveillance program in identifying high risk workers, though they acknowledge that quantitative predictions on the magnitude of the risk of disease progression are not possible based on available data. Further, the United Kingdom's Health and Safety Executive (HSE) recently published a review of the use of the BeLPT for screening or surveillance of beryllium workers (ref. 45). That review concludes:

If the intent of health surveillance is to identify early beryllium sensitisation as a marker of those at risk of progressing to CBD (or as a minimum to characterise sensitisation in a group of exposed workers), then by definition the programme must include the BeLPT with an appropriate occupational health policy to deal with positive results, including educating the workforce about the implications of a positive test. The natural history of beryllium sensitisation is not fully understood, but in theory offers an early opportunity to identify early immune responses, to decrease exposure and hence intervene to improve prognosis.

HSE ultimately concludes that BeLPT represents the currently most sensitive screening test available, samples are easy to obtain, and the test provides the potential to identify subclinical disease and allow exposures to be modified.

DOE believes that the use of the peripheral blood BeLPT in medical evaluations is justified for its workforce, even for groups with low prevalence rates of beryllium disease. This belief is

based on DOE's experience in identifying and removing BeS workers from additional exposure and on the supportive findings of the literature referenced above in using BeLPT as an effective medical surveillance tool (refs. 7, 13, 16, 45).

DOE welcomes improvements to the efficacy of the peripheral blood BeLPT. DOE has published a technical standard that can be used to reduce variation among laboratories in the procedures used in performing the test (ref. 46), and the Department expects that BeLPTs will be evaluated by laboratories that are certified by the College of American Pathologists. Furthermore, researchers continue to develop alternatives to the tritiated thymidine method currently used for counting proliferated lymphocytes (e.g., counting lymphocytes by flow cytometry), which may further improve the efficacy of the peripheral blood BeLPT (ref. 47).

DOE has evaluated the consistency of imposing mandatory blood BeLPTs in the medical evaluations of DOE Federal and contractor workers with public policy established in Public Law 110–233, *Genetic Information Nondiscrimination Act of 2008*. The blood BeLPT is not a “genetic test” for the purposes of that statute, as section 201(7)(B) of the statute states that “the term ‘genetic test’ does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes.”

Proposed § 850.34(b)(2), would continue to require employers to provide periodic medical evaluations. Employers would be required to provide periodic medical evaluations in order to detect, at an early stage, any pathological changes that could lead to CBD or be aggravated by beryllium exposure. By detecting abnormalities early, workers may be medically removed to prevent further beryllium exposure. Specifically, proposed § 850.34(b)(2)(i) (A)–(B) would require employers to provide periodic medical evaluations annually to beryllium workers, and every three years to beryllium-associated workers who voluntarily participate in the program. Proposed § 850.34(b)(2)(i)(C) would require employers to provide a medical evaluation to beryllium workers, or beryllium-associated workers who voluntarily participate in the program, and who exhibit signs and symptoms of BeS or CBD, if the SOMD determines that an evaluation is warranted. This change was made in recognition of the fact that a worker may show signs or symptoms of beryllium sensitization or CBD before he or she is due for a periodic review, and requires the

employer to provide an evaluation if the SOMD determines that it is warranted.

Proposed § 850.34(b)(2)(ii) would continue to require employers to provide periodic medical evaluations to beryllium workers, and beryllium-associated workers who voluntarily participate in the program, which would include the following:

- A chest radiograph (posterior-anterior, 14 x 17 inches), or a standard digital chest radiographic image, interpreted by a NIOSH B-reader of pneumoconiosis or a board-certified radiologist unless there is a chest radiograph obtained in the previous five years that may be used to meet this requirement [proposed § 850.34(b)(2)(ii)(A)];
- Updates to the worker's medical and work history with emphasis on exposures to levels of beryllium [proposed § 850.34(b)(2)(ii)(B)];
- A respiratory symptom questionnaire [proposed § 850.34(b)(2)(ii)(C)];
- A physical examination, with special emphasis on the respiratory system, skin, and eyes [proposed § 850.34(b)(2)(ii)(D)];
- Two peripheral blood Be-LPTs [proposed § 850.34(b)(2)(ii)(E)]; and
- Any other test deemed appropriate by the SOMD for evaluating beryllium-induced medical conditions [proposed § 850.34(b)(2)(ii)(F)].

Proposed § 850.34(b)(3) would continue to require employers to provide medical evaluations for workers when a beryllium emergency occurs as defined in proposed § 850.3 in this proposed rule. In these cases, medical evaluations would include the tests and examinations required as part of periodic medical evaluations provided pursuant to paragraph (b)(2)(ii) of this section.

Proposed § 850.34(b)(4) is being added to require employers to provide an exit medical evaluation to a beryllium worker, or offer an exit medical evaluation to a beryllium-associated worker who voluntarily participates in the medical surveillance program, if a baseline or periodic evaluation had not been performed within the previous six months at the time of separation from employment. The purpose of the exit medical evaluation is to determine and document the worker's health status at the time of separation. While 10 CFR part 851, appendix A, section 8(g)(2)(v) provides for a health evaluation at the time of separation when determined necessary by the occupational medicine provider, DOE believes that obtaining information about a beryllium or beryllium-associated worker's health

status at termination is important for contributing to the information available for performance feedback about the employer's CBDPP.

Accordingly, proposed § 850.34(b)(4)(i)(A) would require employers to provide an exit medical evaluation to beryllium workers upon separation from employment, and to beryllium-associated workers who voluntarily participate in the program at the time of separation [proposed § 850.34(b)(4)(i)(B)] if a baseline or periodic evaluation has not been performed within the previous six months. The exit medical evaluation would include the following:

- A chest radiograph (posterior-anterior, 14 x 17 inches), or a standard digital chest radiographic image, interpreted by a NIOSH B-reader of pneumoconiosis or a board-certified radiologist unless there is a chest radiograph obtained in the previous five years that may be used to meet this requirement [proposed § 850.34(b)(4)(ii)(A)];
- Updates to the worker's medical and work history with emphasis on exposures to levels of beryllium [proposed § 850.34(b)(4)(ii)(B)];
- A respiratory symptom questionnaire [proposed § 850.34(b)(4)(ii)(C)];
- A physical examination, with special emphasis on the respiratory system, skin, and eyes [proposed § 850.34(b)(4)(ii)(D)];
- Two peripheral blood Be-LPTs [proposed § 850.34(b)(4)(ii)(E)]; and
- Any other test deemed appropriate by the SOMD for evaluating beryllium-induced medical conditions [proposed § 850.34(b)(4)(ii)(F)].

Proposed § 850.34(c)—[Reserved]

Note that following separation, these workers would be eligible for continued health monitoring under the Former Worker Medical Screening Program. Certain current or former workers who have contracted work-related illnesses from work performed at DOE sites may be eligible to receive compensation through the Energy Employee Occupational Illness Compensation Program Act (EEOICPA).

*e. Reporting the results of the medical evaluations.* Proposed § 850.34(d) [currently § 850.34(e)], would be revised to clarify the requirements for the SOMD's reporting the results of the medical evaluations performed pursuant to paragraph (b) of this section. SOMDs are required to provide their written medical opinions to the worker within 15 working days after receiving the results of the evaluations performed

pursuant to paragraphs (b)(1) through (3) of this section.

Specifically, proposed

§ 850.34(d)(1)(i) would require the SOMD to provide a beryllium or beryllium-associated worker with:

- A written medical opinion containing the purpose and results of all medical test or procedures [proposed § 850.34(d)(1)(i)(A)];
- An explanation of any abnormal findings [proposed § 850.34(d)(1)(i)(B)];
- The basis for the SOMD's medical opinion [proposed § 850.34(d)(1)(i)(C)];

Proposed § 850.34(d)(1)(i)(D) would be added to require the SOMD to provide in this written medical opinion any determination of whether:

- In the case of a beryllium worker, temporary or permanent removal of the beryllium worker from beryllium exposure is warranted pursuant to § 850.36 [proposed § 850.34(d)(1)(i)(D)(1)];
- A medical restriction is appropriate for the worker pursuant to 10 CFR 851, appendix A, section 8(h) [proposed § 850.34(d)(1)(i)(D)(2)]; and
- The SOMD would also be required to give the worker an opportunity to ask and have answered, their questions regarding the information provided [proposed § 850.34(d)(1)(i)(E)];

Proposed § 850.34(d)(1)(ii) would require the SOMD's written medical opinion to take into account the findings, determinations and recommendations of examining physicians who have examined the worker and provided written results of the examination to the SOMD, provided that the examining physician is qualified to diagnose beryllium-induced conditions. This proposed change responds to DOE's recognition, through its experience implementing this part, that many of those working at the DOE complex received regular medical evaluations from their private physician or through the DOL managed EEOICPA. While the SOMD must make the final decision regarding the worker's fitness for duty, and issues such as restriction and removal, the SOMD must take into account the findings, determinations and recommendations of qualified physicians who have examined the worker and provided their written recommendations to the SOMD.

Proposed § 850.34(d)(1)(iii) would be added to require the SOMD to obtain the workers signature on a dated copy of the written opinion and to include this information in the worker's medical record documenting that the employee received a copy of the opinion. If the worker declines to sign the statement, then the SOMD must make a record of that fact in the worker's medical record.

Proposed § 850.34(d)(1)(iv) would be added to clarify that within 15 working days after receiving the results from an exit evaluation performed pursuant to § 850.34(b)(4) of this part, the SOMD is required to provide the worker with:

- A written medical opinion containing the purpose and results of all medical tests or procedures [proposed § 850.34(d)(1)(iv)(A)];
- An explanation of any abnormal findings [proposed § 850.34(d)(1)(iv)(B)];
- The basis for the SOMD's medical opinion [proposed § 850.34(d)(1)(iv)(C)]; and
- An opportunity to ask, and have answered, questions regarding the information provided [proposed § 850.34(d)(1)(iv)(D)].

Proposed § 850.34(d)(2)(i) would require the SOMD, within 5 working days after delivering the written medical opinion pursuant to paragraph (d)(1)(i) of this section to the beryllium or beryllium-associated worker, to provide to the employer a written medical opinion that includes the following:

- The diagnosis of the worker's condition relevant to occupational exposure to beryllium, and any other medical condition for which exposure to beryllium at or above the action level would be contraindicated [proposed § 850.34(d)(2)(i)(A)].

In this written medical opinion to the employer, the SOMD would be required to include a determination of whether:

- In the case of a beryllium worker, temporary or permanent removal of the worker from exposure to beryllium is warranted pursuant to § 850.36 of this part [proposed § 850.34(d)(2)(i)(B)(1)]. DOE is adding this requirement to clarify that the SOMD is the only individual who can medically determine when a worker is to be removed from exposures to beryllium; or
- A medical restriction pursuant to 10 CFR 851, appendix A, section 8(h) is appropriate for the worker [proposed § 850.34(d)(2)(i)(B)(2)].

Proposed § 850.34(d)(2)(i)(C) would continue to require the SOMD or examining physician to provide a statement that he or she has clearly explained to the worker the results of the medical evaluations, including all test results and any medical condition related to beryllium exposure that requires further evaluations or treatment.

Proposed § 850.34(d)(2)(ii) would be revised to conform with the requirements in 10 CFR part 851, appendix A, section 8(h)(1) and would require that the SOMD not include in the written medical opinion any specific

records, determinations, or diagnoses that are not related to beryllium-induced medical conditions or to any other medical condition indicating the worker should not perform certain job tasks.

Proposed § 850.34(d)(2)(iii) would be added to clarify that within 5 working days after delivering the written medical opinion pursuant to paragraph (d)(1)(iv) of this section, for an exit evaluation performed pursuant to § 850.34(b)(4) of this part, the SOMD would be required to provide the employer with the diagnosis of the worker's condition that is relevant to occupational exposure to beryllium, or indicates the worker should not perform certain job tasks.

*f. Multiple physician review process.* Proposed § 850.34(e) [currently § 850.34(c)], would continue to require the establishment of a multiple physician review process for review of the initial findings, determinations, or recommendations from the medical evaluations. DOE adopted the multiple physician review mechanism as a means of providing workers with an opportunity to obtain independent review of the determinations of physicians selected by the employer. More importantly, use of this review mechanism should serve to engender worker trust and confidence in the employer-retained physician where merited. If workers distrust an employer's physician and the diagnoses of a second physician on several occasions proves there is no basis for distrust, then workers will be much more likely to trust the employer's physician in the future. If the choice of a second and third physician repeatedly results in medical determinations that greatly differ with that of the employer-retained physician, then the multiple physician review mechanism will have served the beneficial purposes of (1) correcting possibly inadequate medical determinations, and (2) exposing potential deficiencies in the employer's medical surveillance program. Therefore, DOE has identified the following benefits of providing a multiple physician review process: (1) It strengthens and broadens the basis for medical decisions that would be made in response to this rule when a beryllium or beryllium-associated worker questions the findings, recommendations, or determinations of an initial physician retained by the employer; (2) it increases workers' confidence in the soundness of medical findings, recommendations, and determinations that are made under this rule; and (3) it increases the workers' acceptance of, and participation in the medical surveillance program. These

independent reviews are likely to show that either a perceived low level of confidence in the physician retained by the employer is unwarranted, or the employer should improve the quality of the medical evaluations. In either case, the multiple physician review process will have served a beneficial purpose.

Accordingly, proposed § 850.34(e)(1) [current § 850.34(c)(1)] would continue to require employers to establish a multiple physician review process for beryllium and beryllium-associated workers that allows for the review of the initial medical findings, determinations, or recommendations from any medical evaluation conducted in accordance with paragraphs (b)(1)–(3) of this section. Note that the rule as proposed would not require the employer to provide a multiple physician review process for exit evaluations which would be provided pursuant to proposed § 850.34(b)(4).

The Department recognizes the value to employers and workers alike of the process operating in an expeditious fashion, and thus has established explicit criteria for the beginning of the process. Therefore, proposed § 850.34(e)(2) would clarify that the employer must notify a beryllium or beryllium-associated worker in writing within 15 working days after receiving the written medical opinion and determination regarding removal and/or work restriction pursuant to proposed paragraph (d)(2) of this section, of the worker's right to elect the multiple physician review process.

Proposed § 850.34(e)(3) [currently § 850.34(c)(3)] would provide that the employer's participation in, and payment for the multiple physician review process or the alternative physician review process for a beryllium-associated worker would be conditioned on the worker's participation in the medical surveillance program pursuant to paragraph (b) of this section.

Proposed § 850.34(e)(4)(i) and (ii) would require the beryllium or beryllium-associated worker to notify the employer in writing within 15 working days after receiving the employer's written notification pursuant to paragraph (e)(2) of this section, of the worker's intention to seek a second medical opinion on the results of any medical evaluation conducted pursuant to paragraphs (b)(1) through (3) of this section; and the beryllium or beryllium-associated worker identifying in writing to the SOMD within 20 working days after delivering the notice pursuant to paragraph (e)(4)(i) of this section, a physician who is qualified to diagnose

beryllium-induced medical condition to:

- Review all findings, determinations, or recommendation of the initial physician [proposed § 850.34(e)(4)(ii)(A)];
- Conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review [proposed § 850.34(e)(4)(ii)(B)]; and
- Provide the employer and the worker with a written medical opinion within 30 working days after completing the review pursuant to paragraphs (e)(4)(ii)(A) and (B) of this section [proposed § 850.34(e)(4)(ii)(C)].

Proposed § 850.34(e)(5) would clarify that if the findings, determinations, or recommendations of the two physicians differ substantively, then the employer and the worker would be required to assist the two physicians in resolving any disagreement. DOE expects that the two physicians will communicate with each other to resolve their differences, but the rule requires the employer and worker to encourage such a resolution. In most cases, this professional interaction should resolve any differences of opinion.

If the first two physicians are unable to resolve expeditiously any significant differences of opinion with respect to a beryllium or beryllium-associated worker, then it would be necessary for a third qualified physician to resolve the dispute. It is important that this third physician be competent to resolve the dispute. Consequently, proposed § 850.34(e)(6) [currently § 850.34(c)(5)], would require the employer and the worker together, through their respective physicians, to designate a third physician. It is the responsibility of the employer and the worker to assure that a third physician is selected, but the selection is to be made by the two prior physicians. Since the third physician is chosen by the joint endorsement of the two prior physicians, the professional competence of the third physician will be assured. Proposed § 850.34(e)(6) [currently § 850.34(c)(5)], would allow the third physician a full opportunity to:

- Review the findings, determinations, and recommendations of the two prior physicians [proposed § 850.34(e)(6)(i)];
- Conduct such examinations, consultations, laboratory tests, and consultations with the other two physicians as the third physician deems necessary to resolve the disagreement among them [proposed § 850.34(e)(6)(ii)]; and
- Provide the employer and the worker with a written medical opinion

within 30 working days after completing the review pursuant to paragraph (e)(5)(i) and (ii) of this section [proposed § 850.34(e)(6)(iii)].

Proposed § 850.34(e)(7) [currently § 850.34(c)(6)], would continue to require the SOMD to take action consistent with the findings, determinations, and recommendations of the third physician, unless the SOMD and the worker reach an agreement that is otherwise consistent with the recommendations of at least one of the other two physicians.

The Department's experience in implementing the final rule provisions has shown there was some confusion among employers and workers about the multiple physician review process for a worker who has been laid off or whose contract ended during the multiple physician review process. To address these situations proposed § 850.34(e)(8) would require the employer to complete the multiple physicians review process and treat the worker as though he is a current worker, even when a worker is laid off or his contract ends before the review process is complete, subject to the following conditions: (1) The worker must have elected the multiple physician review while he was in fact a current worker and in accordance with the conditions set forth in paragraph (e)(4) of this section; and (2) the worker must participate in good faith in the multiple physician review process. If a worker's job would have ended prior to the end of the multiple physician review process (e.g., if the worker was hired to do a particular job which has been completed), the proposed rule provides that the employer may place the worker on unpaid leave status until the review process is completed.

Proposed § 850.34(e)(9) would be added to clarify that the employer would not be required to provide the multiple physician review process in those cases where the worker had not elected the process in accordance with the conditions specified in paragraph (e)(4) of this section before the worker was laid off or contract ended. In these cases the workers may still be eligible for medical screening through DOE's FormerWorker Medical Screening Program.

