DEPARTMENT OF ENERGY

10 CFR Part 850

[Docket No. EH–RM–98–BRYLM]

RIN 1901–AA75

Chronic Beryllium Disease Prevention Program

AGENCY: Office of Environment, Safety and Health, Department of Energy.

ACTION: Notice of proposed rulemaking and public hearings.

SUMMARY: The Department of Energy (DOE or the Department) is proposing regulations to establish a chronic beryllium disease prevention program (CBDPP) to reduce the number of workers currently exposed to beryllium in the course of their employment with DOE or its contractors, minimize the levels of and potential for exposure to beryllium, and establish medical surveillance requirements to ensure early detection and treatment of disease. The proposed rule would be applicable to DOE Federal and contractor employees and subcontractors during the performance of beryllium work at DOE facilities. This action would codify the interim program requirements currently prescribed in DOE directives and protect the health and safety of workers.

DATES: The comment period for this proposed rule will end on March 9, 1999. Public hearings will be held on: February 3, 1999, in Oak Ridge, TN, from 9:00 a.m. to 1:00 p.m. and 6:00 p.m. to 9:00 p.m.; February 9, 1999, in Golden, CO (Denver), from 9:00 a.m. to 1:00 p.m. and 6:00 p.m. to 9:00 p.m.; and February 11, 1999, in Washington, DC, from 9:00 a.m. to 1:00 p.m.

Requests to speak at any of the hearings should be phoned in to Andi Kasarsky, 202–586–3012, by February 1, 1999, for the Oak Ridge, TN, hearing; February 5, 1999, for the Golden, CO, hearing; and February 10, 1999, for the Washington, DC, hearing. Each presentation is limited to 10 minutes.

ADDRESSES: Written comments (ten copies) should be addressed to: Jacqueline D. Rogers, U.S. Department of Energy, Office of Environment, Safety and Health, EH–51, Docket Number EH–RM–98–BRYLM, 1000 Independence Avenue, SW, Washington, D.C. 20585. Where possible, commenters should identify the specific section to which they are responding.

Copies of the public hearing transcripts, written comments received, technical reference materials referred to in this notice, and any other docket material may be reviewed and copied at the DOE Freedom of Information Reading Room, Room 1E–190, 1000 Independence Avenue, SW, Washington, DC 20585 between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays. The docket file material for this rulemaking will be filed under ''EH–RM–98–BRYLM.'' In addition, related prerulemaking docket material is filed under ''BERYLLIUM STANDARD.'' This material may also be reviewed and copied at the DOE Freedom of Information Reading Room at the address noted previously. The technical material from the BERYLLIUM STANDARD docket file may also be reviewed at the DOE Rocky Flats Freedom of Information Reading Room and the DOE Oak Ridge Public Reading Room.

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

Oak Ridge, TN: The American Museum of Science and Energy, 300 South Tulane Avenue, Auditorium, Oak Ridge, TN 37830

Golden, CO (Denver): National Renewable Energy Laboratory, Visitor Center, Auditorium, 15013 Denver West Parkway, Golden, CO 80401 (I–70, Exit 263, right at top of exit ramp if coming from Denver, left at stop sign, building on right)

Washington, DC: U.S. Department of Energy, Room 1E–245 (first floor, E corridor), 1000 Independence Avenue, SW, Washington, DC 20585

For more information concerning public participation in this rulemaking proceeding, see Section VIII of this notice (Public Comment Procedures).

FOR FURTHER INFORMATION CONTACT: Jacqueline D. Rogers, U.S. Department of Energy, Office of Environment, Safety and Health, EH–51, 1000 Independence Avenue SW, Washington, DC 20585, 301–903–5684 or Edward LeDuc, U.S. Department of Energy, Office of General Counsel for Environment, 1000 Independence Avenue SW, Washington, DC 20585, 202–586–6947.

For information concerning the public hearings, requests to speak at the hearings, submittal of written comments, or to obtain copies of materials referenced in this notice, contact: Andi Kasarsky, 202–586–3012.

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I. Overview

The 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.

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

As of June 1998, 110 workers have been diagnosed with CBD, and another 232 workers have become sensitized to beryllium from among the 8,951 current and former DOE Federal and contractor workers who were screened for the disease. DOE anticipates an increase in the number of workers who may be exposed to beryllium as the Department moves forward with deactivating and decommissioning former nuclear weapons production facilities.

The current worker protection permissible exposure limit (PEL) of 2 $\mu g/m^3$, measured as an 8-hour, time-weighted average (TWA), was adopted by the Occupational Safety and Health Administration (OSHA) as codified in 29 CFR 1910.1000 Tables Z–1, Z–2 and Z–3 in 1971 by reference to existing

national consensus standards. This limit of 2 μg/m³ was set by DOE and its predecessor agencies, the Energy Research and Development Administration (ERDA) and the Atomic Energy Commission (AEC), for application at their facilities in 1949. Between the 1970s and 1984, there was a significant reduction in the incidence rate of the disease. This, coupled with the long latency period for the disease, led to the assumption that CBD was occurring only among workers who had been exposed to high levels of beryllium decades earlier (e.g., in the 1940's). However, DOE medical surveillance programs are discovering cases of CBD among workers who were first exposed after 1970, when DOE facilities were expected to maintain worker exposure to beryllium at levels below the OSHA PEL.

The number of confirmed cases of CBD, data suggesting the occurrence of CBD among workers with low-level exposures, and the expected future increase in the number of workers potentially exposed to beryllium all indicate a need for more aggressive workplace controls to minimize worker exposure to beryllium in the DOE complex. Accordingly, DOE has developed this notice of proposed rulemaking (NOPR) to establish a performance-based approach to protecting DOE Federal and contractor employees from the adverse health effects resulting from occupational exposure to beryllium and preventing cases of CBD resulting from DOE operations. DOE proposes to accomplish this goal through the implementation of a comprehensive chronic beryllium disease prevention program (CBDPP), which is designed to reduce the number of workers exposed, minimize the levels of beryllium exposure and the potential for beryllium exposure, and establish medical surveillance protocols to ensure early detection of disease. Because the occupational health community, including OSHA and the American Conference of Governmental Industrial Hygienists (ACGIH), does not at this time have sufficient exposure and health effects data to establish a new 8-hour TWA exposure limit for beryllium exposure, DOE is instead including in the proposed regulation a short-term exposure limit (STEL) of 10 μg/m³ for small-scale, short-duration operations, an 8-hour TWA action level of 0.5 μg/m³ for triggering certain precautions and control measures, and an exposure reduction and minimization requirement that will encourage contractors to reduce potential exposures to the action level or below. This combined approach should provide a reasonably safe and achievable added layer of protection to beryllium workers in view of data, which suggest that CBD or beryllium sensitization has occurred at exposures of 2 μg/m³ or less, and in view of the related scientific uncertainty with respect to the adequacy of the existing PEL. In addition to these immediate efforts, DOE intends to adopt a revised OSHA PEL for beryllium if OSHA rulemaking efforts for beryllium conclude that a new PEL for beryllium is appropriate. DOE acknowledges that Great Britain, which also employs a 2 μg/m³ 8-hour TWA PEL, has experienced a minimal number of CBD cases among its exposed work force. The Department recognizes that the difference between DOE's and Great Britain's experiences with the occurrence of CBD may be indicative of the use of more stringent work practice controls at Great Britain's facilities. DOE believes, however, that the fortified approach set forth in the proposed regulation will work towards eradicating CBD within the Department.