The employer would be required to pay for the expenses of the multiple physician review process when a beryllium-associated worker elects it in writing and in a timely manner. DOE does not expect the cost of this process to be burdensome to its contractor employers since DOE contractors typically receive reimbursement for the cost of complying with this process. If the employer establishes and

administers a medical surveillance program that engender worker confidence, workers should have little or no need to seek second medical opinions.

The requirement for a multiple physician review is not intended to preclude employers from establishing and implementing alternate medical protocols. DOE would continue to include language in proposed § 850.34(f) [currently § 850.34(d)] that establishes an alternate physician review process. Under this section, the employer, beryllium and beryllium-associated worker, or the worker's designated representative, would be allowed to agree on the use of any expeditious alternate physician determination process, instead of the multiple physician review process. The only condition is that the alternate process is reasonable, expeditious and adequately protects the worker's health. For example, a jointly agreed upon physician might be used in the first instance without recourse to other physicians. DOE would continue to encourage employers and workers to adopt medical determination procedures in which all parties have trust and confidence.

Proposed § 850.34(g)(1) would be revised to comply with the reporting requirements in 10 CFR part 851.23(a)(2). Proposed § 850.34(g)(2) and (3) would be added to comply with the reporting requirements for cases involving medical removal. Accordingly, proposed § 850.34(g)(2) would require employers to record each case of medical removal on the applicable OSHA form when a worker is being medically removed in accordance with proposed § 850.36 of this part. Proposed § 850.34(g)(3) would require employers to enter each case of medical removal either as a case involving days away from work (if the worker does not work during the medical removal period) or as a case involving restricted work activity (if the worker continues to work but in an area where beryllium exposures are below the action level).

DOE is proposing to delete § 850.34(h) in the final rule. This section requires employers to establish routine and systematic analyses of medical, job and exposure data. The purpose of this requirement is to collect and analyze information so that the prevalence of disease can be accurately described and conclusions reached on causes or risk factors for disease. The Department intends to rely on the data collected from the Beryllium Registry for this purpose.

#### Proposed § 850.35—Medical Restriction

Proposed § 850.35 would be added to establish the medical restriction provisions of the CBDPP. Part 850 is intended to address and prevent disease caused by exposure to beryllium at DOE sites. Medical removal benefits under the rule are not intended to apply in cases where beryllium is not the cause of the worker's illness. In the case where the worker is not suffering from beryllium disease or has not been sensitized to beryllium, but exposure to beryllium at or above the action level is contraindicated, medical restriction would ensure that workers with other medical conditions are not exposed to beryllium which could put them at a materially higher risk for developing serious medical problems. Other medical conditions include, but are not limited to, chronic obstructive pulmonary disease (COPD), sarcoidosis, asthma, emphysema, or any other medical condition with respect to which the SOMD may determine that exposure to beryllium at or above the action level is contraindicated.

Proposed § 850.35(a) would require medical restrictions to be conducted in accordance with 10 CFR part 851, appendix A, section 8(h). In such cases where medical restrictions appropriate, proposed § 850.35(b) would require employers to, within 15 working days after receiving the SOMD's written opinion pursuant to § 850.34(d)(2) that it is medically appropriate to restrict a worker, restrict the worker from a job that involves a beryllium activity.

The Department's experience in implementing the final rule provisions has shown there was some confusion among employers and workers about medical restriction and when to offer, or not offer, medical removal benefits. Therefore, DOE would add proposed § 850.35(c) to clarify that employers would only be required to provide the beryllium medical removal benefits specified in § 850.36 of this proposed rule to beryllium workers who have been diagnosed with BeS or CBD, or pending the outcome of medical evaluations to determine whether the worker has BeS or CBD and the SOMD believes that further exposure to beryllium at or above the action level may be harmful to the health of the worker, or pending the alternate physician review or multiple physician review. Employers are not required to provide removal benefits to other types of workers with a medical restriction.

Proposed § 850.35(d) would be added for those situations when the SOMD determines that a beryllium worker should not work with beryllium at or

above the action level due to BeS or CBD. In such cases, the SOMD would be required to recommend medical removal under § 850.36 of this proposed rule, not medical restriction.

#### Proposed § 850.36—Medical Removal and Benefits

Proposed § 850.36 [(currently § 850.35)] would continue to require employers to implement the medical removal (currently known as "*medical removal protection*") and benefits (currently known as "*medical removal protection benefits*") provisions of the CBDPP. DOE believes medical surveillance can only be effective in detecting and preventing disease if workers: (1) Seek medical attention when they feel ill; (2) refrain from efforts to conceal their true health status; and (3) fully cooperate with examining physicians to facilitate accurate medical diagnoses and effective treatment. This type of worker participation and cooperation will occur only where no major disincentives to meaningful worker participation exists. Without such participation, it would be much more difficult to adequately monitor workers' health and to identify workers who need temporary or permanent medical removal.

Medical removal is a logical result of the medical surveillance program. Without medical removal, employees with BeS or CBD may remain undiagnosed and continue to be exposed to beryllium at or above the action level which would not be sufficiently protective of their health. Also, without medical removal benefits, workers with BeS or CBD could be terminated or transferred from higher-paying jobs where exposure to beryllium is at or above the action level to lower-paying jobs that do not include such exposure. This might be protective, but it would impair the workers' earning ability. In either case, the effectiveness and integrity of the medical surveillance program may be compromised.

With medical removal, beryllium workers with BeS or CBD would be assured of being removed to jobs where the exposure to beryllium is below the action level, if such jobs are available and if removal is determined to be necessary to protect their health. With medical removal benefits, beryllium workers with BeS or CBD would be assured that, if the results require removal from their beryllium job, their normal earnings will be protected for a pre-determined period.

Proposed § 850.36(a)(1) would clarify that, subject to the terms set forth in this proposed section, employers would be required to remove beryllium workers

from jobs where the exposure to beryllium is at or above the action level. As set forth in this section, temporary or permanent removal is required when the SOMD has determined in a written medical opinion that it is appropriate to remove the beryllium worker from exposure to beryllium at or above the action level. This determination would be required to be based on a diagnosis that the worker has BeS or CBD, as defined in this proposed rule.

The Department's experience in implementing the current rule provisions has shown there was some confusion about who has the authority to recommend temporary or permanent removal of a beryllium worker. Therefore, proposed § 850.36(a)(2) would clarify that only the SOMD may recommend temporary or permanent removal of a beryllium worker from exposure to beryllium at or above the action level. DOE proposes revising the wording used in this section to clarify that the SOMD would make the final medical determination, even when a multiple physician review or alternative physician determination process is used. The SOMD, in making the final medical determination would be expected to take into account the findings, determinations and recommendations of other examining physicians who may have examined the worker, but the SOMD makes the final determination.

*Mandatory medical removal of beryllium workers.* In response to its RFI, DOE received several comments concerning whether to continue to require a worker's consent for medical removal, or instead require mandatory medical removal. The majority of commenters recommended that DOE establish a mandatory medical removal practice; however, many of those commenters also recommended that DOE provide enhanced medical removal benefits. Some commenters suggested that mandatory removal should be implemented by DOE complex-wide. Some commenters suggested that DOE mandate that the employer offer a vocational training program to the affected worker to assist the employee in maintaining the financial compensation and benefits from his or her previous position, and that the length of time for medical removal benefits should be increased from two to five years. A minority of commenters believed that DOE should continue to leave medical removal up to the worker, pointing out that the National Academies suggests that the worker's consent be obtained. Some commenters indicated that DOE should retain voluntary medical removal only if DOE

will accept the risk of future health issues from allowing a worker to resume activities after the SOMD has recommended medical removal.

After consideration of all commenters' suggestions, DOE's experience in implementing the current rule provisions, and other available information, proposed § 850.36(c)(1) would require mandatory medical removal for beryllium workers in jobs that include a beryllium activity in cases where an employee has a diagnosis of BeS or CBD. DOE proposes this amendment because removing workers from jobs that risk additional exposure will avoid increasing their body burden of beryllium, and potentially reduce the risk of symptomatic beryllium disease, or minimize the magnitude of symptoms that may occur.

DOE recognizes that it is very difficult to establish policy that involves trade-offs between the unfettered pursuit of livelihood and other potential financial effects, such as insurability and the risk of debilitating disease; however, DOE believes that the medical removal benefits provisions in proposed § 850.36(d) and the counseling provisions in proposed § 850.38(b) of this part would be sufficient to assist workers in effectively preparing for, and responding to, possible medical removal. For these reasons, DOE believes that the proposed policy of mandatory removal is its optimal risk management strategy.

Proposed § 850.36(a)(3) [currently § 850.35(a)(1)] would clarify the requirements for temporary or permanent removal of a beryllium worker from exposure to beryllium at or above the action level. Accordingly, proposed § 850.36(a)(3) would require the SOMD to recommend to employers temporary removal of a beryllium worker:

- Pending the outcome of the medical evaluations conducted pursuant to § 850.34(b) of this part, if the beryllium worker is showing signs or symptoms of BeS or CBD and the SOMD believes that further exposure to beryllium at or above the action level may be harmful to the worker's health [proposed § 850.36(a)(3)(i)]; or
- Pending the outcome of the multiple physicians or alternative physician review process pursuant to proposed § 850.34(e) and (f) of this part, if the beryllium worker is showing signs or symptoms of BeS or CBD and the SOMD believes that further exposure to beryllium at or above an action level may be harmful to the worker's health [proposed § 850.36(a)(3)(ii)].

Proposed § 850.36(a)(4) would require the SOMD to recommend permanent removal of a beryllium worker from exposure to beryllium at or above the action level only when he or she makes a final medical determination that the worker should be permanently removed. The SOMD's determination to permanently remove a worker would be required to be based on a diagnosis of BeS or CBD as defined in § 850.3 of this proposed rule.

Proposed § 850.36(a)(5) would require, within 15 working days after a final medical determination has been made, the SOMD to provide the employer with a written notice to either return the temporarily removed beryllium worker to his or her previous job status, along with the steps needed to protect the workers' health including any work restrictions [proposed § 850.36(a)(5)(i)]; or, to permanently remove the beryllium worker [proposed § 850.36(a)(5)(ii)]. If a worker is temporarily removed and the final medical determination is made that the beryllium worker does not have a medical condition caused by beryllium, the temporary medical removal benefits specified in paragraph (d)(1) of this section would end, and the affected worker would be able to return to his or her normal duties, unless work restrictions would prevent the worker from doing so. If the SOMD makes a final medical determination that the worker is not sensitized to beryllium and does not have CBD, but further exposure to beryllium at or above the action level is medically contraindicated, the SOMD would be able to recommend a medical restriction for the worker.

DOE has learned through its experience implementing this part, as issued in December 1999, that a lack of explicit expectations has resulted in different understandings of how the SOMD should recommend temporary or permanent removal of a worker. Accordingly, proposed § 850.36(a)(6) would be added to clarify that the SOMD is not required to recommend temporary removal first and then permanent removal. If it is clear based on the SOMD's medical evaluation that the worker should be permanently removed, based on a diagnosis of BeS or CBD, then the SOMD may recommend permanent removal.

Proposed § 850.36(b) [currently § 850.35(a)(3)] would establish the counseling requirements for beryllium workers before they are placed on either temporary or permanent medical removal, as well as clarify the requirements for notifications to the employer. This proposed addition

would help beryllium workers understand and effectively manage the potential effects of medical removal.

DOE has learned through its experience implementing this part, as issued in December 1999, that a lack of explicit expectations has resulted in different understandings of the individual worker's medical removal status. DOE, therefore, proposes adding requirements that will help workers understand their medical removal status. Accordingly, proposed § 850.36(b)(1) would require that if the SOMD determines a beryllium worker should be temporarily or permanently removed, the SOMD would be required to perform the following when communicating the written medical opinion and determination to the worker pursuant to § 850.34(d)(1):

- Advise the beryllium worker diagnosed with BeS or CBD or suspected of having BeS or CBD of the determination that medical removal is necessary to protect his or her health, and specify whether the SOMD is recommending temporary or permanent removal from work that involves exposure to beryllium at or above the action level [proposed § 850.36(b)(1)(i)]; and

- Provide the beryllium worker with a copy of the rule, including its preamble, and information on the risks of continued exposure to beryllium at levels at or above the action level, as well as the benefits of removal [proposed § 850.36(b)(1)(ii)].

Proposed § 850.36(b)(2) would be added to clarify the notifications the SOMD gives to the employers for removal of workers. The SOMD, in communicating the written medical opinion and determination to the employer, would be required to comply with § 850.34(e)(2) of this part. In the case of a final medical determination regarding permanent removal, the SOMD would be required to provide the employer with a written notice recommending that the employer either:

- If the worker has been on temporary removal, return the temporarily removed beryllium worker to his previous job status if the SOMD determines that removal is no longer warranted [proposed § 850.36(b)(2)(i)]; or

- Permanently remove the beryllium worker [proposed § 850.36(b)(2)(ii)]; or
- Medically restrict the worker pursuant to § 850.35 of this part [proposed § 850.36(b)(2)(iii)].

Proposed § 850.36(c) would clarify the employer's responsibilities for removal of a worker. Proposed § 850.36(c)(1) would require the employer, within 15 working days after receiving the

SOMD's written opinion pursuant to paragraph (b)(2) of this section, stating that it is medically appropriate to remove a worker, to remove the beryllium worker from the job that involves a beryllium activity, regardless of whether at the time of removal a job is available into which the removed worker may be transferred.

Proposed § 850.36(c)(2) would require employers to formally notify beryllium workers in writing that they are in medical removal status when the employer receives the SOMD's determination that removal is warranted. Employers would be required to include a start date for medical removal in the written notification. This proposed addition should resolve difficulties that have occurred at DOE sites in determining when medical removal officially began.

Proposed § 850.36(c)(3) would establish that when a beryllium worker is medically removed, the employer must transfer the removed worker to a comparable job, if such a job is available, and provide removal benefits in accordance with paragraphs (d)(1) of this section, for temporary removal or (d)(2) of this section, for permanent removal.

DOE is proposing to add § 850.36(c)(4) to clarify that employers would not be able to return a worker who has been medically removed to his or her former job status unless the SOMD has determined in a written medical opinion that continued medical removal is no longer necessary to protect the worker's health.

Proposed § 850.36(d) [currently § 850.35(b)] would continue to establish the medical removal benefits that must be provided to removed workers. DOE continues to believe that medical removal benefits are critical to minimize the disability associated with CBD. Removal from exposure and effective job-placement efforts, coupled with early diagnosis and treatment, will increase the likelihood that affected beryllium workers would continue as productive members of the DOE workforce.

Proposed § 850.36(d)(1)(i) would specify that when a beryllium worker has been temporarily removed from a job pursuant to paragraph (a)(2) of this section, employers would be required to, consistent with any applicable collective bargaining agreement:

- Transfer the worker to a comparable job [proposed § 850.36(d)(1)(i)(A)]; where beryllium exposures are below the action level [proposed § 850.36(d)(1)(i)(A)(1)]; and for which the worker is qualified or can be trained

for in 6 months or less [proposed § 850.36(d)(1)(i)(A)(2)];

- Maintain the worker's total normal earnings, and other employment rights, as they existed at the time of removal, on each occasion that the worker is temporarily removed. The purpose of this requirement is to ensure that a removed worker does not suffer immediate economic loss due to removal [proposed § 850.36(d)(1)(i)(B)]. Note, benefits received under the Energy Employees Occupational Illness Compensation Program (EEOICP) do not constitute wage replacement, and therefore would not offset the employee's medical removal benefits.

DOE has learned with experience implementing this part, as issued in December 1999, that a lack of explicit expectations has resulted in different understandings of what happens when a job is not available for a beryllium worker. Therefore, proposed § 850.36(d)(1)(ii) would be added to clarify the requirements for the employer. Specifically, if there is no such job for the beryllium worker, the employer would be required to provide the workers total normal earnings, seniority (to the extent allowed in an applicable bargaining agreement), and other employment rights, as if the worker were not removed. For temporary removal, the employer would be required to provide the beryllium worker's total normal earnings and other employment rights, until:

- A comparable job becomes available that meets the requirements of (d)(1)(i)(A), and the worker is placed in that job [proposed § 850.36(d)(1)(ii)(A)];

- The SOMD determines that the beryllium worker is not sensitized to beryllium and does not have CBD and medical removal is ended [proposed § 850.36(d)(1)(ii)(B)];

- The beryllium worker is permanently medically removed from the job [proposed § 850.36(d)(1)(ii)(C)]; or

- The term of the removal period has expired [proposed § 850.36(d)(1)(ii)(D)].

Proposed § 850.36(d)(1)(iii) would be added to clarify that each period of temporary removal could not exceed one year and no term of temporary removal can immediately succeed a prior term of temporary removal to extend the term beyond one year.

Proposed § 850.36(d)(1)(iv) would be added to require that periods of temporary removal received by a worker not be considered part of any permanent removal period should the employer provide the beryllium worker with temporary and then permanent removal. This clarification supports DOE's intent to provide workers with sufficient time

to plan and implement changes in pursuing their livelihood as necessitated by permanent medical removal from jobs that involve beryllium activities at or above the action level.

Proposed § 850.36(d)(2) [currently § 850.35(b)(1)] would continue to provide permanent medical removal benefits of the CBDPP. Accordingly, in proposed § 850.36(d)(2)(i)(A) and (B), if a beryllium worker has been permanently removed from a job because of a beryllium-induced medical condition pursuant to paragraph (a)(4) of this section, the employer would be required to, consistent with any applicable collective bargaining agreement, transfer the worker to a comparable job [proposed § 850.36(d)(2)(i)(A)], where beryllium exposures are below the action level [proposed § 850.36(d)(2)(i)(A)(I)], and for which the worker is qualified or can be trained within a period of up to one year [proposed § 850.36(d)(2)(i)(A)(II)].