DOE contractors are already required, under DOE Order 440.1A, Worker Protection Management for DOE Federal and Contractor Employees, to have general worker protection programs. DOE Order 440.1A contains a set of minimum general requirements that establish the framework for the worker protection program. The proposed rule would enhance and supplement these existing programs with hazard-specific provisions to manage and control beryllium exposure hazards.

This proposed CBDPP rulemaking initiative has been preceded by 2 years of information-gathering and data analysis by the Department. In 1996, the Department surveyed its contractors to characterize the extent of beryllium usage, the types of tasks involving beryllium usage, the controls in place for each task, the estimated number of workers exposed during each task, and the estimated exposure levels associated with each task.

In summary, this survey found that between 1994 and 1996, 10 of the 15 DOE sites surveyed performed 64 different operations or processes that could expose workers to beryllium. The surveyed DOE sites estimated that between 518 and 530 workers in 58 different job categories were potentially exposed to beryllium in the performance of these 64 operations or processes. Where available, reported 8-hour TWA exposure data (personal breathing zone monitoring results) for these workers ranged from nondetectable to 25 μg/m³. Most of these exposure levels were reported to be below the 2 μg/m³ 8-hour TWA PEL. To control worker exposures in the affected processes or operations, the surveyed sites reported the use of various engineering and administrative controls, including ventilation hoods, glove boxes, wet machining methods, high-efficiency particulate air (HEPA) vacuums, regulated areas, action levels and administrative warning levels, and personal protective equipment. Copies of this survey are available for review and copying at the DOE headquarters, Rocky Flats, and Oak Ridge Public Reading Rooms (see the **ADDRESSES** section of this NOPR for addresses and details) as part of the prerulemaking docket filed under BERYLLIUM STANDARD.

To supplement the data obtained from the 1996 survey, the Department published a **Federal Register** notice on December 30, 1996, requesting scientific data, information, and views relevant to a DOE beryllium health standard (61 FR 68725). The survey and **Federal Register** notice were followed by two Beryllium Public Forums, held in Albuquerque, New Mexico, and Oak Ridge, Tennessee, in January 1997. Responses to the **Federal Register** notice and the proceedings of the public forums are also available in the ''BERYLLIUM STANDARD'' docket file.

Acting on the information compiled from these various sources, and in view of the time needed to promulgate a rule, former Secretary of Energy Peña directed the Office of Environment, Safety and Health to publish a new DOE policy to protect the workforce while the Department moved forward with its rulemaking process. DOE Notice 440.1, Interim Chronic Beryllium Disease Prevention Program, was signed by former Secretary Peña and issued on July 15, 1997. The Department decided to issue the interim Notice to direct immediate action for the protection of workers while the rulemaking efforts continued. This interim Notice established a CBDPP that enhanced and supplemented worker protection programs already required by DOE Order 440.1A with hazard-specific provisions that are designed to manage and control beryllium exposure hazards in the DOE workplace.

Because of the complexity and significance of issues regarding the development of a DOE health standard for beryllium, former Secretary Peña also established the Beryllium Rule Advisory Committee (BRAC) in June 1997 to advise the Department on issues pertinent to the proposed rulemaking activity. The BRAC, which consisted of a diverse set of stakeholders and

recognized experts from DOE, other Federal agencies, industry, labor, medicine, and academia, generated a set of recommendations for consideration in the development of a CBDPP rule.[1]

DOE used the BRAC recommendations and the lessons learned in the implementation of DOE Notice 440.1 to develop this NOPR. Consistent with the Department's worker protection philosophy and the BRAC recommendations, the objectives of this proposed rule are to: (1) Minimize the number of workers exposed to beryllium; (2) minimize the levels of beryllium exposure and the potential for beryllium exposure; (3) establish medical surveillance protocols to ensure early detection of CBD; and (4) assist affected workers who are dealing with beryllium health effects. In addition, the Department intends to collect and analyze as appropriate the resulting exposure and health data as part of its ongoing beryllium-related research efforts to ensure the protection of workers' health. DOE will consider the desirability of amendments to its regulations as additional information and feedback are collected.

This proposed rule is not being promulgated as a nuclear safety requirement as defined in 10 CFR part 820, Procedural Rules for Nuclear Activities. Any radiological implications of the two radioisotopic forms of beryllium would be addressed under the provisions of 10 CFR part 835, Occupational Radiation Protection.

II. Legal Authority and Relationship to Other Regulatory Programs

The Department of Energy has broad authority as provided by the Atomic Energy Act, 42 U.S.C. 2201(i)(3) and (p) to develop generally applicable policies covering all aspects of defense nuclear facilities, including protection of the health of workers. Under the Atomic Energy Act, DOE may impose requirements on its contractors either by regulation, or by administrative directive (orders and notices) that are made binding through incorporation into DOE contracts.

DOE contractors currently are required by DOE Order 440.1A, Worker Protection Management for DOE Federal and Contractor Employees, to have general worker protection programs. Additionally, on July 15, 1997, former Secretary Peña issued DOE Notice 440.1, Interim Chronic Beryllium Disease Prevention Program, to supplement the general worker protection programs with provisions specifically aimed at the hazards of beryllium in the DOE work place. Implementation of the interim Notice depended upon negotiation with DOE contractors to include compliance with Notice 440.1 as a term of their contracts, or their agreement voluntarily to comply.

As discussed in the Overview section of this preamble, former Secretary Pẽna established a Beryllium Rule Advisory Committee in June of 1997 to assist DOE to develop a rule to establish permanent Chronic Beryllium Disease Prevention Program provisions that would apply to all covered DOE contractors and employees. The Department's decision to use rulemaking to establish a CBDPP requirement is based on the need for consistency in the implementation of particular CBDPP requirements and a desire to give all potentially affected persons and institutions a meaningful opportunity to provide information and views on the proposed program. Without a DOE rule, DOE contractors would be obligated to bargain about such provisions with the organizations representing the contractors' employees for purposes of collective bargaining. That approach would likely produce inconsistent outcomes in areas such as worker exposure monitoring and medical surveillance. DOE believes a rule or regulation would result in more uniform implementation across the DOE complex and, thus, improve worker protection and the quality of information generated regarding the health effects of exposure to beryllium.

DOE recognizes that it may be necessary in the future to amend its CBDPP regulations if other Federal agencies promulgate rules governing worker exposure to beryllium. Although DOE facilities currently are exempt from regulation by the Occupational Safety and Health Administration (OSHA), DOE routinely adopts OSHA health standards, as a matter of policy. DOE is aware that OSHA plans to initiate a rulemaking to examine, and possibly revise, their current health standard for beryllium. Additionally, DOE is working with the Congress on plans to eventually transfer responsibility for regulating health and safety at DOE facilities to another Federal agency (probably OSHA). In light of the uncertain timing of future actions by OSHA or another external regulator, and the present and potential risk to workers at DOE facilities from beryllium exposure, DOE has decided to proceed with this rulemaking now. However, considering OSHA's decision to examine the health standard for beryllium, DOE proposes (in proposed section 850.22, Exposure Limits) to express the permissible exposure limit (PEL) as 2 ug/m^3 calculated as an 8-hour TWA exposure, as measured in the worker's breathing zone, or any more stringent limit that OSHA may promulgate pursuant to section 4(b)(1) of the OSH Act. This language would permit DOE to continue its policy of requiring compliance with OSHA health standards without conducting notice and comment rulemaking to amend these regulations.

III. Chemical Identification and Use

Beryllium (atomic number 4) is a silver-gray metal with a density of 1.85 g/cm^3 and a high stiffness. Beryllium is found in the earth's surface in about 45 minerals. Bertrandite ($Be_4Si_2O_7[OH]_2$) is the major source of beryllium; other important beryllium-containing materials include beryl ($3BeO.Al_2O_36.SiO_2$), chrysoberyl ($BeAl_2O_4$), and phenacite ($BeSiO_4$). The alloying property of beryllium confers on metals specific properties of resistance to corrosion, vibration, and shock; beryllium can also improve alloy hardness and ductility. For example, the addition of only 2 percent or less beryllium to copper forms an alloy with high strength and hardness. Few other copper alloys are capable of this type of strengthening.

Because of their strength, formability, thermal and electrical conductivities, magnetic transparency, and corrosion resistance, beryllium alloys (especially beryllium-copper) are used extensively in industries such as automotive, electronics, aerospace, and defense. In electronics, for example, beryllia ceramics provide good electrical insulators with superior thermal conductivity to remove heat. Beryllium's low neutron absorption, high neutron scattering characteristics, and ability to multiply neutrons have led to its use in experimental nuclear reactors and nuclear weapons.

IV. Health Effects

A. Introduction

Chronic beryllium disease (CBD) is a disease of the lungs. CBD is caused by the body's reaction to inhaled beryllium dust or fumes. The time in which an individual may develop CBD may vary from several months to many years after exposure to beryllium. The body's reaction to beryllium is often called ''sensitization.'' Sensitization means that beryllium specific lymphocyte

[1] BRAC recommendations were made by individual members and groups of members, not by majority vote. They were generated by the facilitated process used during the meetings and were not adopted by the committee as consensus opinions. For convenience of reference these recommendations are referred to as the ''BRAC recommendations.''

proliferation testing has demonstrated that an individual is able to mount a cell mediated immune response to beryllium. Data suggest that even brief or small exposures can lead to CBD. Beryllium is also classified as a human carcinogen (cancer-causing agent) by the International Agency for Research on Cancer (IARC) and by the American Conference of Governmental Industrial Hygienists (ACGIH).

Symptoms of CBD include one or more of the following: cough, difficulty breathing, fever, night sweats, fatigue, weight loss, or appetite loss. On physical examination, a doctor may find signs of CBD, such as changes in lung sounds, fever, and weight loss. A radiograph (X-ray) of the lungs may show many small scars. There may also be an abnormal breathing test, pulmonary function tests, and a blood test, the beryllium-induced lymphocyte proliferation test (Be-LPT). Examination of lung tissue under the microscope may show granulomas, which are signs of damage due to the body's reaction to beryllium. CBD may be confused with other lung diseases, especially sarcoidosis.

Patients with CBD can be treated with medication and, in more serious cases, with oxygen. Patients who are sensitized to beryllium do not need medical treatment, but they must be checked regularly for signs or symptoms of CBD. CBD cannot be cured. Severe CBD may be very disabling.

B. Chronic Beryllium Disease

Chronic beryllium disease is a granulomatous disease affecting primarily the lungs, although systemic involvement may also occur. Exposure occurs via inhalation of beryllium metal or insoluble beryllium salts. Beryllium is a hapten (a substance that provokes an immune response only when combined with another substance, generally a protein) that binds to peptides on mucosal surfaces. In susceptible individuals the beryllium-peptide complex initiates an immune response, which may progress ultimately to granuloma formation in the pulmonary interstitium. Data have suggested that CBD occurs at relatively low exposure levels and, in some cases, after relatively brief durations of exposure. The typical latency period is 5 to 10 years, but it varies from several months to 30 years or more.

Frequently reported symptoms include dyspnea on exertion, cough, chest pain and, less frequently, arthralgias, fatigue, and weight loss. Physical examination may be normal or it may reveal rales, cyanosis, digital clubbing, or lymphadenopathy. In advanced cases, there may be manifestations of right-sided heart failure, including cor pulmonale.

The peripheral blood beryllium-induced lymphocyte proliferation test (Be-LPT) is used to detect *in vitro* the immunologic response of human lymphocytes to beryllium. A positive Be-LPT indicates sensitization to beryllium-containing antigens. A diagnostic evaluation by means of bronchoscopy with bronchoalveolar lavage (BAL) and transbronchial biopsy is indicated. The presence of granulomata in the lung in a patient with a positive lung Be-LPT is diagnostic of CBD. In the absence of granulomata or other clinical evidence of CBD, individuals with positive Be-LPTs are classified as sensitized to beryllium.

The rate of progression from sensitization to disease is unknown. Once sensitization has occurred, it is medically prudent to prevent additional exposure to beryllium. However, this measure has not been shown to prevent or delay the progression of sensitization to CBD.

The clinical course of CBD is highly variable. Some individuals deteriorate rapidly; most experience long, gradual deteriorations. Treatment consists of oral corticosteroid therapy. Individuals with impaired respiratory gas exchange may require continuous oxygen administration.