Proposed § 850.36(d)(2)(i)(B) would clarify that if a beryllium worker could not be transferred to a comparable job that meets the requirements of (d)(2)(i)(A), the employer would be required to maintain the worker's total normal earnings and benefits at the time of removal, as if the worker were not permanently removed for up to two years. DOE continues to select 2 years as the maximum period during which the employer is required to pay medical removal benefits to a worker instead of the 18-month protection period established in OSHA's lead and cadmium standards. DOE established a different protection period for beryllium because of the toxicological differences between beryllium and the two metals covered in the OSHA standards. Specifically, the early stages of the health impairments associated with exposure to lead or cadmium will reverse in time with no additional exposure, but the health effects from BeS and CBD typically do not. The objective of OSHA's 18-month period is to provide workers with sufficient recovery time so they can return to their job. The objective of DOE's two-year period, however, is to allow workers permanently medically removed sufficient time to be retrained and placed in a different job. DOE believes that this period should be long enough to enable the majority of removed workers to be retrained and placed in another job or, for those workers who can be returned to their former job status, to be returned before their medical removal benefits expire. Proposed § 850.36(d)(2)(i)(B) would also clarify that employers are not required to continue providing medical removal

benefits after a worker has been permanently removed for up to two years. The removed worker who is transferred to a comparable job is not guaranteed removal benefits in the form of such job after the two-year removal period because permanent medical removal benefits consist of either the opportunity to transfer to a comparable job or to receive the earnings and benefits associated with a comparable job, if a comparable job is not available (e.g., due to layoffs, illness of the worker, etc.). After the two-year benefit period expires, employers are expected to treat removed workers who have been transferred to a comparable job in a neutral and nondiscriminatory fashion, in accordance with all applicable state and Federal labor laws.

DOE does not intend for the beryllium medical removal benefit to function as a workers' compensation program. Workers' compensation and other work-related compensation for beryllium illness are provided by public or employer-funded compensation programs, including the Federal EEOICP administered by the DOL.

Proposed § 850.36(d)(3) [currently § 850.35(b)(5)] would continue to establish additional conditions for both temporary and permanent removal benefits. Proposed § 850.36(d)(3)(i) would clarify that employers providing medical removal benefits is not intended to expand upon, restrict or change any rights a worker has or would have had, absent medical removal, regarding a specific job classification or position under the terms of a collective bargaining agreement.

Proposed § 850.36(d)(3)(ii) [currently § 850.35(b)(2)] would continue to establish that during a temporary or permanent removal period, employers are required to continue to provide a worker total normal earnings and benefits.

DOE has learned from implementing this part, as issued in December 1999, that not addressing medical removal benefits when there is a change in the worker's job status, caused confusion and different implementation among DOE sites. Therefore, proposed § 850.36(d)(3)(iii) would be added to clarify and require employers to continue providing workers medical removal benefits during the removal period designated by the SOMD regardless of changes in the workers' jobs (e.g., worker is laid off or the contract ends before the removal period ends) or whether workers can be transferred into comparable jobs because the workers are too sick to work, provided that:

- If the workers are on temporary removal, the employers are not required to continue the worker's benefits, as set forth in paragraph (d)(1) of this section, beyond one year [proposed § 850.36(d)(3)(iii)(A)];

- If the worker is on permanent removal, the employer is not required to continue the worker's benefits, as set forth in paragraph (d)(2) of this section, beyond two years [proposed § 850.36(d)(3)(iii)(B)].

Proposed § 850.36(d)(3)(iv) [currently § 850.35(b)(3)] would continue to establish that if a removed worker files a claim for workers' compensation payments for a beryllium-related disability, the employer must continue to provide benefits pending disposition of the claim, but no longer than a period of two years. The employer must receive no credit for the workers' compensation payments received by the worker for treatment related expenses.

Proposed § 850.36(d)(3)(v) [currently § 850.35(b)(4)] would continue to establish that the employer's obligation to provide medical removal benefits to a removed worker is reduced to the extent that the worker receives compensation for earnings lost during the period of removal from a publicly- or employer-funded compensation program, or from employment with another employer made possible by virtue of the worker's removal. This provision is necessary to ensure that medical removal benefits do not result in a "windfall" to the worker who collects other compensation, including a salary from another job, while the worker is on medical removal from beryllium exposure.

Proposed § 850.36(d)(3)(vi) would be added to inform worker that they may also apply for compensation through EEOICP for any additional benefits beyond those provided in this proposed section.

DOE is proposing to delete current § 850.35(a)(4). DOE has learned through its experience implementing this part, as issued in December 1999, that it would not be a prudent practice to return a beryllium worker who has been permanently removed to a job in which the worker will be exposed to beryllium at or above the action level.

#### Proposed § 850.37—Medical Consent

Proposed § 850.37 [currently § 850.36], would continue to establish the medical consent provisions of the CBDPP. This section is necessary to ensure that beryllium and beryllium-associated workers receive adequate information to make an informed decision about the medical surveillance program. Accordingly, proposed

§ 850.37(a) would require that in order to provide each beryllium and beryllium-associated worker with the information necessary for the workers to make informed decisions about consenting to the medical evaluation established in proposed § 850.34 of this part, the employer must ensure that the SOMD has the worker sign and date the consent form in appendix A (for beryllium workers) or appendix B (for beryllium-associated workers) before performing any medical evaluation. The dated signature of the worker serves to document the worker consented to being tested. DOE would expect employers to make reasonable efforts to help workers understand the material.

Proposed § 850.37(b) would require employers to inform beryllium workers that testing is mandatory to transfer into or remain in a job involving exposure to beryllium at or above the action level, and that a beryllium worker who decides not to consent to the medical evaluations that would be required in § 850.34 will be removed from a beryllium activity and will not receive medical removal benefits.

#### Proposed § 850.38—Training and Counseling

Proposed § 850.38 [currently § 850.37], would continue to establish the worker training and counseling requirements regarding exposure to beryllium, and the potential health effects associated with such exposure. This worker training is necessary because appropriate implementation of the required workplace procedures of the CBDPP ultimately rests upon the front-line workers who will be performing work on, with, or near beryllium or beryllium-contaminated materials. These workers cannot be expected to comply with the required CBDPP procedures if they are not aware of such procedures.

DOE expects employers would conduct training in a manner that is easy to understand. Training material should be appropriate in content and vocabulary for the education level and language background of affected workers. The goal of the training would be to ensure all workers, regardless of cultural or educational background, have the knowledge necessary to reduce and minimize their exposure to beryllium.

DOE's experience in implementing the training requirements of this part, as issued in December 1999, demonstrates that greater differentiation of training requirements for different types of workers is needed. Therefore, proposed § 850.38 would continue to maintain the training requirements of the CBDPP but

would clarify the training needs of beryllium workers and add training for these workers on the benefits of medical evaluations and the content of this part.

Proposed § 850.38(a)(1) [currently § 850.37(a)(1)] would continue to require employers to develop and implement a training program for beryllium workers, beryllium-associated workers, and all other workers who work at a site where beryllium activities are conducted and ensure their participation in the program.

Proposed § 850.38(a)(2) would establish the training requirements for beryllium workers. Specifically, employers would be required to provide beryllium workers training on the following:

- The contents of the CBDPP [proposed § 850.38(a)(2)(i)];
- The potential health risks to family members and others who may come in to contact with beryllium if beryllium controls are not followed [proposed § 850.38(a)(2)(ii)]. This section relies on the workers to relay the relevant beryllium hazard information to their families. DOE encourages employers to provide beryllium workers with information about beryllium risks that is also readily understandable to family members.

- Benefits of medical evaluations for diagnosing BeS and CBD [proposed § 850.38(a)(2)(iii)]; and

- The contents of the final rule [proposed § 850.38(a)(2)(iv)].

Proposed § 850.38(a)(3) would establish the training requirements for beryllium-associated workers and other workers identified in paragraph (a)(1) of this section. The training for these individuals would continue to require general awareness about beryllium hazards and controls training for other workers at a site where beryllium activities are conducted. This training should also address the benefits of medical evaluations for early diagnosis of BeS or CBD.

Proposed § 850.38(a)(4) would continue to require employers to provide training to workers prior to or at the time of initial assignment, and at least every two years thereafter, to ensure that workers are appropriately prepared to deal with the hazards and risks of working with beryllium. The initial training requirement of this paragraph is important to ensure workers have the information they need to protect themselves before they are subject to actual or potential exposure hazards. Periodic training is necessary to reinforce and update initial training; especially with regard to the protective actions workers must take at their current jobs to reduce their potential for

exposure to beryllium. DOE has established two years as the minimum frequency requirement.

Proposed § 850.38(a)(5) would require employers to provide retraining when they have reason to believe that a beryllium worker lacks the proficiency, knowledge, or understanding needed to work safely with beryllium. The retraining would include, at a minimum, the following situations:

- To address any new beryllium hazards resulting from a change to the beryllium inventory, activities, or controls about which the worker was not previously trained [proposed § 850.38(a)(5)(i)]; or

- When a worker's performance involving beryllium activities indicates that the worker has not retained the requisite proficiency [proposed § 850.38(a)(5)(ii)].

Proposed § 850.38(b) [currently § 850.37(f)], would continue require employers to develop and implement a workers counseling program to assist workers diagnosed by the SOMD with BeS or CBD. The purpose of the counseling program is to communicate information to workers that may help them make important health- and work-related decisions and perform administrative activities, such as filing workers' compensation claims. Accordingly, proposed § 850.38(b)(1) would require employers to develop and implement a counseling program to assist beryllium and beryllium-associated workers who are diagnosed by the SOMD with BeS or CBD.

Proposed § 850.38(b)(2) would require the counseling program for beryllium workers to include communicating with the worker concerning:

- The medical surveillance program provisions and procedures [proposed § 850.38(b)(2)(i)];
- Medical treatment options [proposed § 850.38(b)(2)(ii)];
- Medical, psychological, and career counseling [proposed § 850.38(b)(2)(iii)];
- Medical removal benefits [proposed § 850.38(b)(2)(iv)];

- Administrative procedures and worker rights under EEOICPA and applicable workers' compensation laws and regulations [proposed § 850.38(b)(2)(v)]; and

- The risk of continued exposure to beryllium at or above the action level and practices to limit exposure [proposed § 850.38(b)(2)(vi)].

Proposed § 850.38(b)(3) would clarify the counseling requirements for beryllium-associated workers. For beryllium-associated workers, employers would be required to communicate information to workers concerning the following topics:

- The medical surveillance program provisions and procedures [proposed § 850.38(b)(3)(i)];

- Medical treatment options [proposed § 850.38(b)(3)(ii)];

- Medical, psychological, and career counseling [proposed § 850.38(b)(3)(iii)]; and

- Application procedures under EEOICPA and applicable workers' compensation laws and regulations [proposed § 850.38(b)(3)(iv)].

In this section, DOE would include the qualifying language "application procedures and workers rights" and "under . . . applicable workers compensation laws and regulations" to make clear that DOE still does not intend to establish any new workers' compensation obligations. DOE understands that employers may develop such counseling programs in consultation with labor organizations representing workers, and that employer may wish to advise the workers to consult their own attorneys on these matters.

#### Proposed § 850.39—Warning Signs and Labels

Proposed § 850.39 [currently § 850.38], would continue to require employers to post warning signs and labels to ensure that the presence of, and dangers associated with beryllium and beryllium-contaminated items or areas are communicated to workers.

DOE received several comments in response to its RFI concerning whether DOE should require warning labels for the transfer—to either another DOE entity or an entity to whom this rule does not apply—of items with surface areas that are free of removable beryllium but that might contain surface contamination that is inaccessible or has been sealed with hard-to-remove substances (e.g., paint). Most of the commenters suggested that DOE should require warning labels when individuals could be exposed during the handling of an item (e.g., servicing a seldom-accessed part, opening a waste container), or to warn the uninformed so as to prevent unplanned beryllium exposures. DOE pointed out that the further removed a worker is from direct DOE employment (e.g., some DOE facility general contractors hire subcontractors, who in turn hire their own subcontractors, and so on), the more likely it is that verbal instructions and warnings will be insufficient. Other commenters suggested that DOE's labeling requirement should allow flexibility to convey the beryllium exposure hazard without unduly alarming downstream individuals and without preventing potential

downstream users from accepting items because of unfounded health concerns.

DOE, in considering suggestions of the RFI commenters and other available information, has proposed minor changes to the wording of this section, as issued in December 1999. Proposed § 850.39(a) would continue to require the posting of warning signs demarcating beryllium regulated areas and these signs bear the following warning:

BERYLLIUM REGULATED AREA  
DANGER  
CANCER AND LUNG DISEASE HAZARD  
AUTHORIZED PERSONNEL ONLY

The purpose of these warning signs is to minimize the number of individuals entering a beryllium regulated area by warning workers prior to entry. The signs alert workers that they must have the appropriate authorization from their supervisor to enter the beryllium regulated area. This is especially important when regulated areas are established on a temporary basis, such as during cleanup operations. In such cases, workers who typically work in or travel through the area may not be aware of the new potential for beryllium exposures and thus, may not be appropriately equipped for or aware of the need to protect themselves from potential exposures. Warning signs also serve as a constant reminder to those who work in beryllium regulated areas that the potential for exposure to beryllium exists in the area and that appropriate controls must be used.

Proposed § 850.39(b) would continue to require employers use warning labels to ensure that individuals who come in contact with containers of beryllium, or other beryllium-contaminated items are aware of their content and the need to implement special handling precautions. Accordingly, this proposed section would add a provision requiring employers affix warning labels to all bags, containers, equipment, or items that have surface levels of beryllium that exceed 0.2 µg/100 cm<sup>2</sup>, or that will be released and have beryllium material on the surface at levels above the level in soil at the point of release. Because the effectiveness of the warning label is greatly dependent upon the visibility, accuracy, and understandability of the content of the labels, proposed § 850.39(b)(1) would specify that labels bear the following information:

DANGER  
CONTAMINATED WITH BERYLLIUM  
DO NOT REMOVE DUST BY BLOWING OR  
SHAKING  
CANCER AND LUNG DISEASE HAZARD

Proposed § 850.39(b)(2) would add a new provision that would require

employers to affix warning labels to equipment or items that contain sources of beryllium in typically inaccessible locations or embedded in hard-to-remove substances. This label is for less hazardous situations in which the beryllium is normally inaccessible but could be released with effort (e.g., by disassembling machine tools that were used for processing beryllium, or by removing paint that encapsulates beryllium particulates). This proposed section would require that labels bear the following information:

CAUTION  
CONTAINS BERYLLIUM IN INACCESSIBLE  
LOCATIONS OR EMBEDDED IN HARD-  
TO-REMOVE SUBSTANCES  
DO NOT RELEASE AIRBORNE BERYLLIUM  
DUST  
CANCER AND LUNG DISEASE HAZARD

#### Proposed § 850.40—Recordkeeping and Use of Information

Proposed § 850.40 [currently § 850.39] would continue to require employers to establish and effectively manage records that relate to the CBDPP and to periodically submit to the Office of Environment, Health, Safety and Security a registry of beryllium and beryllium-associated workers. Proposed § 850.40 would also clarify recordkeeping requirements that are not clearly defined in the current rule, and the use of such information by both DOE contractor and Federal employers. Proposed § 850.40(a) would require contractor employers to:

- Establish and maintain records in accordance with 10 CFR part 851, *Worker Safety and Health Program*, for records generated by their CBDPP, and include records of beryllium medical evaluations and training [proposed § 850.40(a)(1)]. This would revise the current requirement for consistency with 10 CFR 851.26, *Recordkeeping and reporting*.

- Maintain employees' medical records in accordance with DOE System of Records DOE-33, *Personnel Medical Records* [proposed § 850.40(a)(2)]. This requirement would be added to clarify the system of records with which employers are required to comply.

- Maintain all records required by this part in current and accessible electronic systems [proposed § 850.40(a)(3)]. This requirement, currently in § 850.39(f), is necessary to facilitate timely, efficient, and cost-effective transfer and analysis of CBDPP-related data. DOE continues to use the phrase "current and accessible" in this section because DOE's experience indicates that the ability to use information held in electronic records is severely hampered if the

electronic systems are out-of-date or the records are difficult to retrieve.

- Convey all record series required by this rule to the appropriate Head of DOE Field Element, or his or her designee, if this part ceases to be applicable (e.g., if the employer ceases to be a DOE contractor) [proposed § 850.40(a)(4)]. This requirement would be added to ensure that DOE has access to and ownership of such records generated during contract performance for its contractors performing beryllium activities at DOE sites and clarifies management, retention and disposal of records after contract termination.

Proposed § 850.40(b) would continue to require Federal employers to:

- Establish and maintain complete and accurate records generated by the CBDPP submitted by DOE offices, including all beryllium inventory information, hazard assessments, exposure measurements of Federal employees, exposure control, medical evaluations, and training for operations or activities implemented by DOE offices [proposed § 850.40(b)(1)].

- Maintain Federal employees' medical records in accordance with the Office of Personnel Management's OPM/GOVT-10, *Employee Medical File System Records for Federal Employees* [proposed § 850.40(b)(2)]. This requirement would be added to clarify the system of records for Federal employees.

- Maintain all records required by this part in current and accessible electronic systems. This requirement is necessary to facilitate timely, efficient, and cost-effective transfer and analysis of CBDPP-related data [proposed § 850.40(b)(3); currently § 850.39(f)].

Proposed § 850.40(c) would continue to require Heads of DOE Field Elements and CSOs to designate all record series required by this rule as agency records and ensure that these records are retained for a minimum of 75 years. This practice is consistent with DOE's policy on retaining medical records. This requirement would continue to ensure that required CBDPP records that relate to workplace conditions will be available to correlate with the beryllium and beryllium-associated workers' medical records. DOE expects that Heads of DOE Field Elements will direct their DOE contracting officers to stipulate DOE ownership of these documents in those contracts.

Proposed § 850.40(d)(1) would require both contractor and Federal employers to ensure the confidentiality of all personally identifiable information in work-related records generated in response to this rule by making sure that:

- All records that are transmitted to other parties are transmitted consistent with the Privacy Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and their implementing regulations [proposed § 850.40(d)(1)(i)]. DOE recognizes that employers must take these precautions to prevent the violation of privacy laws because personal information could be obtained from transmitted records, or inferred from information other than personal identifiers in the records, unless these precautions are taken.

- Individual medical information generated by the CBDPP is [proposed § 850.40(d)(1)(ii)]:

- Either included as part of the worker's site medical records and maintained by the SOMD, or is maintained by another physician designated by the employer [proposed § 850.40(d)(1)(ii)(A)];

- Required to be maintained as confidential medical records separately from non-medical records [proposed § 850.40(d)(1)(ii)(B)]; and

- Used or disclosed in conformance with any applicable requirement of the American with Disabilities Act of 1990, HIPAA, and any other applicable law or regulation [proposed § 850.40(d)(1)(ii)(C)].

Proposed § 850.40(d)(2) would continue to require employers to maintain all records generated as required by this rule, in current and accessible electronic systems, which include the ability to readily retrieve data in a format that maintains confidentiality. This requirement is necessary to facilitate timely, efficient, and cost-effective transfer and analysis of CBD-related data.