Individuals sensitized to beryllium are asymptomatic and not disabled. Individuals with CBD have clinical illness varying from mild to severe. In severe cases, the affected individuals may be permanently and totally disabled. Mortality directly attributable to CBD and its complications is estimated to be 30 percent (ref.1).[2] The mortality estimate of 30% is based upon historical data reflecting both the higher levels of exposure that occurred in the workplace prior to regulation of workplace exposure in the late 1940s and a tracking of the medical history of subjects of CBD over several decades. DOE's more recent experience suggests a lower mortality rate of 3% for CBD cases.

C. Beryllium Exposures at DOE Operations

Personal monitoring of occupational exposures to beryllium was not widely adopted at DOE sites until the 1980s. Prior to the 1980s many sites relied on area monitoring to assess occupational exposures to beryllium. However, these have been shown to significantly underestimate actual exposure levels. Since 1984, personal sampling data have provided more precise information on occupational exposure to beryllium at DOE sites.

Available personal sampling data provides a clear indication of the low levels of beryllium exposure which can be achieved in both fabrication and machining operations and decommissioning and decontamination projects when effective control strategies are implemented. Most beryllium fabrication and machining operations at DOE to date have been at the Rocky Flats facility and at the Y–12 plant in Oak Ridge. Over time, engineering improvements and advanced control strategies have significantly reduced occupational beryllium exposure levels in these operations.

Since 1980, and continuing through 1996, about 1600 personal samples have been collected at the Oak Ridge Y–12 Plant (Table 1). These samples were taken at several different Y–12 operations with a bias toward sampling those jobs where exposure potential was greatest or where previous monitoring results were high. Despite this bias, over two thirds of sample results were below the limit of detection of 0.1 μg/m^3 (usually reported as ''none detected'').

TABLE 1.—OAK RIDGE Y–12 PLANT PERSONAL SAMPLING

	1980–1989	1990–1996
Number of samples	148	1448.
Arithmetic Mean	0.9 μg/m^3	0.3 μg/m^3.
Percent of samples less than 2 μg/m^3.	94%	98%.

These data are from beryllium operations that are associated with cases of chronic beryllium disease. The facilities where these operations take place have not been remodeled since the 1970s. Increased monitoring in the 1990s led to investigations of exceedences over the existing exposure limit and resulted in changes to work practices that contributed to the high readings. This focus on levels exceeding the limit also led to a significant reduction in average exposure levels.

Personal sampling data from the Rocky Flats Building 444 Beryllium Machine Shop (Table 2) collected in 1984–85 and after extensive remodeling to the ventilation system in 1986 illustrate the impact and effectiveness of engineering modifications to control exposure.

[2] A listing of references is included at the end of the preamble to this Notice of Proposed Rulemaking.

TABLE 2.—ROCKY FLATS BUILDING 444 BERYLLIUM MACHINE SHOP PERSONAL SAMPLING DATA

	1984–1985	1986
Number of Samples	99	279.
Arithmetic Mean	1.19 μg/m³.	0.035 μg/m³.
Percent of samples less than 2 μg/m³.	84%	99.6%.

The samples collected in 1984 were the first personal samples collected in this shop following the discovery of a case of CBD that year. Controls in that machine shop had previously been judged to be adequate based on area monitoring. In addition to the extensive remodeling of the ventilation system in the shop to minimize leakage from hoods, operations performed outside of hoods were eliminated to the extent possible. The decision to implement improved engineering controls in this shop reduced average exposure levels by a factor greater than 30 to levels approaching 1% of the limits established by the existing PEL.

A final example, taken from personal sampling data collected during decontamination of Rocky Flats buildings 865 and 867 in 1995–1996, further demonstrates the low levels of beryllium exposure which can be achieved through effective control planning (See Table 3). Each worker was sampled during each work shift during this time period.

TABLE 3.—DECONTAMINATION OF ROCKY FLATS BUILDINGS 865 AND 867 PERSONAL SAMPLING, 1995–1996

Number of Samples	7673.
Arithmetic Mean	0.03 μg/m³.
Percent of samples less than 2 μg/m³.	99.8%.

As can be seen from the foregoing examples, Rocky Flats machining and D&D operations achieved an exceptional level of exposure control.

While the application of controls eliminates predictable sources of exposure, there still can be large day-to-day variations in exposure. The exposures that remain are likely to reflect accidents, equipment failures, or poor work planning. Meeting exposure minimization goals will require planning to limit the potential for such occurrences and monitoring to detect those that do occur so they can be investigated and prevented from reoccurring.

The personal monitoring results at Rocky Flats and Y–12 indicate that most exposures are very low with a few exceptions. These exceptions account for much of the total exposure that workers receive.

D. Epidemiology

The first evidence of the existence of chronic beryllium disease (CBD) was reported in a 1946 paper by Hardy and Tabershaw (ref. 2). The paper described ''delayed chemical pneumonitis'' among fluorescent lamp workers exposed to beryllium compounds. The differential diagnosis included tuberculosis and sarcoidosis, an immune disease of unknown etiology.

There were also reports of CBD in individuals without known occupational exposure to beryllium. Under the direction of Dr. Thomas Mancuso, 16 cases of CBD were diagnosed (by X-ray examination) among 20,000 residents living near a beryllium production facility in Lorain, Ohio (ref. 3). Likewise, a 1949 report described 11 patients with CBD who lived near a beryllium extraction plant (ref. 4). Ten of these 11 lived within ¾ of a mile of the plant, and exposure from plant discharges into the air was the suggested cause for 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 [μg/m³]).

In addition, CBD has been reported among family members of beryllium workers who were presumably exposed to contaminated work clothing during the 1940's and 1950's (refs. 5, 6). The virtual disappearance of CBD as a result of air pollution or household exposures has been attributed to more stringent control of air emissions and improved work practices, such as mandatory work clothing exchange. This reduction in disease incidence is also attributed to improvements in diagnostic testing (ref. 7). However, as recently as 1989, a woman previously diagnosed with sarcoidosis was diagnosed with CBD. She had no occupational exposure, but her husband was a beryllium production worker. This is the first new case of non-occupational CBD reported in 30 years.

Sterner and Eisenbud suggested that CBD was a highly selective immunologic response. Their conclusion was based on epidemiologic evidence that (1) severe cases have occurred at low exposure; (2) the level of beryllium contained in tissue did not correlate with the extent of the disease; (3) there was a correlation between disease and low atmospheric concentration, but not high concentrations; (4) the onset of symptoms could occur years after the termination of exposure; and (5) pulmonary lesions were not easily reproduced in animals (ref. 6).