Proposed § 850.40(d)(3) would require employers to transmit all records generated by this rule to the Office of Environment, Health, Safety and Security, upon request.

Proposed § 850.40(d)(4) would continue to require employers to semi-annually transmit to the Office of Environment, Health, Safety and Security an electronic registry of beryllium and beryllium-associated workers that protects confidentiality, and the registry must include, a unique identifier for each individual, date of birth, gender, site job history, medical screening test results, exposure measurements, surface contamination levels, and results of referrals for specialized medical evaluations. The format of the information transmitted should currently comply with DOE Technical Standard 1187-2007 (DOE-STD-1187-2007), *Beryllium-Associated Worker Registry Data Collection and*

*Management Guidance*, June 2007.

Using this format would ensure consistency among DOE sites with respect to Beryllium Registry submittals. DOE expects employers to submit only the information that is already available. DOE does not propose requiring the employer to generate information solely for the purpose of submitting that information to the Beryllium Registry. DOE also believes that using the Beryllium Registry's format would implement DOE's Office of Inspector General's recommendation for CBDPPs in DOE/IG-0726, *Implementation of the Department of Energy's Beryllium-Associated Worker Registry*, April 2006, that Departmental program offices and sites adopt DOE-STD-1187-2007 in their individual CBDPPs.

Proposed § 850.41—Performance Feedback.

Proposed § 850.41 [currently § 850.40] would continue to establish the performance feedback provisions for the CBDPP. Accordingly, proposed § 850.41(a) [currently § 850.40(a)] would be revised for consistency among the sites and would require employers to conduct semi-annual assessments of the following:

- Monitoring results [proposed § 850.41(a)(1)];
- Hazard assessments [proposed § 850.41(a)(2)];
- Medical surveillance [proposed § 850.41(a)(3)]; and
- Exposure reduction efforts [proposed § 850.41(a)(4)].

DOE believes that the assessment of this data is important for the continuous improvement of the program.

Proposed § 850.41(b), would be added to require the assessments to identify any:

- Individuals at risk for beryllium-induced medical conditions and the working conditions that may be contributing to that risk [proposed § 850.41(b)(1)]; and
- Need for additional exposure controls [proposed § 850.41(b)(2)].

To ensure that workers have the information necessary to safely perform their assigned tasks, proposed § 850.41(c) [currently § 850.40(b)], would require employers to notify and make the assessment available to the appropriate Head of DOE Field Element, line managers, work planners, worker protection staff, medical staff, workers, and labor organizations representing beryllium workers performing beryllium activities. DOE believes that the requirement would improve communication among employers, managers, and others to more effectively

evaluate and monitor program effectiveness.

*D. Appendix A to Part 850—Beryllium Worker Chronic Beryllium Disease Prevention Program Consent Form (Mandatory) [Currently Appendix A to Part 850—Chronic Beryllium Disease Prevention Program Informed Consent Form]*

Proposed appendix A would revise the Chronic Beryllium Disease Prevention Program Informed Consent Form in the current rule by adding text to reflect the proposed amendments to §§ 850.34 and 850.37 requiring mandatory medical evaluations for beryllium workers. As stated earlier, DOE is aware that the term “informed consent” has a different meaning when used in other contexts (e.g., human subject research). The Department, however, used this term in the original 10 CFR part 850 published in December 1999 to ensure beryllium associated workers were informed of the medical evaluation process before medical evaluations were performed. However, DOE is proposing to not use “informed consent” but would use the term “consent” and expand it to address consent for medical evaluations for beryllium workers and beryllium associated workers.

*E. Appendix B to Part 850—Beryllium-Associated Worker Chronic Beryllium Disease Prevention Program Consent Form (Mandatory)*

Proposed Appendix B would be added to reflect the proposed amendments to §§ 850.34 and 850.37 as they relate to the voluntary medical evaluations for beryllium-associated workers.

## V. Procedural Requirements

*A. Review Under Executive Orders 12866 and 13563*

This regulatory action has been determined to be a significant regulatory action under Executive Order 12866, “Regulatory Planning and Review,” 58 FR 51735 (October 4, 1993). Accordingly, this action was subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA). The assessment of the potential costs and benefits of the rule required by section 6(a)(3) of the Executive Order has been made a part of the rulemaking file and is available for public review as provided in the **ADDRESSES** section of this NOPR.

Before conducting the assessment, DOE profiled the 22 sites and activities affected by the proposed CBDPP rule and estimated the number of workers

affected by the proposed rule. DOE estimated that 20,444 workers may have been or be exposed or potentially exposed in the DOE complex. Based on exposure monitoring data submitted since 2002 to the Beryllium-Associated Worker Registry (BAWR), DOE estimated that 1,261 of these workers are potentially exposed at or above the proposed action level (0.05 µg/m<sup>3</sup>) or the permissible exposure limit prescribed in the CBDPP rule.

DOE estimated the compliance costs of the proposed amendments to the CBDPP rule for its 22 beryllium sites. The proposed rule is estimated to cost from 13.6 million to \$17.2 million (annualized first year costs plus annual costs in 2014 dollars, using a 7 percent discount rate and a 10 year period lifetime of investment. This includes un-annualized first year costs of \$41.4 million to \$42.7 million, of which \$7.8 million to \$11.2 million are annually recurring costs. Most costs are related to establishing additional regulated areas, which are estimated to average \$37.1 million in initial costs, or 84 to 87 percent of total initial costs. In addition, DOE expects its sites will experience cost-savings attributable to linguistic changes and clarifications in the proposed amendments to 10 CFR part 850.

DOE assessed potential benefits and cost-savings of the proposed amendments to the CBDPP for DOE, DOE contractors, and workers. DOE assessed the following benefits of the proposed CBDPP rule if it is adopted as a final rule: (1) Reduced medical costs; (2) reduced mortality; (3) increased quality of life; (4) increased medical surveillance for workers at risk; (5) increased work-life for beryllium workers; (6) reduced confusion and dispute over the legal liability of DOE and DOE contractors; (7) reduced restrictions and costs for the release and transfer of equipment or areas with potential beryllium contamination; (8) reduced control of areas where measured beryllium is a result of naturally high levels of beryllium in the soil or surrounding environment; (9) reduced turnaround time for sample analysis due to the use of portable laboratories; and (10) reduced medical costs for periodic evaluations due to the Site Occupational Medicine Director’s ability to judge that certain medical tests may be unnecessary for some workers.

DOE also assessed the potential economic impact of the proposed rule on the provision of public goods that contain beryllium and the impact on the market for beryllium. DOE assessed each of these potential impacts and determined neither will impose a

significant economic impact. DOE determined that the potential reduction in the provision of beryllium-containing public goods will be minimal and, consequently, the reduction in demand for beryllium will be small.

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011 (76 FR 3281, Jan. 21, 2011). Executive Order 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that Executive Order 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. DOE believes that this NOPR is consistent with these principles, including the requirement that, to the extent permitted by law, agencies adopt a regulation only upon a reasoned determination that its benefits justify its costs and, in choosing among alternative regulatory approaches, those approaches maximize net benefits.

### *B. Review Under the Regulatory Flexibility Act*

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires that an agency prepare an initial regulatory flexibility analysis for any regulation for which a general notice of proposed rulemaking is required, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)).

This proposed rule would update DOE's regulations on CBDPP. This proposed rule applies only to activities conducted by DOE or by DOE's contractors. The contractors who manage and operate DOE facilities would be principally responsible for implementing the rule requirements. DOE considered whether these contractors are "small businesses" as the term is defined in the Regulatory Flexibility Act (5 U.S.C. 601(3)). The Regulatory Flexibility Act's definition incorporates the definition of small business concerns in the Small Business Act, which the Small Business Administration (SBA) has developed through size standards in 13 CFR part 121. DOE expects that any potential economic impact of this proposed rule on small businesses would be minimal because work performed at DOE sites is under contracts with DOE or the prime contractor at the site. DOE contractors are usually reimbursed through their contracts for the costs of complying with CBDPP requirements. Therefore, most would not be adversely impacted by the requirements in this proposed rule. For these reasons, DOE certifies that this proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities, and therefore, no regulatory flexibility analysis has been prepared.

### *C. Review Under the Paperwork Reduction Act*

The information collection provisions of this proposed rule are not substantially different from those contained in DOE contracts with DOE prime contractors covered by the current CBDPP rule, and were previously approved by the Office of Management and Budget (OMB) and assigned OMB Control No. 1910–5112. That approval covered submission to develop and submit an initial CBDPP to DOE for approval; periodically revise the CBDPP; conduct a baseline inventory of beryllium at the site; notify workers of exposure monitoring results; develop and maintain a registry of beryllium workers; require workers to

sign consent forms for beryllium work and medical surveillance; establish and maintain records related to the beryllium inventory and hazard assessment, exposure monitoring, workplace controls and medical surveillance; and establish a performance feedback process for continually evaluating and improving the CBDPP. Accordingly, no additional OMB clearance is required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and the procedures implementing that Act, 5 CFR 1320.1 *et seq.*

### *D. Review Under the National Environmental Policy Act*

DOE has determined that this proposed rule is covered under the Categorical Exclusion found in DOE's National Environmental Policy Act regulations at paragraph A.5 of appendix A to subpart D, 10 CFR part 1021, which applies to a rulemaking that amends an existing rule or regulation that does not change the environmental effect of the rule or regulation being amended.

### *E. Review Under Executive Order 12988*

Section 3 of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), instructs each agency to adhere to certain requirements in promulgating new regulations. Executive agencies are required by section 3(a) to adhere to the following general requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required

review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

### *F. Review Under Executive Order 13132*

Executive Order 13132, "Federalism" (64 FR 43255, August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this proposed rule and has determined that it would not preempt State law and would not have a substantial direct effect on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

### *G. Review Under Executive Order 13175*

Under Executive Order 13175 (65 FR 67249, November 6, 2000) on "Consultation and Coordination with Indian Tribal Governments," DOE may not issue a discretionary rule that has "tribal" implications and imposes substantial direct compliance costs on Indian tribal governments. DOE has determined that the proposed rule would not have such effects and concluded that Executive Order 13175 does not apply to this proposed rule.

### *H. Review Under the Unfunded Mandates Reform Act of 1995*

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires each Federal agency to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency regulation that may result in the expenditure by states, tribal, or local governments, on the aggregate, or by the private sector, of \$100 million in any one year. The Act also requires a Federal agency to develop an effective process to permit timely input by elected officials of state, tribal, or local governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity to provide timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. DOE has determined that the proposed rule published does not contain any Federal mandates affecting small governments, so these requirements do not apply.

*I. Review Under Executive Order 13211*

Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to the OMB a Statement of Energy Effects for any proposed significant energy action. A “significant energy action” is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that:

- (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and
- (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or
- (3) is designated by the Administrator of OIRA as a significant energy action.

For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy and is therefore not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

*J. Review Under the Treasury and General Government Appropriations Act, 1999*

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well being. The proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

*K. Review Under the Treasury and General Government Appropriations Act, 2001*

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB.

OMB’s guidelines were published at 67 FR 8452 (February 22, 2002), and DOE’s guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this proposed rule under the

OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

**VI. Public Participation***A. Attendance at the Public Hearings*

Public hearings will be held at the times, dates, and places indicated in the **DATES** and **ADDRESSES** sections at the beginning of this NOPR. Any person who is interested in making an oral presentation should, by 4:30 p.m. on the date specified, make a phone request to the telephone number in the **DATES** section of this NOPR. The person should provide a daytime telephone number where he or she may be reached. A person requesting an opportunity to speak will be notified as to the approximate time he or she will be speaking. Each presentation is limited to 10 minutes. A person making an oral presentation should bring a copy of their statements to the hearing on a CD or USB flash drive and submit them at the registration desk. Foreign nationals visiting DOE Headquarters are subject to advance security screening procedures. Please note that foreign nationals visiting DOE Headquarters are subject to advance security screening procedures. Any foreign national wishing to participate in this public hearing should advise DOE as soon as possible by contacting Ms. Rogers to initiate the necessary procedures. Please also note that those wishing to bring laptops into the Forrestal Building will be required to obtain a property pass. Visitors should avoid bringing laptops, or allow an extra 45 minutes.

*B. Conduct of the Public Hearings*

A DOE official will be designated to preside at each hearing, which will not be judicial or evidentiary. Only those conducting the hearing may ask questions. Any further procedural rules needed to conduct the hearing properly will be announced by the DOE presiding official. A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to select the people who will speak. In the event that requests exceed the time allowed, DOE also reserves the right to schedule speakers’ presentations and to establish the procedures for conducting the hearing.

A transcript of each hearing will be included in the docket, which can be viewed as described in the Docket section at the beginning of this notice. In addition, transcripts may be purchased from the transcribing reporter.

If DOE must cancel the hearings, it will make every effort to give advance notice.

*C. Submission of Comments*

DOE will accept comments, data and information regarding this proposed rule before or after the public hearings, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested individuals are invited to participate in this proceeding by submitting data, views, or arguments with respect to this proposed rule using any of the methods described in the **ADDRESSES** section at the beginning of this notice. To help the Department review the submitted comments, commenters are requested to reference the paragraph(s), *e.g.*, § 850.3(a), to which they refer where possible.

1. *Submitting comments via regulations.gov.* The regulations.gov Web page will require you to provide your name and contact information. Your contact information will be viewable to DOE’s Office of Environment, Health, Safety and Security staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment. However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to regulations.gov information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through regulations.gov cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the

Confidential Business Information section below.

DOE processes submissions made through *regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *regulations.gov* provides after you have successfully uploaded your comment.

2. *Submitting comments via email, mail or hand delivery/courier.* Comments and documents submitted via email, mail, or hand delivery/courier, also will be posted to *regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery/courier, please provide all items on a CD or USB flash drive, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

3. *Confidential Business Information.* Pursuant to the provisions of 10 CFR 1004.11, anyone submitting information or data he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail two well-marked copies: One copy of the document marked "CONFIDENTIAL BUSINESS INFORMATION" including all the information believed to be confidential, and one copy of the document marked "NO CONFIDENTIAL BUSINESS INFORMATION" with the information believed to be confidential deleted. Submit these documents via email or CD, if feasible. DOE will make its own determination as to the confidentiality of the information and treat it

accordingly. Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

4. *Campaign form letters.* Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

## References

1. Smith DB, Cannon WF, Woodruff LG, Garrett RG, Klassen R, Kilburn JE, Horton JD, King HD, Goldhaber MB, and Morrison JM. "Major- and Trace-Element Concentrations in Soils from Two Continental-Scale Transects of the United States and Canada." Open-File Report 2005–1253, U.S. Geological Survey, 2005. Accessed on March 25, 2015 at: <http://pubs.usgs.gov/of/2005/1253/pdf/OFR1253.pdf>.
2. Stonehouse AJ, Zenczak S. "Properties, Production and Applications." In: Beryllium Biomedical and Environmental Aspects. Rossman MD, Preuss OP, and Powers MB, eds. Baltimore: Williams and Wilkins, 1991.
3. Occupational Safety and health Administration. *Occupational Exposure to Beryllium and Beryllium Compounds, Proposed Rule*. (80 FR 47565, August 7, 2015. Accessed on December 1, 2015 at: <https://www.federalregister.gov/articles/2015/08/07/2015-17596/occupational-exposure-to-beryllium-and-beryllium-compounds>.
4. National Toxicology Program. Thirteenth Report on Carcinogens. "Beryllium and Beryllium Compounds." 2014. Accessed on 10/26/2015 at: <http://ntp.niehs.nih.gov/ntp/roc/content/profiles/beryllium.pdf>.
5. IARC Monographs on the Evaluations on of Carcinogenic Risk to Humans. Beryllium and beryllium compounds. Accessed on 10/27/2015 at: [http://monographs.iarc.fr/ENG/Classification/latest\\_classif.php](http://monographs.iarc.fr/ENG/Classification/latest_classif.php).
6. ACGIH®. Documentations of the Threshold Limit Values and Biological

Exposure Indices 7th Edition—2009 Supplement: Beryllium and Compounds, American Conference of Governmental Industrial Hygienists, Cincinnati, OH.

7. "Managing Health Effects of Beryllium Exposure." Committee on Beryllium Alloy Exposures, The National Academies Press, 2008.

8. Maier LA, Newman LS. "Beryllium Disease." Environmental and Occupational Medicine, 3rd edition. Rom WN, Ed. Lippincott-Raven, New York, 1998.

9. Tinkle SS, Antonini JM, Rich BA, Roberts JR, Salman R, DePree K, Adkins EJ. "Skin as a route of exposure and sensitization in chronic beryllium disease." Environmental Health Perspectives. 2003; 111:1202–1208.

10. Henneberger PK, Cumro D, Deubner, DD. "Beryllium Sensitization and Disease Among Long-term and Short-term Workers In Beryllium Ceramics." International Archives of Occupational and Environmental Health. 2001; 74(3):167–176.

11. Day GA, Stefaniak AB, Weston A, Tinkle SS. "Beryllium Exposure: Dermal and Immunological Considerations." International Archives of Occupational and Environmental Health. 2006; (79)(2):161–164.

12. Green DM, Newman LS. "Agency for Toxic Substances and Disease Registry (ASTDR) Case Studies in Environmental Medicine. No.19, Beryllium Toxicity." U. S. Department of Health and Human Services. 1992.

13. Stange AW, Furman FJ, Hilmas DE. "The beryllium lymphocyte proliferation test: Relevant issues in beryllium health surveillance." American Journal of Industrial Medicine. 2004 Nov; 46(5):453–62.

14. Stange AW, Hilmas DE, Furman FJ, Gatcliffe TR. "Beryllium sensitization and chronic beryllium disease at a former nuclear weapons facility." Applied Occupational Environmental Hygiene. 2001 Mar;16(3):405–17.

15. Newman LS, Mroz MM, Balkissoon R, Maier LA. "Beryllium sensitization progresses to chronic beryllium disease: a longitudinal study of disease risk." American Journal of Respiratory and Critical Care Medicine. 2005;171:54–60

16. Mroz MM, Maier LA, Strand M, Silveira L, Newman LS. "Beryllium lymphocyte proliferation test surveillance identifies clinically significant beryllium disease." American Journal of Industrial Medicine. 2009 Oct; 52(10):762–73.

17. Rosenman K, Hertzberg V, Rice C, Reilly MJ, Aronchick J, Parker JE, Regovich J, Rossman M. "Chronic beryllium disease and sensitization at a beryllium processing facility." Environmental Health Perspectives. 2005 Oct; 113(10):1366–72. Erratum in: Environmental Health Perspectives. 2006 Apr; 114(4):A214.