A registry of production plant CBD cases was started at Columbia University in 1947. A second registry of phosphor-lamp CBD cases was started around the same time. In 1952, a Beryllium Case Registry was established at the Massachusetts Institute of Technology (MIT) where files from the other beryllium registries were consolidated. The consolidated Beryllium Case Registry was moved to Massachusetts General Hospital in the 1960's and ultimately relocated to the National Institute for Occupational Safety and Health (NIOSH) in 1978. At that time, the Beryllium Case Registry contained 622 cases of CBD, 224 cases of acute beryllium disease, and 44 acute cases that developed into CBD. Twenty-three cases were attributed to household exposures and 42 to air pollution (ref. 5). The Beryllium Case Registry, which is now inactive, was criticized as deficient in acquiring data on cases, identifying populations at risk (denominator data), maintaining follow up of questionable cases, and obtaining exposure data (ref. 8).

According to criteria utilized by the Beryllium Case Registry, the diagnosis of CBD included at least four of the following six criteria with one of the first two conditions required: (1) the establishment of beryllium exposure based on occupational history or results of air samples, (2) the presence of beryllium in lung tissue or thoracic lymph tissue or in the urine, (3) evidence of lower respiratory tract disease and a clinical course consistent with beryllium disease, (4) pathological changes consistent with beryllium disease on examination of lung tissue or thoracic lymph nodes, (5) radiologic evidence of interstitial lung disease, and (6) decreased pulmonary function tests (ref. 9).

The beryllium-induced lymphocyte proliferation test (Be-LPT) in blood and bronchoalveolar lavage (BAL) fluid has allowed early identification of the disease and is one of the criteria required for diagnosis (refs. 10–12). Beryllium has been found to act as a specific antigen, causing proliferation and accumulation of beryllium-specific helper T lymphocytes (CD4) in the lung (ref. 13). Current data suggest that the peripheral blood Be-LPT is a specific and sensitive method for testing

beryllium sensitivity (ref. 10). The presence of granulomatous tissue in the lung along with a positive BAL Be-LPT is considered definitive evidence for diagnosis of CBD (ref. 11). Probable CBD is also diagnosed based on signs and symptoms of CBD and a positive blood Be-LPT when bronchoscopy is not indicated or is refused.

An article published by Cullen et al. in 1987 reported on cases of CBD among precious-metal refinery workers (ref. 14). In 1993, researchers at the National Jewish Medical and Research Center (NJMRC) published two reports on epidemiologic studies that were designed to determine the incidence of CBD among beryllium workers and the value of the Be-LPT in detecting CBD (refs. 15, 16). One study was conducted at DOE's Rocky Flats Environmental Technology Site (Rocky Flats). The three epidemiologic studies showed that CBD incidence among exposed workers was the same as had been reported among workers exposed in the 1940's, when the disease was first recognized. These were the first studies of exposed workers since the adoption of the current Occupational Safety and Health Administration (OSHA) 8-hour, time-weighted average (TWA) permissible exposure limit (PEL) of 2 $\mu g/m^3$. The exposure limit was originally derived by analogy to other toxic metals (ref. 17). A decline in the number of reports of CBD led to the assumption that the 2 $\mu g/m^3$ limit had been effective in preventing CBD (ref. 5). It is now clear that these standards have not eliminated the incidence of disease.

In 1991, following the NJMRC study, the DOE Office of Environment, Safety and Health initiated a beryllium worker health surveillance program at Rocky Flats to provide medical screening to current and former beryllium workers who had not participated in the earlier NJMRC study. In addition, the Office of Environment, Safety and Health initiated a study at the Oak Ridge Y–12 Plant (Y–12) in 1991 to learn if the NJMRC findings on CBD incidence and the effectiveness of the Be-LPT could be replicated. Results to date confirm NJMRC findings that CBD incidence rates are high and that the Be-LPT is an effective screening test for CBD as shown in Table 4.

TABLE 4.—RESULTS OF MEDICAL SCREENING OF BERYLLIUM-EXPOSED WORKERS AT 3 DOE SITES THROUGH DECEMBER 1997

	Rocky Flats	Y–12	Mound
Individuals Examined	6257	1949	632
Abnormal Be-LPT, Number (percent)	221 (3.5)	77 (4)	[1]1
Completed Diagnostic Exams	186	33	0
CBD[2] Number (percent)	79[3] (1.3)	25[4] (1.3)	0

[1] The one Mound employee who was found to be consistently positive declined to go on for diagnostic testing. Four others had one positive blood test result and were awaiting retesting.

[2] Includes 44 cases confirmed through biopsy and testing of lavage cells and 35 presumptive cases in which the pulmonologist diagnosed CBD but biopsy and/or lavage could not be completed.

[3] Includes 56 cases found through the surveillance program since 1991, 17 through the 1987–1991 NJMRC study, and 6 between 1984 and 1987 for a total of 79 CBD cases. Six of the 79 cases had consistently normal Be-LPT results and were identified through lung disease symptoms or abnormal chest X-rays.

[4] Includes 17 cases found in the surveillance program since 1993, 2 found in 1991 among beryllium workers who had been diagnosed with other lung diseases, and 6 cases found by the site clinic in 1993 among 146 currently exposed beryllium workers provided the Be-LPT.

In 1996, three studies reported on exposure to beryllium associated with CBD and immunologic sensitization to beryllium (refs. 18–20). Two of the studies reported on cases of CBD at Rocky Flats (refs. 18, 19). The third reported on an epidemiology study of a private sector beryllia ceramics fabrication plant that began operating in 1981 (ref. 20). Both Rocky Flats and the ceramics plant were extensively monitored for compliance with the current OSHA 8-hour TWA exposure standard of 2 $\mu g/m^3$. The authors concluded that exposures among the highest exposed groups in the plants were, on average, below the 2 $\mu g/m^3$ limit. At both plants, cases of CBD and sensitization to beryllium were found among administrative and other personnel, whose average exposures were lower, as well as among the more highly exposed workers.

Stange and colleagues reported on the findings of a health surveillance program at Rocky Flats that used the Be-LPT to screen for CBD (ref. 18). Of 97 individuals who tested positive on the Be-LPT, 28 were found to have CBD. The article included an analysis of the work histories of these 97 current and former workers. A qualitative exposure estimate based on the work histories of individuals who developed CBD concluded that exposures varied by more than an order of magnitude. Extensive air monitoring data were available for one of the highest exposed groups, machinists.

Barnard and colleagues completed an extensive analysis of the monitoring data associated with machining operations at Rocky Flats (ref. 19). Prior to 1984, air monitoring was accomplished with fixed area monitors located near the machine tools that were thought to be the primary sources of emissions into the work rooms. In 1984, personal sampling was initiated, which was more representative of individual exposure. The article reported a high degree of uncertainty in exposure assessments prior to 1984 due to the lack of correlation between area monitoring and personal monitoring. The authors concluded that machinists, as a group, shared similar exposure potential, that average exposures were less than but near the 2 $\mu g/m^3$ limit, and that excursions above the limit were common.