18. Welch L, Ringen K, Bingham E, Dement J, Takaro T, McGowan W, Chen A, Quinn P. "Screening for beryllium disease among construction trade workers at Department of Energy nuclear sites." American Journal of Industrial Medicine. 2004 Sep; 46(3):207–18.

19. Arjomandi M, Seward J, Gotway MB, Nishimura S, Fulton GP, Thundiyil J, King TE Jr, Harber P, Balmes JR. "Low prevalence of chronic beryllium disease among workers

at a nuclear weapons research and development facility." *Journal of Occupational and Environmental Medicine*. 2010 Jun; 52(6):647–52.

20. Powers MB. "History of Beryllium." In *Beryllium Biomedical and Environmental Aspects*. Rossman MD, Preuss OP, and Powers MB editors. Baltimore: Williams and Wilkins, 1991.

21. Eisenbud M et al. "Non-occupational Berylliosis." *Journal of Industrial Hygiene Toxicology*. 1949; 31:282–294.

22. Eisenbud M, Lissan J. "Epidemiologic Aspects of Beryllium-Induced Nonmalignant Lung Disease: A 30-Year Update." *Journal of Occupational Medicine*. 1983; 25:196–202.

23. Sterner JH, Eisenbud M. "Epidemiology of Beryllium Intoxication." *Archives of Industrial Hygiene and Occupational Medicine*. 1951; 4: 123–157.

24. Newman LS, Kreiss K.

"Nonoccupational Beryllium Disease Masquerading as Sarcoidosis: Identification by Blood Lymphocyte Proliferation Response to Beryllium." *American Review of Respiratory Disease*. 1992; 145: 1212–1214.

25. McCanlies EC, Yucesoy B, Mnatsakanova A, Slaven JE, Andrew M, Frye BL, Schuler CR, Kreiss K, Weston A. "Association between IL-1A single nucleotide polymorphisms and chronic beryllium disease and beryllium sensitization." *American Journal of Occupational Environmental Medicine*. 2010 Jul; 52(7):680–4.

26. McCanlies EC, J.S. Ensey, C.R. Schuler, K. Kreiss, A. Weston. "The association between HLA-DPB1Glu69 and chronic beryllium disease and beryllium sensitization." *American Journal of Industrial Medicine*. 2004; 46:95–103.

27. Pappas GP, Newman LS. "Early pulmonary physiologic abnormalities in beryllium disease." *American Review of Respiratory Disease*. 1993 Sep; 148(3):661–6.

28. Marchand-Adam S, El Khatib A, Guillon F, Brauner MW, Lamberto C, Lepage V, Naccache JM, Valeyre D. "Short- and long-term response to corticosteroid therapy in chronic beryllium disease." *European Respiratory Journal*. 2008 Sep; 32(3):687–93.

29. ACGIH® Documentations of the Threshold Limit Values and Biological Exposure Indices 7th Edition—2009 Supplement: Beryllium and Compounds, American Conference of Governmental Industrial Hygienists, Cincinnati, OH.

30. Stefaniak, AB et al. "Dissolution of beryllium in artificial lung alveolar macrophage phagolysosomal fluid." *Chemosphere*. doi:10.1016/j.chemosphere.2010.12.088, 2011.

31. Finch G, Mewhinney L, Eidson A, Hoover, M, Rothenberg, S. "In Vitro Dissolution Characteristics of Beryllium Oxide and Beryllium Metal Aerosols. *Journal of Aerosol Science*. 1988; 19(3):333–342.

32. Stefaniak AB, Day GA, Hoover MD, Breyse PN, Scripsick R. "Differences in dissolution behavior in phagolysosomal stimulant fluid for single-constituent and multi-constituent materials associated with beryllium sensitization and chronic beryllium disease." *Journal of Toxicology and Environmental Health, Part A*. 2008; 71(22):1468–1481.

33. Cummings KJ, Stefaniak AB, Virji MA, Kreiss K. A reconsideration of acute beryllium disease. *Environmental Health Perspective*. 117(8):1250–6, 2009.

34. Occupational Safety and Health Administration. "Preventing adverse health effects from exposure to beryllium on the job." *Hazard Information Bulletin*, September 2, 1999.

35. 29 CFR 1910.1000(b), Table Z–2. Accessed on March 25, 2015 at: [https://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p\\_id=9993](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9993).

36. Dufay SK, Archuleta, M. "Comparison of collection efficiencies of sampling methods for removable beryllium surface contamination." *Journal of Environmental Monitor*. 2006:8630–633.

37. Epstein WL. "Cutaneous Effects of Beryllium." In: *Beryllium Biomedical and Environmental Aspects*. Rossman MD, Preuss OP, and Powers MB, eds. Baltimore: Williams and Wilkins, 1991.

38. NIST/SEMATECH e-Handbook of Statistical Methods. Accessed on March 25, 2015 at <http://www.itl.nist.gov/div898/handbook/prc/section3/prc3.htm>.

39. Frome EL, Newman LS, Cragle DL, Colyer SP, Wambach PF. "Identification of an abnormal beryllium lymphocyte proliferation test." *Toxicology*. 2003 Feb 1;183(1–3):39–56. Erratum in: *Toxicology*. 2003 Jun 10;188(2–3):335–6.

40. National Jewish Health. Chronic Beryllium Disease: Overview. "How do you develop CBD?" 2011. Accessed on 10/26/2015 at: <http://www.nationaljewish.org/healthinfo/conditions/beryllium-disease/>.

41. Kreiss K, Wasserman S, Mroz MM, Newman LS. "Beryllium disease screening in the ceramics industry. Blood lymphocyte test performance and exposure-disease relations." *Journal of Occupational Medicine*. 1993 Mar;35(3):267–74.

42. Borak J, Woolf SH, Fields CA. "Use of Beryllium Lymphocyte Proliferation Testing for Screening of Asymptomatic Individuals: An Evidence-based Assessment." *Journal of Occupational and Environmental Medicine*. 2006 September; 48:937–947.

43. Greene M, Smith SM. "Consenting to uncertainty: challenges for informed consent to disease screening—a case study." *Theoretical Medicine and Bioethics*. 05 Dec 2008.

44. Poulin M, Ricard S. "The Blood Beryllium Lymphocyte Proliferation Test (Belpt) from Theory to Practice." Québec National Public Health Institute. April 2004.

45. Darby A, Fishwick D. "Beryllium: A review of the health effects and the evidence for screening or surveillance in workers exposed to beryllium." Research Report RR873, Health and Safety Executive, HSE Books, 2011.

46. DOE–SPEC–1142–2001: Beryllium Lymphocyte Proliferation Testing (BeLPT). Accessed on March 25, 2015 at: <http://www.energy.gov/ehss/downloads/doe-spec-1142-2001>.

47. Milovanova TN, Popma SH, Cherian S, Moore JS, Rossman MD. "Flow Cytometric Test for Beryllium Sensitivity." *Cytometry Part B Clinical Cytometry*. 2004;60B:23–30.

## List of Subjects in 10 CFR Part 850

Beryllium, Hazardous substances, Lung diseases, Occupational safety and health, Reporting and recordkeeping requirements.

Issued in Washington, DC, on May 16, 2016.

Ernest J. Moniz,  
Secretary of Energy.

For the reasons set forth in the preamble, the Department of Energy proposes to revise part 850 of chapter III of title 10 of the Code of Federal Regulations to read as follows:

## PART 850—CHRONIC BERYLLIUM DISEASE PREVENTION PROGRAM

### Subpart A—General Provisions

Sec.

- 850.1 Scope.
- 850.2 Applicability.
- 850.3 Definitions.
- 850.4 Enforcement.
- 850.5 Dispute resolution.
- 850.6 Interpretations, binding interpretive rulings and requests for information.

### Subpart B—Administrative Requirements

- 850.10 Development and approval of the CBDPP.
- 850.11 General CBDPP requirements.
- 850.12 Implementation.
- 850.13 Compliance.

### Subpart C—Specific Program Requirements

- 850.20 Beryllium inventory.
- 850.21 Hazard assessment and abatement.
- 850.22 Permissible exposure limit.
- 850.23 Action level.
- 850.24 Exposure monitoring.
- 850.25 Exposure reduction.
- 850.26 Beryllium regulated areas.
- 850.27 Hygiene facilities and practices.
- 850.28 Respiratory protection.
- 850.29 Protective clothing and equipment.
- 850.30 Housekeeping.
- 850.31 Release and transfer criteria.
- 850.32 Waste disposal.
- 850.33 Beryllium emergencies.
- 850.34 Medical surveillance.
- 850.35 Medical restriction.
- 850.36 Medical removal and benefits.
- 850.37 Medical consent.
- 850.38 Training and counseling.
- 850.39 Warning signs and labels.
- 850.40 Recordkeeping and use of information.
- 850.41 Performance feedback.

### Appendix A to Part 850—Beryllium Worker Chronic Beryllium Disease Prevention Program Consent Form (Mandatory)

### Appendix B to Part 850—Beryllium-Associated Beryllium Worker Chronic Beryllium Disease Prevention Program Consent Form (Mandatory)

**Authority:** 42 U.S.C. 2201(i)(3), (p); 42 U.S.C. 2282c; 29 U.S.C. 668; 42 U.S.C. 7101 *et seq.*, 50 U.S.C. 2401 *et seq.*, E.O. 12196, as amended.

## Subpart A—General Provisions

### § 850.1 Scope.

This part provides for the establishment of a chronic beryllium disease prevention program (CBDPP) for DOE employees and DOE contractor employees, and supplements and is deemed an integral part of the worker safety and health program required under part 851 of this chapter for DOE contractor employees. If there is a conflict between the requirements of this part, and part 851, this part controls.

### § 850.2 Applicability.

(a) This part applies to:

(1) DOE contractors and DOE offices responsible for operations or activities that involve present or past exposure, or the potential for exposure, to airborne concentrations of beryllium at or above the action level at DOE sites;

(2) Any current DOE contractor employee and DOE employee at a DOE site who was exposed or potentially exposed to airborne concentrations of beryllium at or above the action level at a DOE site; and

(3) The Site Occupational Medical Directors (SOMD) responsible for providing the overall direction and operation of the employer's beryllium medical surveillance program.

(b) This part does not apply to:

(1) Activities involving beryllium articles; and

(2) DOE laboratory operations that meet the definition of laboratory use of hazardous chemicals in 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*.

### § 850.3 Definitions.

(a) As used in this part:

*Action level* means the airborne concentration of beryllium which, at or above, triggers the implementation of worker protection provisions as specified in § 850.23 of this part are required.

*Authorized person* means any person required by work duties to be in a regulated area.

*Beryllium* means elemental beryllium, beryllium oxide, and any alloy containing 0.1% or greater of beryllium by weight that may be released as an airborne particulate.

*Beryllium activity* means any activity taken for or by DOE at a DOE site that can expose workers to levels of airborne beryllium at or above the action level, including the disturbance of legacy beryllium-containing dust.

*Beryllium article* means a “commercially available, off-the-shelf” item composed of beryllium that is

formed to a specific shape or design during manufacture, has end-use functions that depend in whole or in part on its shape or design during end use, and which does not release particulate beryllium at or above the action level under normal conditions of use.

*Beryllium-associated worker* means a current worker, who was exposed or potentially exposed to airborne concentrations of beryllium at a DOE site, including a worker:

(1) Whose work history shows that the worker may have been exposed to airborne concentrations of beryllium at a DOE site;

(2) Who exhibits signs or symptoms of beryllium exposure; or

(3) Who is receiving medical removal benefits under this part.

*Beryllium emergency* means any occurrence such as, but not limited to, equipment failure, container rupture, or failure of control equipment or operations that results in an unexpected and significant release of beryllium at a DOE site.

*Beryllium-Induced Lymphocyte Proliferation Test (BeLPT)* is an in vitro measure of the beryllium antigen-specific, cell-mediated immune response to beryllium. In this part, a split sample BeLPT (where one blood draw is split and sent to two different testing facilities) would constitute two tests for purposes of diagnosing BeS.

*Beryllium-induced medical condition* refers to CBD and BeS. Other diseases may resemble CBD, but are not attributable to beryllium.

*Beryllium Registry* refers to the DOE Beryllium-Associated Worker Registry.

*Beryllium regulated area* means an area demarcated by the employer in which the airborne concentration of beryllium at or above, or can reasonably be expected to be at or above, the action level.

*Beryllium sensitization or sensitivity (BeS)* means a condition diagnosed by the SOMD based on any of the following:

(1) Two abnormal blood BeLPT results;

(2) One abnormal and one borderline blood BeLPT; or

(3) One abnormal BeLPT test of alveolar lung lavage cells.

*Beryllium worker* means a current worker who is exposed or potentially exposed to levels of airborne concentration of beryllium at or above the action level in the course of the worker's employment in a DOE beryllium activity.

*Breathing zone* is a hemisphere forward of the shoulders, centered on

the mouth and nose, with a radius of 6 to 9 inches.

*Chronic beryllium disease (CBD)* means a condition diagnosed by the SOMD based on the worker having the following:

(1) BeS as defined in this section; and

(2) A lung biopsy showing non-caseating granulomas or lymphocytic process consistent with CBD; or radiographic (including computed tomographic (CT) scans) and pulmonary function testing results consistent with pulmonary granulomas.

*Cognizant Secretarial Officer (CSO)* means, with respect to a particular situation, the Assistant Secretary, Deputy Administrator, Program Office Director, or equivalent DOE official who has primary line management responsibility for a contractor, or any other official to whom the CSO delegates in writing a particular function under this part.

*Contractor* means any entity, including affiliated entities, such as a parent corporation, under contract with DOE, or a subcontractor at any tier that has responsibilities for performing beryllium work at a DOE site in furtherance of a DOE mission.

*DOE* means the U.S. Department of Energy.

*DOE site* means a DOE-owned or -leased area or location or other area or location controlled by DOE where activities and operations are performed at one or more facilities or places by a contractor in furtherance of a DOE mission.

*Employer* means:

(1) For DOE contractors employees, the DOE contractor that is directly responsible for the safety and health of DOE contractor employees while performing a beryllium activity or other activity at a DOE site; or

(2) For DOE employees, the DOE office that is directly responsible for the safety and health of DOE Federal employees while performing a beryllium activity or other activity at a DOE site; or

(3) Any person acting directly or indirectly for a DOE office or contractor with respect to terms and conditions of employment of beryllium and beryllium-associated workers.

*Final medical determination* means the final written medical determination of the SOMD as to whether the beryllium worker should be permanently removed because of BeS or CBD as those terms are defined in this part. If the worker is eligible and has elected the multiple physician review or alternate physician's review, the SOMD issues the final medical determination at the conclusion of such process. The

initial determination is also the final determination if the worker does not make a timely request for a multiple physician review or alternate physician review.

*Head of DOE Field Element* means an individual who is the manager or head of the DOE operations office or field office.

*High-efficiency particulate air (HEPA) filter* means a filter capable of trapping and retaining at least 99.97% of 0.3 micrometer mono-dispersed particles.

*Medical removal benefits* means the employment benefits established by § 850.36 of this part for beryllium workers who are temporarily or permanently medically removed from beryllium activities at or above the action level following a determination by the SOMD that removal is warranted.

*Medical restriction* means the outcome of the process in which the SOMD recommends that the worker be restricted from a job that involves a beryllium activity when health evaluations indicate the worker is not suffering from CBD or has not been sensitized to beryllium, but the SOMD determines that exposure to beryllium at or above the action level is contraindicated due to other medical conditions of the worker. In addition, medical restrictions must be performed in accordance with 10 CFR part 851, appendix A, section 8.

*Qualified Individual* means an individual designated by the employer who possesses the knowledge, skills, and abilities needed to implement an industrial hygiene program (*i.e.*, an individual who is either a certified industrial hygienist or has a college degree in industrial hygiene or a related scientific, engineering, or technical degree); who has completed special studies and training in industrial hygiene; and who has at least five years of full-time employment in the professional practice of industrial hygiene.

*Site Occupational Medical Director (SOMD)* means the physician responsible for the overall direction and operation of the site occupational medicine program.

*Surface levels of beryllium* means the amount of beryllium easily removed from surfaces by means such as casual contact, wiping, or brushing.

*Unique identifier* means the part of a paired set of labels, used in records that contain confidential information that does not identify individuals except by using the matching label.

*Worker* means an employee of DOE, or a DOE contractor or subcontractor at any tier, who performs work in

furtherance of a DOE mission at a DOE site.

(b) Terms undefined in this part that are defined in the Atomic Energy Act of 1954, as amended, or 10 CFR part 851, *Worker Safety and Health Program*, have the same meaning as under that Act and regulation, as applicable.

#### **§ 850.4 Enforcement.**

DOE may take appropriate steps pursuant to part 851 of this chapter to enforce compliance by contractors with this part and any DOE-approved contractor CBDPP.

#### **§ 850.5 Dispute resolution.**

(a) Any worker who is adversely affected by an action taken, or a failure to act, under this part may petition the Office of Hearings and Appeals for relief in accordance with 10 CFR part 1003, subpart G, *Office of Hearings and Appeals Procedural Regulations; Private Grievances and Redress*, subject to paragraphs (b) and (c) of this section.

(b) The Office of Hearings and Appeals may elect not to accept a petition from a worker unless the worker had requested that the employer correct the violation, and the employer refused or failed to take corrective action within a reasonable time.

(c) If the dispute relates to a term or condition of employment that is covered by a grievance-arbitration provision in a collective bargaining agreement, the worker must exhaust all applicable grievance-arbitration procedures before filing a petition for relief with the Office of Hearings and Appeals. A worker is deemed to have exhausted all applicable grievance-arbitration procedures if 150 days have passed since the filing of a grievance and a final decision has not been issued.

#### **§ 850.6 Interpretations, binding interpretive rulings, and requests for information.**

Requests for legal interpretations, binding interpretive rulings, and requests for information regarding this part must be in accordance 10 CFR 851.6, *Petitions for generally applicable rulemaking*, 851.7, *Requests for a binding interpretative ruling*, or 851.8, *Informal requests for information*, respectively.