Kreiss and colleagues studied CBD occurring in a beryllium oxide ceramics manufacturing plant (ref. 20). They found that machinists had the highest incidence rate of beryllium sensitization and the highest exposure potential. The area monitoring conducted in this plant was aimed at estimating exposures associated with job titles and was found to correlate with personal sampling. The authors concluded that ''the existing data suggests that the machining exposures resulting in the 14.3 odds ratio for beryllium sensitization were largely within those permitted by current regulations.'' This article confirmed the findings of a study of CBD in the neighborhood of a beryllium extraction plant, which showed a correlation between ambient beryllium levels and incidence of CBD (ref. 4). Further analyses of CBD incidence at Rocky Flats, as yet unpublished, showed a similar higher risk for machinists compared to that for other workers (See Table 5).

TABLE 5.—INCIDENCE RATES OF CBD AT ROCKY FLATS

Job category [1]	Number tested	CBD cases	Incidence rate (percent)
Beryllium Machinist	223	21	9.4
Administrative	1,903	23	1.2
Professional	1,396	15	1.1
All Employees Tested	6,254	64	1.0

[1] Many employees held more than one job title.

Cases of CBD have occurred in machinists who worked in the Y–12 beryllia ceramic machine shop, where levels have been quite low. Only a small percentage of samples have detected beryllium. Applying a nonparametric tolerance limit test to 1980 and 1990 personal sampling results from this shop shows, with 95 percent confidence, that 90 percent of exposures were lower than the detection limit (0.1 $\mu g/m^3$ in the 1980–1990 timeframe). Only one of several hundred personal samples was over the 2 $\mu g/m^3$ limit. Continuous area air monitors have operated in the shop throughout its existence. One area sample indicated levels above 2 $\mu g/m^3$ when a machine tool was operated with a disconnected exhaust duct. No other area measurement above 2 $\mu g/m^3$ were recorded, and the median measurement was at the level of detection.

Several authors have highlighted the uncertainty that exists in the exposure assessments (refs. 19–21). The chemical composition of the beryllium materials used and the particle size distribution of the aerosol created by the work operation affect the bioavailability of beryllium, and neither is accounted for by current personal sampling and analytical methods. It is not known what percentage of the beryllium that is being measured in air is capable of reaching the regions of the lung where the health effect occurs. In addition, area monitoring used in the past does not correlate with the personal monitoring that is thought to be more representative of exposure (refs. 19, 21).

Epidemiologic investigations to date have failed to show whether the time course of exposure (dose rate) is biologically significant. High day-to-day variation in exposure level and excursions above the 2 $\mu g/m^3$ limit have occurred in all groups studied. Excursions make up a significant contribution to individuals' total doses, confounding attempts to understand if dose rate is an important risk factor. Beryllium oxide and metal in the lung dissolve slowly over a period of months and years (ref. 22), producing the beryllium ion that elicits an immune response (ref. 23). The persistent presence of the beryllium ion in the lung makes CBD a chronic disease (ref. 24). Either intermittent or chronic exposure to less soluble forms of beryllium can create and maintain a lung burden that will not clear for many years, if at all (ref. 25).

Certain individuals are more susceptible to CBD than others. It has long been suspected that genetic predisposition plays an important role in determining who will develop CBD. Recent advances in genetics and immunology have made it possible for researchers to investigate the basis for CBD and to identify a genetic component (ref. 26).

Differences in individual susceptibility have made it difficult to understand the relationship between exposure and CBD. Early epidemiologic studies detected similar disease rates among high- and low-exposure occupational groups (Table 6). The NJMRC researchers detected differences in disease rates among the workers they studied (Table 7). The DOE surveillance findings supported this conclusion (See Table 5). NJMRC researchers have found cases of CBD among those who had been exposed for periods as short as 1 month and those who had unrecognized or seemingly trivial exposure. However, they also found evidence that disease incidence increased with increasing exposure and concluded that exposure to beryllium should be minimized.

TABLE 6.—CHRONIC BERYLLIUM DISEASE RATES

Exposed during the 1940's	Estimated exposed	Cases	Estimated incidence per 100 exposed	Estimated level of exposure $\mu g/m^3$
Residents Living Within 0.25 Mile of a Beryllium Extraction Plant [1]	500	5	1.0	1
Fluorescent Lamp Manufacturing [1]				
Massachusetts	15,000	175	1.16	100
Ohio	8,000	32	0.4	100
Machine Shop [1]	225	11	4.9	500
Beryllium-Copper Foundry [1]	1,000	13	1.3	500
Beryllium Extraction [1]				
Lorain, Ohio	1,700	22	1.3	1000
Painesville, Ohio	200	0	0.0	1000
Reading, Pennsylvania	4,000	51	1.3	1000
Exposed from the 1970's to the 1980's	**Study participants**	**Cases**	**Incidence per 100 exposed**	**Estimated level of exposure $\mu g/m^3$**
Beryllia Ceramics Plant [2]	505	9	1.8	NA
The DOE Rocky Flats Plant [3]	895	15	1.7	1

Exposed from the 1970's to the 1980's	Study participants	Cases	Incidence per 100 exposed	Estimated level of exposure µg/m³
Second Beryllia Ceramics Plant [4]	709	8	1.1	0.5

[1] Eisenbud and Lisson, ''Epidemiologic Aspects of Beryllium-Induced Non Malignant Lung Disease: A 30-Year Update,'' JOM, Vol. 25, pp 196–202, 1983.
[2] Kathleen Kreiss et al., ''Beryllium Disease Screening in the Ceramics Industry,'' JOM, Vol. 35, pp 267–274, 1993.
[3] Kathleen Kreiss et al., ''Epidemiology of Beryllium Sensitization and Disease in Nuclear Workers,'' Am. Rev. Res. Dis., Vol. 148, pp 985–991, 1993.
[4] Kathleen Kreiss et al., ''Machining Risk of Beryllium Disease and Sensitization with Median Exposures Below 2 µg/m³,'' Am. J. Ind. Med., Vol. 30, pp 16–25, 1996.

TABLE 7.—BERYLLIUM SENSITIZATION AND DISEASE RATES AT ROCKY FLATS

Beryllium process title	Workers sensitized	Workers doing process	Sensitization rate (percent)
Cleaning Tools, Machines	7	255	2.7
Machining	6	189	3.2
Inspection	2	138	1.4
Metallurgical Sample Preparation	3	115	2.6
Sawing	5	06	4.7
Trepanning	3	77	3.9
Band Sawing	4	67	6.0
Decanning, Shearing	2	65	3.1
Precision Grinding	2	31	6.5
All participants	**Number**	**Participants**	**Rate (percent)**
Sensitized	18	895	2.0
Confirmed CBD Cases	15	895	1.7

From Kathleen Kreiss et al. ''Epidemiology of Beryllium Sensitization and Disease in Nuclear Workers,'' Am. Rev. Res. Dis., Vol. 148, pp 985–991, 1993.