### **Subpart B—Administrative Requirements**

#### **§ 850.10 Development and approval of the CBDPP.**

(a) *Preparation and submittal of CBDPP to DOE.* (1) Subject to the provisions of § 851.13 of this part, each employer engaged in beryllium activities at a DOE site must submit a

CBDPP for review and approval, as indicated in § 850.10(b), no later than [date 90 days after effective date of final rule];

(2) Each employer at a DOE site which is not engaged in beryllium activities but which employs beryllium-associated workers must submit a CBDPP with the provisions applicable to those workers (*e.g.*, medical evaluations, training, recordkeeping) for review and approval as indicated in § 850.10(b), no later than [date 90 days after effective date of final rule];

(3) If the CBDPP has separate sections addressing the beryllium activities of multiple contractors at the site, the Head of DOE Field Element will designate a single contractor to review the sections prepared by the other contractors, so that a single consolidated CBDPP for the site is submitted to the Head of DOE Field Element for review and approval; and

(4) Employers at a multiple contractor site must share relevant information generated by the assessment required by § 850.41(a), to ensure the safety and health of their workers.

(b) *DOE review and approval.* (1) The appropriate Head of DOE Field Element must review and provide written approval or rejection of the applicable contractor's CBDPP, or any updates to the CBDPP, within 90 working days of receiving the document. The appropriate Head of DOE Field Element may direct the applicable contractor to modify the CBDPP or any updates to the CBDPP during their review.

(2) The appropriate CSO must review and provide written approval or rejection of the CBDPP, or any updates to the CBDPP submitted by DOE offices within 90 working days of receiving the document. The appropriate CSO may direct the DOE office to modify the CBDPP or any updates to the CBDPP during their review.

(3) The CBDPP and any updates are deemed approved 90 working days after submission to the Head of DOE Field Element or the CSO, if they are not specifically approved or rejected earlier.

(4) Employers must furnish a copy of the approved CBDPP to the Office of Environment, Health, Safety and Security; DOE program offices; and affected workers or their designated representative upon request.

(c) *Updates.* Employers must submit an update of the CBDPP for review and approval within 30 working days after a significant change or significant addition to the CBDPP is made or warranted, or a change in contractors occurs. The Head of DOE Field Element or appropriate CSO, as applicable, must review the CBDPP at least annually and,

if appropriate, require the employer to update the CBDPP.

(d) *Labor organizations.* If an employer employs or supervises workers who are represented for collective bargaining purposes by a labor organization, the employer must:

(1) Give the labor organization timely notice of the development and implementation of the CBDPP and any updates thereto; and

(2) Upon timely request, bargain concerning implementation of this part, consistent with Federal labor laws and this part.

#### **§ 850.11 General CBDPP requirements.**

(a) The CBDPP must specify existing and planned beryllium activities.

(b) The scope and content of the CBDPP must be commensurate with the hazard of the activities performed. In all cases it must:

(1) Include formal plans and measures for maintaining exposures to beryllium that are below the levels prescribed in § 850.22;

(2) Satisfy the requirements in subpart C, *Specific Program Requirements*, of this part; and

(3) Contain provisions for minimizing the number of:

(i) Workers exposed to airborne concentrations of beryllium at or above the action level; and

(ii) Instances in which workers are exposed to airborne concentrations of beryllium at or above the action level.

#### **§ 850.12 Implementation.**

(a) Employers must manage and control beryllium activities consistent with the approved CBDPP.

(b) Activities that are outside the scope of the approved CBDPP involving unexpected exposure to airborne concentrations of beryllium at or above the action level may only be initiated upon written approval by the Head of DOE Field Element or appropriate CSO, as applicable.

(c) No person employed by DOE or a DOE contractor may take or cause any action inconsistent with the requirements of this part, an approved CBDPP, or any other applicable Federal statute or regulation concerning the exposure of workers to levels of beryllium at a DOE site.

(d) Nothing in this part precludes an employer from taking any additional protective actions that it determines to be necessary to protect the safety and health of workers provided that the employer continues to comply with the requirements of this part.

(e) Nothing in this part is intended to diminish the responsibilities of DOE officials under the Federal Employee

Occupational Safety and Health Program (29 CFR part 1960) and related DOE directives.

#### **§ 850.13 Compliance.**

(a) Employers may continue to conduct beryllium activities in compliance with their previously approved CBDPP until *[date 1 year after the effective date of the final rule]*.

(b) Employers must conduct activities under their approved CBDPP in compliance with this part as issued on *[effective date of the final rule]* by *[1 year after the effective date of the final rule]*.

(c) With respect to a particular beryllium activity, the contractor in charge of the activity is responsible for complying with this part. If no contractor is responsible for the beryllium activity, and Federal employees perform the activity, DOE must ensure implementation of, and compliance with, this part.

### **Subpart C—Specific Program Requirements**

#### **§ 850.20 Beryllium inventory.**

(a) The employer must identify and develop an inventory of beryllium activities and locations of potential beryllium contamination. In developing the inventory the employer must:

(1) Review current and historical records;

(2) Interview workers;

(3) Conduct air, surface, and bulk sampling, as appropriate, to characterize the beryllium and its locations; and

(4) Document the locations of beryllium at or above the action level at the site.

(b) Inventory results obtained within 12 months prior to *[effective date of the final rule]* may be used to satisfy this requirement if a Qualified Individual determines that conditions represented by the results have not changed in a manner that warrants changes in the beryllium inventory. The employer must update the beryllium inventory at least annually and when significant changes occur to beryllium activities.

(c) The employer must ensure that the beryllium inventory is conducted and managed by a Qualified Individual as defined in this rule.

#### **§ 850.21 Hazard assessment and abatement.**

(a) Employers must conduct a beryllium hazard assessment if the inventory establishes the presence of airborne beryllium that is potentially at or above the action level.

(b) The beryllium hazard assessment must be conducted in accordance with

10 CFR 851.21, *Hazard Identification and Assessment*.

(c) Beryllium hazards must be abated in accordance with 10 CFR 851.22, *Hazard prevention and abatement*.

(d) Employers must ensure that paragraphs (a) through (c) of this section are managed by a Qualified Individual as defined in this part.

#### **§ 850.22 Permissible exposure limit.**

(a) Employers must ensure that no worker is exposed to an airborne concentration of beryllium greater than the 8-hour TWA PEL established in 29 CFR 1910.1000, as measured in the worker's breathing zone by personal monitoring, or a more stringent 8-hour TWA PEL that may be promulgated by the Occupational Safety and Health Administration (OSHA) as an expanded health standard for beryllium.

(b) DOE must inform employers through a notice in the **Federal Register** of any applicable changes to the OSHA 8-hour TWA PEL described in paragraph (a) of this section.

#### **§ 850.23 Action level.**

(a) Employers must include in their CBDPPs an action level that is no greater than 0.05 µg/m<sup>3</sup>, calculated as an 8-hour time weighted average exposure, as measured in the worker's breathing zone by personal monitoring.

(b) If the airborne level of beryllium is at or above the level specified in paragraph (a) of this section, employers must implement §§ 850.24(c) (periodic exposure monitoring), 850.25 (exposure reduction), 850.26 (beryllium regulated areas), 850.27 (hygiene facilities and practices), 850.28 (respiratory protection), 850.29 (protective clothing and equipment), 850.30 (housekeeping), and 850.39 (warning signs and labels).

#### **§ 850.24 Exposure monitoring.**

(a) *General.* (1) The employer must ensure that exposure monitoring is managed by a Qualified Individual and conducted as specified in the approved CBDPP.

(2) The employer must ensure that:

(i) Air exposure levels are determined by conducting breathing zone sampling and reported as the 8-hour time-weighted average level to which a worker would be exposed if the worker were not using respiratory protective equipment.

(ii) Surface levels of beryllium are determined by using:

(A) Wet wipes; or

(B) Dry wipes if wet wipes would have an undesirable effect on the surface being sampled or surrounding surfaces, or if it is not technically feasible because the texture of the

surface is not compatible with wet wiping methods; or

(C) Vacuum surface sampling if wipes are not technically feasible because the texture of the surface is not compatible with wiping methods; or

(D) Bulk sampling where accumulations of material on a surface exceed amounts that are conducive to wipe or vacuum sampling.

(3) Surface sampling is not required for the interior of installed closed systems such as enclosures, glove boxes, chambers, or ventilation systems, or normally inaccessible surfaces such as under fixed cabinets or on the tops of overhead structural beams, unless these surfaces will become accessible or disturbed by planned work activity.

(b) *Initial exposure monitoring.* (1) Employers, except as provided for in paragraphs (b)(2) and (3) of this section, must perform initial exposure monitoring when the inventory and hazard assessment show there is, or the potential for, airborne concentrations of beryllium at or above the action level.

(2) Monitoring results obtained within 12 months prior to [effective date of the final rule] may be used to satisfy this requirement if a Qualified Individual determines that conditions represented by the results have not changed in a manner that would necessitate changes in beryllium controls.

(3) Where the employer has relied upon objective data that demonstrate that beryllium is not capable of being released in airborne concentrations at or above the action level under the expected conditions of processing, use, or handling, then no initial monitoring is required.

(c) *Periodic exposure monitoring.* (1) The employer must conduct periodic exposure monitoring of workers in locations where the airborne concentration of beryllium is at or above the action level. The monitoring must be conducted:

(i) In a manner and at a frequency necessary to represent workers' exposures; and

(ii) For the first year of operation, at least quarterly (every three months).

(2) After the first year, and subject to paragraph (d) of this section, the employer may reduce or terminate monitoring if it demonstrates that the airborne concentration of beryllium is below the action level for 6 months, based on an analysis of monitoring results and of any activities, controls, or other conditions that would affect beryllium levels. If the employer cannot demonstrate that the airborne concentration of beryllium is below the action level, the employer must

continue periodic monitoring on a quarterly basis.

(d) *Additional exposure monitoring.* The employer must conduct additional monitoring whenever there has been a production, process, control, or other change that may result in an exposure to beryllium that is at or above the action level. This monitoring must continue on a quarterly basis until the employer can demonstrate that the airborne concentration of beryllium is below the action level.

(e) *Analysis quality assurance.* (1) All samples collected to satisfy the monitoring requirements of this part must be analyzed in a laboratory that:

(i) Is accredited for beryllium analysis by the American Industrial Hygiene Association's Laboratory Accreditation Programs, LLC (AIHA-LAP, LLC), or

(ii) Is certified or accredited by a recognized laboratory quality assurance certifying or accrediting organization and demonstrates quality assurance for metal analysis, including beryllium, that is equivalent to AIHA-LAP, LLC accreditation for beryllium.

(2) The employer may use:

(i) Field or portable laboratories that are accredited by an AIHA-LAP, LLC or in an equivalent quality assurance program that addresses field or portable laboratory analyses of beryllium samples; and

(ii) Air exposure results below laboratory reporting limits.

(f) *Notification of monitoring results.*

(1) The employer must notify workers in the same work area of the exposure monitoring results within 10 working days after receipt of the results. Notifications of exposure monitoring results must be:

(i) In written or electronic format and posted in locations or in electronic systems that are readily accessible to the workers, but in a manner that does not identify an individual worker; and

(ii) For individuals that were sampled, the results must be provided in written or electronic format directly to the individual.

(2) If the monitoring results indicate that exposures are at or above the action level, the employer's notification of exposure monitoring results must include:

(i) A statement that exposures are at or above the specified level;

(ii) A description of the controls being implemented to address those exposures.

(3) If the monitoring results indicate that worker exposure is at or above the action level, the responsible employer must also notify the appropriate Head of DOE Field Element and the SOMD of

these results within 10 working days after receipt of the results.

#### **§ 850.25 Exposure reduction.**

The employer must establish a formal hazard prevention and abatement program in accordance with 10 CFR 851.22, *Hazard Prevention and Abatement*, to reduce exposures to below the action level.

#### **§ 850.26 Beryllium regulated areas.**

(a) Employers must establish a beryllium regulated area in facilities wherever the level of airborne beryllium is at or above the action level;

(b) Employers must:

(1) Demarcate beryllium regulated areas from the rest of the workplace in a manner that adequately alerts workers to the boundaries of such areas;

(2) Limit access to beryllium regulated areas to authorized persons; and

(3) Keep records of all individuals who enter beryllium regulated areas that include the name, date, time in and time out, and work activity.

#### **§ 850.27 Hygiene facilities and practices.**

(a) *General.* The employer must ensure that in beryllium regulated areas:

(1) Food or beverage and tobacco products are not consumed or used;

(2) Cosmetics are not applied, except in changing rooms or areas and shower facilities required under paragraphs (b) and (c) of this section; and

(3) Workers are prevented from exiting areas that contain beryllium with contamination on their bodies or their personal clothing.

(b) *Change rooms or areas.* The employer must:

(1) Provide separate rooms or areas for beryllium workers to change into, and store, personal clothing and clean protective clothing and equipment; and

(2) Ensure that changing rooms or areas being used to remove beryllium-contaminated clothing and protective equipment are kept under negative pressure or located so as to minimize dispersion of beryllium into clean areas.

(c) *Showers and hand washing facilities.* The employer must:

(1) Provide handwashing and shower facilities for beryllium workers who work in beryllium regulated areas; and

(2) Ensure that beryllium workers who work in beryllium regulated areas shower at the end of their work shifts.

(d) *Lunchroom facilities.* The employer must:

(1) Provide lunchroom facilities that are readily accessible to beryllium workers and in which the airborne concentration of beryllium is not at or above the action level.

(2) Ensure that beryllium workers do not enter lunchroom facilities with

protective clothing or equipment that has been used in a regulated area unless the surfaces have been cleaned by HEPA vacuuming or other method that removes beryllium without dispersing it.

(e) The change rooms or areas shower and handwashing facilities, and lunchroom facilities must comply with 29 CFR 1910.141, *Sanitation*.

#### **§ 850.28 Respiratory protection.**

(a) The employers must provide a respiratory protection in accordance with 10 CFR 851.23, *Safety and Health Standards*, and 10 CFR part 851, appendix A, section 6. *Industrial Hygiene*.

(b) [Reserved]

#### **§ 850.29 Protective clothing and equipment.**

(a) The employer must provide protective clothing and equipment to beryllium workers and ensure its appropriate use and maintenance by workers where dispersible forms of beryllium may contact workers' skin, enter openings in workers' skin, or contact workers' eyes including where:

(1) Exposure monitoring has established that the airborne concentration of beryllium is at or above the action level;

(2) Surface contamination levels measured or presumed prior to initiating work are at or above the level prescribed in § 850.30;

(3) Surface contamination levels results obtained to confirm housekeeping efforts are above the level prescribed in § 850.30; and

(4) Any worker requests the use of protective clothing and equipment for protection against airborne beryllium, regardless of the measured exposure level.

(b) Employers must comply with 29 CFR 1910.132, *Personal Protective Equipment General Requirements*, when workers use personal protective clothing and equipment.

(c) Employers must establish procedures for donning, doffing, handling, and storing protective clothing and equipment that:

(1) Prevent beryllium workers from exiting beryllium regulated areas with contamination on their bodies or clothing; and

(2) Include beryllium workers exchanging their personal clothing and footwear for protective clothing and footwear before entering beryllium regulated areas.

(d) Employers must ensure that no worker removes beryllium-contaminated protective clothing and equipment from beryllium regulated

areas except for workers authorized to launder, clean, maintain, or dispose of the clothing and equipment.

(e) Employers must prohibit the removal of beryllium from protective clothing and equipment by blowing, shaking, or other cleaning methods that may disperse beryllium into the air.

(f) Employers must ensure that protective clothing and equipment is cleaned, laundered, repaired, or replaced as needed to maintain effectiveness. Employers must:

(1) Ensure that beryllium-contaminated protective clothing and equipment when removed for laundering, cleaning, maintenance, or disposal is placed in containers that prevent the dispersion of beryllium particulate and that the container is labeled in accordance with § 850.39(b)(1); and

(2) Inform organizations that launder or clean DOE beryllium-contaminated clothing or equipment that exposure to beryllium is harmful, and that clothing and equipment should be laundered or cleaned in a manner prescribed by the informing employer to prevent the dispersion of beryllium particulates.

#### **§ 850.30 Housekeeping.**

(a) Where beryllium is present in operational areas of DOE facilities at or above the action level, the employer must conduct routine surface sampling to determine housekeeping conditions. Surfaces contaminated with beryllium dusts and waste must not exceed a removable contamination level of 3 µg/100cm<sup>2</sup> during non-operational periods. This sampling would not include the interior of installed closed systems such as enclosures, glove boxes, chambers, or ventilation systems.

(b) When cleaning floors and surfaces of removable beryllium, the employer must use a wet method, HEPA vacuuming, or other cleaning methods that avoid the dispersion of dust, such as wiping with sticky cloths. Compressed air or dry methods that may disperse beryllium particulates must not be used for such cleaning.

(c) The employer must use vacuum units that are equipped with HEPA filters, as defined in this part, to clean beryllium-contaminated surfaces, and change the filters as often as needed to maintain the effectiveness of the vacuum unit.

(d) The employer must ensure that the cleaning equipment that is used to clean beryllium-contaminated surfaces is labeled in accordance with § 850.39(b), controlled, and not used for non-hazardous materials.

#### **§ 850.31 Release and transfer criteria.**

(a) *Release and transfer*. Except where the beryllium is in normally inaccessible locations or embedded in hard-to-remove substances, prior to the release or transfer of equipment, items, or areas to areas that are not beryllium regulated areas, the employer must ensure that for formerly beryllium-contaminated equipment, items or areas the removable contamination level does not exceed the following:

(1) Surface level of beryllium is at or below 0.2 µg/100 cm<sup>2</sup>; or

(2) Concentration of beryllium in bulk material on the surface is lower than the concentration in soil at the point of release; or

(3) Airborne levels of beryllium in an enclosure of the smallest practical size surrounding the equipment or item, or in an isolating enclosure of the area do not exceed 0.01 µg/m<sup>3</sup>.

(b) *Release or transfer with inaccessible beryllium*. For the release from a beryllium regulated area of equipment, items, or areas that contain sources of beryllium in normally inaccessible locations or embedded in hard-to-remove substances, the employer must comply with paragraphs (a)(1) through (3) of this section for accessible beryllium, and the employer must ensure that:

(1) The equipment, item, or area is labeled in accordance with

§ 850.39(b)(2); and

(2) The release is conditioned on the recipient's commitment to implement controls that will prevent foreseeable beryllium exposure, considering the nature of the equipment or item or area and its future use.

(c) *Release or transfer with levels that exceed 0.2 µg/100 cm<sup>2</sup>*. For equipment, items, or areas that have removable beryllium above 0.2 µg/100 cm<sup>2</sup>; or that have beryllium in material on the surface at levels above the natural level in soil at the point of release, the employer must:

(1) Provide the recipient with a copy of this part;

(2) Condition the release on the recipient's commitment to control foreseeable beryllium exposures from the equipment, item, or area considering its future use;

(3) Label the equipment, item, or area in accordance with § 850.39(a) or (b)(1), as applicable;

(4) Place any such equipment or items in sealed, impermeable bags or containers, or have sealants applied that prevent the release of beryllium during handling and transportation; and

(5) Ensure that the beryllium that remains removable on the surfaces of areas is below 3.0 µg/100 cm<sup>2</sup>.

**§ 850.32 Waste disposal.**

(a) When disposing of beryllium waste, the employer must:

(1) Use sealed, impermeable bags, containers, or enclosures to prevent the release of beryllium dust during handling and transportation; and

(2) Label the bags, containers and enclosures for disposal according to § 850.39(b)(1).

(b) [Reserved]

**§ 850.33 Beryllium emergencies.**

(a) The employers must provide and ensure compliance with procedures for handling beryllium emergencies as they relate to decontamination and decommissioning operations and all other operations, that are in accordance with 10 CFR 851.23, *Safety and Health Standards*.

(b) [Reserved]

**§ 850.34 Medical surveillance.**

(a) *General.* Employers must establish and implement a medical surveillance program which is mandatory for beryllium workers and voluntary for the beryllium-associated workers.

Employers must:

(1) Designate a SOMD who is responsible for administering the medical surveillance program;

(2) Ensure that the medical evaluations and procedures required by this section are performed by, or under the supervision of, a licensed physician who is qualified to diagnose beryllium-induced medical conditions;

(3) Establish and maintain a list of all beryllium and beryllium-associated workers; and

(4) Provide the SOMD with the information needed to operate and administer the medical surveillance program, including:

(i) The list of workers established pursuant to paragraph (a)(3) of this section;

(ii) Hazard assessment and exposures monitoring data;

(iii) The identity and nature of activities that are covered under the CBDPP;

(iv) A description of the workers' duties as they pertain to exposures to levels of beryllium at or above the action level;

(v) Records of the workers' beryllium exposures;

(vi) A description of the personal and respiratory protective equipment used by the workers; and

(vii) A copy of this part.

(5) Ensure that the SOMD and beryllium or beryllium-associated workers complete the consent form in appendix A of this part for beryllium workers or appendix B of this part for

beryllium-associated workers, before performing any medical evaluations for beryllium or beryllium-associated workers.

(6) Notify beryllium-associated workers on an annual basis of their right to participate in the medical surveillance program. If the beryllium-associated worker declines at that time, he or she may elect to participate at any time during the year, but must notify the employer in writing of his or her intent to participate.

(b) *Medical evaluations and procedures.* Employers must provide the medical evaluations and procedures required by this section at no cost to the worker, without loss of pay, and at a time and place that is reasonable and convenient for the worker.

(1) *Baseline medical evaluations.* (i) Employers must provide baseline medical evaluations that are:

(A) Mandatory for beryllium workers; and

(B) Voluntary for beryllium-associated workers.

(ii) Baseline medical evaluations must include:

(A) A detailed medical and work history with emphasis on exposure or the potential for exposure to beryllium;

(B) A respiratory symptoms questionnaire;

(C) A physical examination, with special emphasis on the respiratory system, skin and eyes;

(D) A chest radiograph (posterior-anterior, 14 x 17 inches) or a standard digital chest radiographic image, interpreted by a NIOSH B-reader of pneumoconiosis or a board-certified radiologist, unless there is an existing baseline chest radiograph that may be used to meet this requirement;

(E) Spirometry consisting of forced vital capacity (FVC) and forced expiratory volume at 1 second (FEV<sub>1</sub>);

(F) Two peripheral blood BeLPTs; and

(G) Any other tests deemed appropriate by the SOMD for evaluating beryllium-induced medical conditions.

(iii) [Reserved]

(2) *Periodic medical evaluations.* (i) Employers must provide:

(A) An annual medical evaluation to beryllium workers;

(B) A medical evaluation every three years to beryllium-associated workers who voluntarily participate in the program; and

(C) A medical evaluation to a beryllium worker or a beryllium-associated worker who voluntarily participates in the program, and when the worker exhibits signs and symptoms of beryllium sensitization or chronic beryllium diseases if the SOMD determines that an evaluation is warranted.

(ii) The periodic medical evaluation must include the following:

(A) A chest radiograph (posterior-anterior, 14 x 17 inches), or a standard digital chest radiographic image, interpreted by a NIOSH B-reader of pneumoconiosis or a board-certified radiologist unless there is a chest radiograph obtained in the previous five years that may be used to meet this requirement.

(B) Updates to the worker's medical and work history with emphasis on exposures to levels of beryllium;

(C) A respiratory symptoms questionnaire;

(D) A physical examination, with special emphasis on the respiratory system, skin and eyes;

(E) Two peripheral blood Be-LPTs; and

(F) Any other tests deemed appropriate by the SOMD for evaluating beryllium-induced medical conditions.

(3) *Emergency evaluation.* The employer must provide a medical evaluation as soon as possible to any worker who may have been exposed to beryllium because of a beryllium emergency, as defined in this part. The medical evaluation must include the tests and examinations listed in paragraph (b)(2)(ii) of this section.

(4) *Exit medical evaluation.* (i) If a baseline or periodic evaluation has not been performed within the previous six months, employers must:

(A) Provide an exit medical evaluation to beryllium workers at the time of the worker's separation from employment; and

(B) Offer an exit medical evaluation to beryllium-associated workers who voluntarily participate in the medical surveillance program at the time of the worker's separation from employment.

(ii) The exit medical evaluation must include:

(A) A chest radiograph (posterior-anterior, 14 x 17 inches), or a standard digital chest radiographic image, interpreted by a NIOSH B-reader of pneumoconiosis or a board-certified radiologist unless there is a chest radiograph obtained in the previous five years that may be used to meet this requirement.

(B) Updates of the workers' medical and work history with emphasis on exposures to levels of beryllium;

(C) A respiratory symptoms questionnaire;

(D) A physical examination, with special emphasis on the respiratory system, skin and eyes;

(E) Two peripheral blood Be-LPTs; and

(F) Any other tests deemed appropriate by the SOMD for evaluating beryllium-induced medical conditions.

(c) [Reserved]

(d) *Written medical opinions and determinations.* The SOMD must provide a written, signed medical opinion and determination after receiving the results from the medical evaluations performed pursuant to paragraph (b) of this section.

(1) *Written medical opinion and determination for beryllium and beryllium-associated workers.* (i) Within 15 working days after receiving the results from the evaluations performed pursuant to paragraph (b)(1) through (3) of this section, the SOMD must provide the beryllium or beryllium-associated worker with:

(A) A written medical opinion containing the purpose and results of all medical tests or procedures;

(B) An explanation of any abnormal findings;

(C) The basis for the SOMD's medical opinion;

(D) Any determination of whether:

(1) In the case of a beryllium worker, temporary or permanent removal of the beryllium worker from beryllium exposure is warranted pursuant to § 850.36; or

(2) A medical restriction pursuant to 10 CFR part 851, appendix A, section 8(h) is appropriate for the worker.

(E) An opportunity to ask, and have answered, questions regarding the information provided.

(ii) The written medical opinion must take into account the findings, determinations and recommendations of physicians who have examined the worker and provided written results of such examination to the SOMD, provided the examining physician is qualified to diagnose beryllium-induced conditions.

(iii) The SOMD must obtain the beryllium or beryllium-associated worker's dated signature on a copy of the written opinion and include it in the worker's medical record. If the worker declines to sign the statement, then the SOMD must make a record of that fact, the date on which the information was provided, and that the worker declined to sign the statement.

(iv) Within 15 working days after receiving the results from an exit evaluation performed pursuant to § 850.34(b)(4), the SOMD must provide the worker with:

(A) A written medical opinion containing the purpose and results of all medical tests or procedures;

(B) An explanation of any abnormal findings;

(C) The basis for the SOMD's medical opinion; and

(D) An opportunity to ask, and have answered, questions regarding the information provided.

(2) *Written medical opinion and determination for the employer.* (i) Within 5 working days after delivering the written medical opinion pursuant to paragraph (d)(1)(i) of this section to the beryllium or beryllium-associated worker, the SOMD must provide the employer with a written medical opinion that includes:

(A) The diagnosis of the worker with BeS or CBD, or any other medical condition for which exposure to beryllium at or above the action level would be contraindicated.

(B) A determination of whether:

(1) In the case of a beryllium worker, temporary or permanent removal of the worker from beryllium exposure is warranted pursuant to § 850.36 of this part; or

(2) A medical restriction pursuant to 10 CFR part 851, appendix A, section 8(h) is appropriate for the worker; and

(C) A statement that the SOMD has clearly explained to the worker the results of the medical evaluations, including all test results and any medical condition related to beryllium exposure that requires further evaluations or treatment.

(ii) The SOMD's written medical opinion to the employer must not reveal specific records, findings, and diagnoses that are not related to beryllium-induced conditions or other medical conditions indicating the worker should not perform certain job tasks.

(iii) Within 5 working days after delivering the written medical opinion pursuant to paragraph (d)(1)(iv) of this section, for an exit evaluation performed pursuant to § 850.34(b)(4) of this part, the SOMD must provide the employer with the diagnosis of the worker's condition or indicating the worker should not perform certain job tasks.

(3) [Reserved]

(e) *Multiple physician review process.*

(1) The employer must establish a multiple physician review process for beryllium and beryllium-associated workers that allows for the review of initial medical findings, determinations, or recommendations from any medical evaluation conducted pursuant to paragraphs (b)(1) through (3) [*i.e.*, baseline, periodic or emergency evaluation] of this section.

(2) Within 15 working days after the employer receives the written medical determination pursuant to paragraph (d)(2) of this section, the employer must notify a beryllium or beryllium-associated worker in writing of the worker's right to elect the multiple physician review process or alternate physician review process pursuant to this section.

(3) The employer's participation in, and payment for, the multiple physician review process for a beryllium-associated worker is conditioned on the worker's participation in the medical surveillance program pursuant to paragraph (b) of this section.

(4) The beryllium or beryllium-associated worker must:

(i) Notify the employer in writing within 15 working days after receiving the employer's written notification pursuant to paragraph (e)(2) of this section, of the worker's intention to seek a second opinion on the results of any medical evaluation conducted pursuant to paragraphs (b)(1) through (3) of this section;

(ii) Identify in writing to the SOMD within 20 working days after delivering the notice pursuant to paragraph (e)(4)(i) of this section, a physician who is qualified to diagnose beryllium-induced medical conditions to:

(A) Review all findings, determinations, or recommendations of the initial physician;

(B) Conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review; and

(C) Provide the employer and the worker with a written medical opinion within 30 working days after completing the review pursuant to paragraphs (e)(4)(ii)(A) and (B).

(5) If the findings, determinations, or recommendations of the two physicians differ significantly, then the employer and the beryllium or beryllium-associated worker must make efforts to encourage and assist the two physicians to resolve the disagreement.

(6) If the two physicians are unable to resolve their disagreement, then the employer and the beryllium or beryllium-associated worker, through their respective physicians, must designate a third physician to:

(i) Review any findings, determinations, or recommendations of the other two physicians;

(ii) Conduct such examinations, consultations, laboratory tests, and consultations with the other two physicians as the third physician deems necessary to resolve the disagreement among them; and

(iii) Provide the employer and the beryllium or beryllium-associated worker with a written medical opinion within 30 working days after completing the review pursuant to paragraphs (e)(6)(i) and (ii) of this section.

(7) The SOMD's written medical opinion must be consistent with the findings, determinations, and recommendations of the third physician, unless the SOMD and the

beryllium or beryllium-associated worker reach an agreement that is consistent with the determinations of at least one of the other two remaining physicians.

(8) The employer must complete the multiple physician review process even in cases where the beryllium or beryllium-associated worker is laid off or his contract ends before the review process is complete, provided the worker:

(i) Elected the multiple physician review while he or she was a current worker and in accordance with the conditions set forth in paragraph (e)(4) of this section; and

(ii) Continues to participate in good faith in the multiple physician review process. If the worker's job is scheduled to end prior to the completion of the multiple physician review process, the employer may elect to place the worker on unpaid leave status until the review process is completed.

(9) The employer is not required to provide the multiple physician review process if the worker had not elected the process in accordance with the conditions set forth in paragraph (e)(4) of this section, before he or she was laid off or contract ended. In this case, the worker may still be eligible for medical screening through DOE's Former Worker Medical Screening Program;

(f) *Alternate physician review.* The employer and the beryllium or beryllium-associated worker, or the worker's designated representative, may agree on the use of an alternate form of physician opinion and recommendation in lieu of the multiple physician review process pursuant to paragraph (e) of this section, as long as the alternative is expeditious and adequately protects the worker.

(g) *Reporting.* (1) When reporting cases of CBD, employers must comply with the reporting requirements in 10 CFR 851.23(a)(2).

(2) When a worker is medically removed in accordance with § 850.36, employers must record the case on the applicable OSHA form.

(3) Employers must enter each medical removal case on the applicable OSHA form as either a case involving days away from work if the worker does not work during the removal period, or a case involving restricted work activity, if the employee continues to work, but in an area where there is no exposure to beryllium.

#### **§ 850.35 Medical restriction.**

(a) Medical restrictions must be conducted in accordance with 10 CFR part 851, appendix A, section 8(h).

(b) Within 15 working days after receiving the SOMD's written opinion pursuant to § 850.34(d)(2), that it is medically appropriate to restrict a worker, an employer must restrict a worker from a job that involves a beryllium activity.

(c) Employers must provide the medical removal benefits specified in § 850.36 of this part only to beryllium workers who are diagnosed with BeS or CBD.

(d) If the SOMD determines that a beryllium worker should not work with beryllium at or above the action level due to a diagnosis of BeS or CBD, the SOMD must recommend medical removal under § 850.36, not medical restriction.

#### **§ 850.36 Medical removal and benefits.**

(a) *Medical removal.* (1) The employer must medically remove a beryllium worker from exposure to beryllium at or above the action level, subject to the terms set forth in this section.

(2) Recommendations for medical removal of a beryllium worker from exposure to beryllium at or above the action level may be temporary or permanent, and shall be made by the SOMD in accordance with this section.

(3) The SOMD must recommend temporary removal of a beryllium worker from exposure to beryllium at or above the action level:

(i) Pending the outcome of the medical evaluations conducted pursuant to § 850.34(b), if the beryllium worker is showing signs or symptoms of BeS or CBD and the SOMD believes that further exposure to beryllium at or above the action level may be harmful to the worker's health; or

(ii) Pending the outcome of the multiple physician review process pursuant to § 850.34(e), or alternative physician review process pursuant to § 850.34(f), if the beryllium worker is showing signs or symptoms of BeS or CBD and the SOMD believes that further exposure to beryllium at or above the action level may be harmful to the worker's health.

(4) The SOMD must recommend permanent removal of a beryllium worker from exposure to beryllium at or above the action level if the SOMD makes a final medical determination that the worker should be permanently removed. The SOMD's determination to permanently remove a worker must be based on a diagnosis of BeS or CBD as defined in § 850.3 of this part.

(5) Within 15 working days after a final medical determination has been made, the SOMD must provide the employer with a notice recommending that the employer either:

(i) Return the temporarily removed beryllium worker to his previous job status, identifying any steps to be taken to protect the worker's health including any necessary work restriction pursuant to 10 CFR part 851, appendix A, section 8(h); or

(ii) Permanently remove the beryllium worker.

(6) The SOMD is not required to recommend temporary removal before recommending permanent removal. The SOMD may recommend permanent removal based on a medical evaluation which results in a determination that the worker has BeS or CBD.

(b) *Counseling before temporary or permanent medical removal and notification to the employer—(1) Counseling.* If the SOMD recommends that a beryllium worker should be temporarily or permanently removed, the SOMD must do the following when communicating the written medical opinion and determination to the worker pursuant to § 850.34(d)(1).

(i) Advise the beryllium worker diagnosed with or suspected of having BeS or CBD of the determination that medical removal is necessary to protect the worker's health, and specify that the SOMD is recommending either temporary or permanent removal from work that involves exposure to beryllium at or above the action level;

(ii) Provide the beryllium worker with a copy of this part, and any other information on the risks of continued exposure to beryllium at or above the action level, and the benefits of removal.

(2) *Notification to the Employer.* The SOMD, in communicating the written medical opinion and determination to the employer, must comply with § 850.34(d)(2). In the case of a final medical determination regarding permanent removal, the SOMD must provide the employer with a written notice recommending that the employer either:

(i) If the worker has been on temporary removal, return the temporarily removed beryllium worker to his previous job status if the SOMD determines that removal is no longer warranted; or

(ii) Permanently remove the beryllium worker; or

(iii) Medically restrict the worker pursuant to § 850.35.

(c) *Employer responsibility to remove worker.* (1) Within 15 working days after receiving the SOMD's written opinion pursuant to paragraph (b)(2) of this section stating that it is medically appropriate to remove the worker from jobs in areas that are at or above the action level or may potentially be at or above an action level, the employer

must remove a beryllium worker from such a job, regardless of whether, at the time of removal, a job is available into which the removed worker may be transferred.

(2) Prior to, or at the time of the removal, the employer must provide the beryllium worker with a formal written notice of removal that includes the start date of the removal period;

(3) When a beryllium worker is medically removed, the employer must transfer the removed worker to a comparable job, if such a job is available, and provide medical removal benefits in accordance with paragraphs (d)(1) of this section, for temporary removal or (d)(2) of this section, for permanent removal.

(4) The employer may not return a beryllium worker who has been medically removed to his or her former job status unless the SOMD determines in a written medical opinion that continued medical removal is no longer necessary to protect the worker's health.

(d) *Medical removal benefits*—(1) *Temporary removal benefits.* (i) When a beryllium worker has been temporarily removed from a job pursuant to paragraph (c) of this section, the employer must, consistent with any applicable collective bargaining agreement:

(A) Transfer the worker to a comparable job:

(1) Where beryllium exposures are below the action level; and

(2) For which the worker is qualified or can be trained for in 6 months or less.

(B) Maintain the worker's total normal earnings, seniority, and other rights and benefits as if the worker had not been removed, on each occasion that the worker is temporarily removed.