A recent publication by Eisenbud in January 1998, (ref. 27), consolidated the previous epidemiologic studies that have questioned the relevance of the current PEL after evaluating the effect of the level of exposure on disease. In this article, Eisenbud concludes that it ''appears'' the current 2 µg/m³ standard is not protective enough. Rather than recommend an alternative exposure limit, however, Eisenbud points to the need for the development of an animal model to aid in better understanding the etiology of CBD and suggests that innovative measures may be needed to control the disease.

In summary, evidence suggests higher incidence of CBD among workers with higher exposures (e.g., machinists), but, at lower exposure levels, other factors may operate to confound a clear dose-response relationship. These factors include: (1) The effect of peak exposures (such that most of the exposure results from short-term episodes); (2) inadequacy of area monitoring in reflecting actual exposure; (3) chemical composition, etc., that may affect bioavailability; (4) inadequate monitoring of beryllium composition/species associated with exposures; and (5) the effect of genetic predisposition. As a result, the existing literature does not point to a clear set of measures that will reduce incidence.

E. Value of Early Detection

Researchers at the National Jewish Medical and Research Center (NJMRC) compared the lung functions of patients with chronic beryllium disease (CBD) who had been identified through abnormal chest X-rays or clinical symptoms to those of patients whose CBD had been identified through positive beryllium-induced lymphocyte proliferation tests (Be-LPTs) (ref. 28). Twelve of 21 Be-LPT-identified patients had lung abnormalities, including reduced exercise tolerance. Fourteen of 15 patients identified through chest X-rays or clinical symptoms had abnormal lung function, and their abnormalities were more severe. The authors concluded that the Be-LPT was useful because it permitted detection of affected individuals earlier in the disease process.

Early identification also allows removal of patients with CBD from jobs with beryllium exposure. There is no direct evidence that removal from exposure improves the prognosis of patients with CBD, because follow up studies have not been done. However, beryllium does clear from the lung over time, and a reduced level of antigen in the lung should reduce the severity of the inflammation and the amount of lung damage.

The 79 cases of CBD diagnosed among Rocky Flats workers showed a range of severity similar to that reported elsewhere. Thirty-nine individuals had symptoms that required treatment ranging from inhaled bronchodilators to corticosteroids to oxygen. Two individuals died of CBD. Seventy-three of the 79 cases were identified among individuals who had abnormal Be-LPT results but normal chest X-rays or pulmonary function screening test results.

V. Request for Information

The Department is considering more stringent requirements in various areas of the proposed NOPR. It is especially interested in comments that are supported by evidence and rationale whenever possible, regarding the following areas.

Industrial hygiene competencies: Proposed sections 850.21(b) and 850.24(a) would require that hazards assessments and exposure monitoring, respectively be conducted by ''individuals with sufficient knowledge in industrial hygiene.'' The Department

is considering using more prescriptive definitions for the qualifications an individual must possess to perform the required hazard assessments and exposure monitoring. One possible alternative approach would be to use OSHA's ''competent person'' definition. OSHA defines a competent person as:

> * * * one who is capable of identifying existing and predictable hazards in the surroundings or working conditions which are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.

Another possible approach would be to require that hazards assessments and exposure monitoring be performed by a ''certified industrial hygienist'' as defined by the American Board of Industrial Hygiene. DOE requests that interested parties submit comments regarding the use of such prescriptive definitions and/or suggestions for alternative approaches.

Permissible exposure limit: To address the uncertainties associated with the existing PEL and the limitations of the existing scientific data, DOE requests that interested parties submit any compelling, scientific evidence that would assist the Department in establishing a new permissible exposure limit that would be more protective of worker health.

Percent exceedance: The Department is considering alternatives to the action level as a basis for judging and interpreting exposure monitoring results. Descriptions of three methods used to interpret exposure level data are contained in the American Industrial Hygiene Association, A Strategy for Occupational Exposure Assessment (ref. 29). Of the three methods described, the percent exceedance approach appears as the best alternative for achieving the policy goal of encouraging periodic monitoring to understand the distribution of exposures and for investigating the causes of high exposures to prevent their reoccurrence. We are considering proposing that monitoring demonstrate 95% confidence that fewer than 5 percent of the 8-hour or 15 minute TWA PEL levels exceed the exposure limit. The advantage of this method is that periodic monitoring is needed to characterize the distribution of exposure before compliance can be demonstrated, usually through an upper tolerance limit test. In addition this method rewards day-to-day management of exposure levels through investigation of the causes of an exceedance and the implementation of corrective actions that will prevent it from reoccurring. A weakness of this method is that it can underestimate the degree of risk in a workplace where day-to-day, or between worker variation, is very large. This weakness can be minimized by assuring that long term mean levels are not high compared to the PEL. DOE requests that interested parties provide information on: the feasibility and implication of a percent exceedance approach to defining an acceptable workplace; the percent exceedance that would still provide the level of protection intended by the 8-hour or 15 minute TWA PEL; and whether mean testing should be specified as well. Commentors should provide the rationale and associated costs for approaches supported in their submittals, as well as input on implementation strategies or issues.

Exposure monitoring: Given the uncertainty regarding the adequacy of the PELs and whether any level of beryllium exposure should be considered safe, DOE is considering establishing a requirement for daily exposure monitoring of all beryllium workers to document and characterize more completely a worker's exposure to beryllium, and to better evaluate the adequacy of existing exposure levels or determine appropriate levels for alternative exposure limits. At the very low exposure levels that the Department is attempting to achieve, work practices that would ordinarily be judged as presenting trivial potential sources of exposure may be significant. The goal of an exposure monitoring program should be routine sampling aimed at characterizing the distribution of exposures due to typical work. Monitoring results help identify both the cause of exposure above limits and measures that can prevent recurrence. DOE requests that interested parties provide information on the feasibility and implications of this more restrictive monitoring requirement. Commentors should also provide the rationale for the approaches supported in their submittals.

Respiratory protection: DOE is considering requiring the use of respiratory protection at the action level instead of the PEL due to uncertainty about the protective value of the PEL. DOE requests that interested parties submit comments regarding the impact of such a change.

Protective clothing and equipment: DOE is requesting information regarding the presence of soluble beryllium compounds within the DOE complex and the appropriateness of the exclusion of such compounds from the definition of beryllium in the proposed rule. In addition, DOE requests comments with appropriate supporting rationale regarding the need for the protective clothing provisions of proposed section 850.29(a)(2) given that soluble beryllium compounds apparently are not present within the DOE complex.