(ii) If there is no such job available for the beryllium worker meeting the requirements of (d)(1)(i)(A) of this section, the employer must continue to provide the worker's total normal earnings, and other benefits as if the worker had not been removed until:

(A) A comparable job becomes available, and the worker is placed in that job;

(B) The SOMD determines that the worker is not beryllium sensitized and does not have CBD and medical removal is ended;

(C) The worker is permanently medically removed from the job; or

(D) The term of the removal period has expired, as provided in (d)(1)(iii) of this section.

(iii) Each term of temporary removal must not exceed one year, and no term of temporary removal can immediately succeed a prior term of temporary

removal in order to extend the term beyond one year.

(iv) Periods of temporary medical removal must not be included in the permanent medical removal benefits period.

(2) *Permanent medical removal benefits.* (i) If a beryllium worker has been permanently removed from a job because of a beryllium-induced medical condition pursuant to paragraph (a)(4) of this section, the employer must consistent with any applicable collective bargaining agreement:

(A) Transfer the beryllium worker to a comparable job:

(1) Where beryllium exposures are below the action level, and

(2) For which the worker is qualified or can be trained within one year.

(B) If the beryllium worker cannot be transferred to a comparable job meeting the requirements of (d)(2)(i)(A), maintain the beryllium worker's total normal earnings as if the worker had not been permanently removed for a period of up to two years.

(3) *Additional Conditions of Temporary or Permanent Removal Benefits.* (i) For the purposes of this section, the requirement that an employer provide medical removal benefits is not intended to expand upon, restrict, or change any rights to a specific job classification or position under the terms of an applicable collective bargaining agreement.

(ii) During a temporary or permanent removal period, the employer must continue to provide total normal earnings and benefits as if the worker were not removed for the removal period designated by the SOMD.

(iii) Subject to paragraph (d)(3)(v) of this section, the employer must continue to provide the worker medical removal benefits throughout the term of the removal period, regardless of changes in the worker's job (*e.g.*, worker is laid off, or the worker's contract ends before the removal period ends) or because the worker cannot be transferred into a comparable job because the worker is too sick to work, provided that:

(A) If the worker is on temporary removal, the employer is not required to continue the worker benefits beyond the one-year period, as set forth in paragraph (d)(1) of this section.

(B) If the worker is on permanent removal, the employer is not required to continue the worker benefits beyond the two-year period, as set forth in paragraph (d)(2) of this section.

(iv) If a removed worker files a claim for workers' compensation payments for a beryllium-related disability, the employer must continue to provide

benefits pending disposition of the claim, but no longer than a period of two years. The employer must receive no credit for the workers' compensation payments received by the worker for treatment-related expenses.

(v) The employer's obligation to provide medical removal benefits to a removed worker is reduced to the extent that the worker receives compensation for earnings lost during the period of removal from a publicly- or employer-funded compensation program, or from employment with another employer made possible by virtue of the worker's removal.

(vi) The worker may also apply for compensation through the Energy Employee Occupational Illness Compensation Program, for any additional benefits beyond those provided in this section.

#### **§ 850.37 Medical consent.**

(a) In order to provide each beryllium and beryllium-associated worker with the information necessary to make an informed decision about consenting to a medical evaluation established in § 850.34, the employer must ensure that the SOMD has the worker sign and date the informed consent form in appendix A (for beryllium workers) or appendix B (for beryllium-associated workers) to this part.

(b) Employers must ensure all beryllium workers understand that testing is mandatory to transfer into or remain in a job involving beryllium activities at or above the action level. A beryllium worker who decides not to consent to the testing, will be removed from the beryllium activity and will not receive any of the medical removal benefits.

#### **§ 850.38 Training and counseling.**

(a) *Training.* (1) The employer must develop and implement a beryllium training program and ensure the participation of beryllium workers, beryllium-associated workers, and all other individuals who work at a site where beryllium activities are conducted.

(2) Beryllium workers' training must include:

(i) The contents of the CBDPP;

(ii) Potential health risks to beryllium workers' family members and others who may come in contact with beryllium on beryllium workers, beryllium workers' clothing, or other personal items as the result of a failure of beryllium control;

(iii) The benefits of medical evaluations for diagnosing BeS and CBD; and

(iv) The contents of this part.

(3) The training provided for beryllium-associated workers and other workers identified in paragraph (a)(1) of this section must consist of general awareness about beryllium hazards and controls and the benefits of medical evaluations for diagnosing BeS and CBD.

(4) The training required by this section must be provided before or at the time of initial assignment and at least every two years thereafter.

(5) Retraining must be provided when the employer has reason to believe that a beryllium worker lacks the proficiency, knowledge, or understanding needed to work safely with beryllium, including, at a minimum, the following situations:

(i) To address any new beryllium hazards resulting from a change to the beryllium inventory, activities, or controls about which the worker was not previously trained; or

(ii) When a worker's performance involving beryllium activities indicates the worker has not retained the requisite proficiency.

(b) *Counseling.* (1) The employer must develop and implement a counseling program to assist beryllium and beryllium-associated workers who are diagnosed by the SOMD as being sensitized to beryllium or having CBD.

(2) For beryllium workers, the counseling program must include communicating with the worker concerning:

(i) The medical surveillance program provisions and procedures;

(ii) Medical treatment options;

(iii) Medical, psychological, and career counseling;

(iv) Medical removal benefits;

(v) Administrative procedures and workers' rights under EEOICPA and other applicable compensation laws and regulations; and

(vi) The risk of continued exposure to levels of beryllium that are not at or above the action level and practices to limit exposures.

(3) For beryllium-associated workers, the counseling program must include communicating with the worker concerning:

(i) The medical surveillance program provisions and procedures;

(ii) Medical treatment options;

(iii) Medical, psychological, and career counseling; and

(iv) Application procedures under the EEOICPA and other applicable compensation laws and regulations.

#### **§ 850.39 Warning signs and labels.**

(a) *Warning signs.* The employer must post warning signs at each access point to a regulated area with the following information:

BERYLLIUM REGULATED AREA  
DANGER  
CANCER AND LUNG DISEASE HAZARD  
AUTHORIZED PERSONNEL ONLY

(b) *Warning labels.* The employer must affix warning labels to all bags, containers, equipment, or items that have beryllium material on the surface at levels that exceed 0.2 µg/100 cm<sup>2</sup> or that will be released and have beryllium material on the surface at levels above the level in soil at the point of release.

(1) Warning labels must contain the following information:

DANGER  
CONTAMINATED WITH BERYLLIUM  
DO NOT REMOVE DUST BY BLOWING OR  
SHAKING  
CANCER AND LUNG DISEASE HAZARD

(2) The employer must affix warning labels to equipment or items that contain sources of beryllium in normally inaccessible locations or embedded in hard-to-remove substances. These warning labels must contain the following information:

CAUTION  
CONTAINS BERYLLIUM IN INACCESSIBLE  
LOCATIONS OR EMBEDDED IN HARD-  
TO-REMOVE SUBSTANCES  
DO NOT RELEASE AIRBORNE BERYLLIUM  
DUST  
CANCER AND LUNG DISEASE HAZARD

#### **§ 850.40 Recordkeeping and use of information.**

(a) *Contractor employers must:*

(1) Establish and maintain records in accordance with 10 CFR part 851, *Worker Safety and Health Program*, for the records generated by their CBDPP and include records of beryllium medical surveillance and training;

(2) Maintain employees' medical records in accordance with DOE Systems of Records DOE-33, *Personnel Medical Record*;

(3) Maintain all records required by this part in current and accessible electronic systems; and

(4) Convey all record series required under this part to the appropriate Head of DOE Field Element or designee, if this part ceases to be applicable to the contractor.

(b) *Federal employers must:*

(1) Establish and maintain complete and accurate records of information generated by the CBDPP submitted by DOE offices, including beryllium inventory information, hazard assessments, and Federal employee exposure measurements, exposure controls, medical evaluations and training for operations or activities implemented by the DOE office;

(2) Maintain Federal employees' medical records in accordance with OPM/GOVT-10, *Employee Medical File*

*System Records for Federal Employees;* and

(3) Maintain all records required by this part in current and accessible electronic systems.

(c) Heads of DOE Field Elements and Cognizant Secretarial Officers must designate all record series as required under this part as agency records and ensure retention for a minimum of 75 years.

(d) *Contractor and Federal employers must:*

(1) Ensure the confidentiality of all personally identifiable information in work-related records generated under this part by ensuring that:

(i) All records that are transmitted to other parties are transmitted in compliance with the Privacy Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and their implementing regulations; and

(ii) Individual medical information generated by the CBDPP is:

(A) Either included as part of the worker's DOE site medical records and maintained by the SOMD or is maintained by another physician designated by the employer;

(B) Maintained as confidential medical records separate from other records; and

(C) Used or disclosed by the employer only in conformance with any applicable requirements imposed by the Americans with Disabilities Act of 1990 and any other applicable law and regulation.

(2) Maintain all records generated as required by this rule, in current and accessible electronic systems, which include the ability to readily retrieve data in a format that maintains confidentiality.

(3) Transmit all records generated as required by this rule to the Office of Environment, Health, Safety and Security upon request.

(4) Semi-annually transmit to the Office of Environment, Health, Safety and Security an electronic registry of beryllium and beryllium-associated workers that protects the confidentiality, and the registry must include, a unique identifier for each individual, date of birth, gender, site job history, medical screening test results, exposure measurements, surface contamination levels, and results of referrals for specialized medical evaluations. This information should comply with the format for the Beryllium Registry.

#### **§ 850.41 Performance feedback.**

(a) The employer must conduct semi-annual analyses and assessments of:

(1) Monitoring results;

- (2) Hazard assessments;  
 (3) Medical surveillance; and  
 (4) Exposure reduction efforts.  
 (b) The assessments must identify

any:

(1) Individuals at risk for beryllium-induced medical conditions and working conditions that may be contributing to that risk; and

(2) Need for additional exposure controls.

(c) The employer must notify, and make the assessments available to the appropriate Head of DOE Field Element, line managers, work planners, worker protection staff, medical staff, workers, and labor organizations representing workers performing beryllium activities.

### Appendix A to Part 850—Beryllium Worker Chronic Beryllium Disease Prevention Program Consent Form (Mandatory)

#### Part A: Consent

Consistent with and subject to the provisions of 10 CFR part 850, *Chronic Beryllium Disease Prevention Program*, I, \_\_\_\_\_, understand the information the Site Occupational Medical Director (SOMD) explained and discussed with me about the Beryllium-Induced Lymphocyte Proliferation Test (BeLPT), on cells obtained from peripheral blood, and the other medical tests, as specified below. I have had the opportunity to ask and have answered any questions that I may have had concerning these tests and my questions have been adequately answered.

I understand that the beryllium worker medical surveillance program is for jobs in which exposure to levels of beryllium may be at or above the action level. I understand that it is mandatory for me to participate in this medical surveillance program.

I understand the tests are confidential, but not anonymous. If the results of any test suggest a health problem, I understand the examining physician will discuss the matter with me, whether or not the result is related to my work with beryllium. I understand my employer will be notified of my diagnosis *only* if I have beryllium sensitization (BeS), chronic beryllium disease (CBD), or another condition indicating that I should not perform certain job tasks. My employer will not receive the results or diagnoses of any health condition not related to beryllium exposure and my ability to perform my job tasks safely.

For test or examination results pertaining to BeS or CBD, I understand I will have the right to seek a second medical opinion from a physician who is qualified to diagnose beryllium-induced medical conditions. My employer will condition its participation and payment for a second opinion on my informing my employer of my intent to seek a second opinion within 15 working days after receiving the employer's written notification of my right to elect the multiple physician review process or the alternate physician review process.

I understand if the results of one or more of these tests suggest I have a health problem

that is related to beryllium or for which exposure to beryllium is contraindicated, additional examinations may be recommended. If I am diagnosed with a condition (other than BeS or CBD) for which exposure to beryllium would be contraindicated, the SOMD may recommend that I be medically restricted from working jobs where exposure to beryllium is at or above the action level. If the tests reveal I have CBD or I am sensitized to beryllium, the SOMD will recommend that I be removed from working in beryllium jobs where exposure to beryllium may be at or above the action level and my employer will remove me from such jobs.

I understand that if I am temporarily removed from a job where exposure to beryllium may be at or above the action level, I may be transferred to another job for which I am qualified (or for which I can be trained within six months), pending the outcome of the medical evaluations, where my beryllium exposures will in no case be at or above the action level, and I will continue to receive my total normal earnings, for up to one year from the date on each occasion that I am temporarily removed, regardless of whether I am transferred to another job.

I understand that if I am permanently removed from a job where exposure to beryllium may be at or above the action level due to a diagnosis of BeS or CBD, I may be transferred to another job for which I am qualified (or for which I can be trained within one year) where my beryllium exposures will in no case be at or above the action level, and I will continue to receive my total normal earnings, for up to two years, regardless of whether I am transferred to another job.

I understand that if I apply for another job or for insurance, there is a possibility that I may be required to release my medical records to a future employer or an insurance company.

I understand my employer will maintain all medical information separate from my personnel files, treat them as confidential medical records, and use or disclose them only as provided by the Americans with Disabilities Act of 1990, the Privacy Act of 1974, the Health Insurance Portability and Accountability Act of 1996, or as required by a court order or under other law.

I understand the results of my medical tests for health problems related to exposure to beryllium will be included in the Beryllium Registry maintained by DOE and that a unique identifier will be used to maintain the confidentiality of my medical information. Personal identifiers will not be included in any reports generated from the Beryllium Registry. I understand that the results of my test and examinations may be published in reports or presented at meetings, but I will not be identified.

\_\_\_\_\_  
 Signature of Employee

Date \_\_\_\_\_

#### Part B: Medical Evaluation Consent

I, \_\_\_\_\_, consent to the following medical evaluations:

/ /Physical examination concentrating on my respiratory system, skin and eyes

/ /Chest X-ray or a standard digital chest radiographic image  
 / /Spirometry (a breathing test)  
 / /Two BeLPTs on peripheral blood  
 / /Other test(s). Specify: \_\_\_\_\_

\_\_\_\_\_  
 Signature of Employee

Date \_\_\_\_\_

I have explained and discussed any questions the employee asked concerning the medical surveillance program, BeLPT (on peripheral blood), physical examination, and other medical tests as well as the implications of those tests.

Examining Physician:

Printed Name: \_\_\_\_\_

Signature of Examining Physician: \_\_\_\_\_

Date: \_\_\_\_\_

#### Part C: Examining Physician Review of the Medical Evaluation Results

I have explained and discussed with, \_\_\_\_\_, the results of the medical evaluations, including all test results and any medical condition related to beryllium exposure that should receive further evaluations or treatment.

Examining Physician:

Printed Name: \_\_\_\_\_

Signature of Examining Physician: \_\_\_\_\_

Date: \_\_\_\_\_

#### DOE Form No. 440.1X (Revised X, 20XX)

### Appendix B to Part 850—Beryllium-Associated Worker Chronic Beryllium Disease Prevention Program Consent Form (Mandatory)

#### Part A: Consent

Consistent with and subject to the provisions of 10 CFR part 850, *Chronic Beryllium Disease Prevention Program*, I, \_\_\_\_\_, understand the information the Site Occupational Medical Director (SOMD) explained and discussed with me about the Beryllium-Induced Lymphocyte Proliferation Test (BeLPT), on cells obtained from peripheral blood and the other medical tests, as specified below. I have had the opportunity to ask and have answered any questions that I may have had concerning these tests and my questions have been adequately answered.

I understand this medical surveillance program is voluntary, and I can withdraw at any time + from all or any part of the program. I understand the tests are confidential, but not anonymous. If the results of any test suggest a health problem, I understand the examining physician will discuss the matter with me, whether or not the result is related to beryllium. I understand my employer will be notified of my diagnosis *only* if I have beryllium sensitization (BeS), chronic beryllium disease (CBD), or another condition indicating that I should not perform certain job tasks. My employer will not receive the results or diagnoses of any health condition not related to my ability to perform my job tasks safely.

I understand I will have the right to seek a second medical opinion from a physician who is qualified to diagnose beryllium-induced medical conditions. My employer

will condition its participation and payment for a second opinion on my informing my employer of my intent to seek a second opinion within 15 working days after receiving the employer's written notification of my right to elect the multiple physician review process or the alternate physician review process, and provided I continue to participate in the medical surveillance program.

I understand that, if the results of one or more of these tests suggest I have a health problem related to beryllium, additional examinations may be recommended. If I am diagnosed with a condition for which exposure to beryllium would be contraindicated, the SOMD may recommend that I be medically restricted from working in jobs where exposure to airborne beryllium is at or above the action level.

I understand that if I apply for another job or for insurance, there is a possibility that I may be required to release my medical records to a future employer or an insurance company.

I understand my employer will maintain all medical information separate from my personnel files, treat them as confidential medical records, and use or disclose them only as provided by the Americans with

Disabilities Act of 1990, the Privacy Act of 1974, the Health Insurance Portability and Accountability Act of 1996, or as required by a court order or under other law.

I understand the results of my medical tests for health problems related to exposure to beryllium will be included in the Beryllium Registry maintained by DOE and that a unique identifier will be used to maintain the confidentiality of my medical information. Personal identifiers will not be included in any reports generated from the Beryllium Registry. I understand that the results of my test and examinations may be published in reports or presented at meetings, but I will not be identified.

I, \_\_\_\_\_, consent to participating in the medical surveillance program.

#### Part B: Medical Evaluation Consent

I, \_\_\_\_\_, consent to the following medical evaluations:

- / /Physical examination concentrating on my respiratory system, skin and eyes
  - / /Chest X-ray or a standard digital chest radiographic image
  - / /Spirometry (a breathing test)
  - / /Two BeLPTs on peripheral blood
  - / /Other test(s). Specify: \_\_\_\_\_
- Signature of Employee \_\_\_\_\_

Date \_\_\_\_\_

I have explained and discussed any questions the employee asked concerning the medical surveillance program, BeLPT (on peripheral blood), physical examination, and other medical tests as well as the implications of those tests.

Examining Physician: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Signature of Examining Physician: \_\_\_\_\_

Date: \_\_\_\_\_

#### Part C: Examining Physician Review of the Medical Evaluation Results

I have explained and discussed with, \_\_\_\_\_, the results of the medical evaluations, including all test results and any medical condition related to beryllium exposure that should receive further evaluations or treatment.

Examining Physician: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Signature of Examining Physician: \_\_\_\_\_

Date: \_\_\_\_\_

#### DOE Form No. 440.1X (Dated X, 20XX)

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