Surface contamination level: DOE requests that interested parties submit comments regarding the validity of the proposed 3 μg/100 cm^2 surface contamination level. If an alternate level is suggested, the Department requests that the rationale and associated cost implications for choosing the alternate surface contamination level also be provided.

Release level: DOE is aware of the need to set an acceptably free-release surface contamination level for beryllium for unrestricted equipment release and transfer to uncontrolled areas and the public. DOE requests that interested parties submit comments regarding the setting of a beryllium free-release public contamination level. If a level is suggested, the Department requests that the rationale and associated cost implications for choosing the associated surface contamination level also be provided.

Medical surveillance: DOE seeks comments on whether all workers with any potential exposure to beryllium, regardless of the level of exposure, should be provided the option to participate in a medical surveillance program to identify workers who may become sensitized to beryllium at exposures less than the action level or STEL.

Anonymous testing: The Department realizes that some workers may elect not to participate in the medical surveillance program because they may believe that a diagnosis of CBD or beryllium sensitization could have a negative impact on future employment opportunities or on their health insurance. To address this concern and to encourage greater worker participation in the medical surveillance program, DOE is considering including a provision in the proposed rule that would allow for anonymous testing for CBD. Such a provision could include assigning an identification number (not traceable to the worker's name) to the worker's blood sample. The tested worker could use the identification number to call into the testing laboratory after a specified amount of time to retrieve the test results.

DOE recognizes that such a system may encourage greater participation in the medical surveillance program, but it also has several drawbacks including the inability to correlate collected exposure data to health outcomes, and problems associated with the need for followup testing to confirm positive

results. DOE request that interested parties comment on appropriate methods for, and the feasibility and utility of provisions for anonymous testing for CBD.

Outreach program: DOE is considering a requirement that contractors develop and implement an outreach education program for family members of beryllium workers. The outreach awareness program would address the hazards of exposure to beryllium and the purpose and content of the CBDPP. The objective of this requirement would be to increase awareness among the families of beryllium workers about the hazards associated with beryllium exposure and the actions being taken within the Department to address these hazards. DOE requests that interested parties comment on the feasibility, utility, and implications of such an outreach program.

VI. Section-by-Section Analysis

Overview of the Proposed Rule

The proposed rule would strengthen the Department's worker protection program established in DOE Order 440.1A, Worker Protection Management for DOE Federal and Contractor Employees (5483.1B, 5480.4, 5480.8A, and 5480.10 for operations not covered contractually under 440.1A), by supplementing the general worker protection program requirements of the order with hazard-specific provisions that are designed to manage and control beryllium exposure hazards in the DOE workplace. These hazard-specific provisions are derived largely from DOE Notice 440.1, ''Interim Chronic Beryllium Disease Prevention Program.''

DOE Notice 440.1 was developed by the DOE Beryllium Rule Development Team and Executive Committee, both of which consisted of representatives of each of the affected DOE headquarters and field offices. The technical basis for the notice was based in part on public input provided to the DOE Office of Environment, Safety and Health (EH) by 43 commentors and organizations in response to a December 30, 1996, **Federal Register** notice requesting scientific data, information, and views relevant to a DOE beryllium standard (61 FR 68725). Much of this information was presented and discussed at public forums held in Albuquerque, NM, and Oak Ridge, TN, in January 1997. Records of these public forums, as well as copies of all related public input and the minutes and recommendations of the BRAC meetings, are available at the DOE Freedom of Information Reading Room in the prerulemaking docket file entitled ''BERYLLIUM STANDARD.'' See the preceding **ADDRESSES** section for details on how to review or obtain copies of this material.

Consistent with DOE Notice 440.1 the proposed rule establishes a CBDPP that is designed to prevent the occurrence of chronic beryllium disease (CBD) among DOE Federal and contractor workers. The CBDPP will accomplish this disease-prevention mission through provisions that (1) reduce the number of current DOE Federal and contractor 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 particles 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 and treatment of disease; and (4) continually monitor the effectiveness of the program in preventing CBD and implement program enhancements as appropriate.

The provisions of the proposed rule are presented in three main subparts: A, B, and C. Subpart A of the proposed rule describes the purpose and applicability of the rule, defines terms that are critical to the rule's application and implementation, and establishes DOE and contractor responsibilities for executing the rule. Subpart B establishes administrative requirements to develop and maintain a CBDPP and to perform all beryllium-related activities according to the CBDPP. Subpart C establishes requirements that focus on protecting workers from the harmful health effects associated with exposure to airborne levels of beryllium. Some of the provisions of Subpart C would apply only when it is determined that the airborne concentrations of beryllium in a specific workplace or operation rise above a specified limit. Table 5 summarizes these provisions and indicates the levels of beryllium at which the provisions would be enacted. Subparts A, B, and C of the proposed rule are discussed in detail in the following sections.

TABLE 5.—LEVELS AT WHICH THE PROVISIONS OF THE CBDPP WOULD BE ENACTED

Provision	Worker exposure or potential exposure levels (8-hour TWA)		
	> 0	≥ Action level or > STEL	> PEL (8-hr TWA or STEL)
Baseline Beryllium Inventory (850.20)	X		
Hazard Assessment (850.21)	X		
Initial Exposure Monitoring (850.24)	X		
Periodic Exposure Monitoring (850.24)		X	
Exposure Reduction and Minimization (850.25)	X[1]	X[2]	X[3]
Regulated Areas (850.26)		X	
Change Rooms (850.27)		X	
Respiratory Protection (850.28)			X
Protective Clothing and Equipment (850.29)		X	
Housekeeping (850.30)	X[4]		
Medical Surveillance (850.33)		X	
Training (850.36)	X[5]		
Counseling (850.36)		X[6]	
Warning Signs (850.37)		X	
Waste Disposal (850.31)	Applies to beryllium waste and beryllium-contaminated waste.		
Beryllium Emergencies (850.32)	Applies to beryllium operations.		

TABLE 5.—LEVELS AT WHICH THE PROVISIONS OF THE CBDPP WOULD BE ENACTED—Continued

Provision	Worker exposure or potential exposure levels (8-hour TWA)		
	> 0	≥ Action level or > STEL	> PEL (8-hr TWA or STEL)
Warning Labels (850.37)	Applies to beryllium and beryllium waste and beryllium-contaminated material and waste.		

[1] If exposure levels are below the action level or STEL, contractors must establish exposure reduction and minimization goals to further reduce worker exposures where practicable.
[2] Contractors must investigate opportunities for and, if feasible, implement controls for reducing exposures to below the action level or STEL.
[3] Contractors must reduce exposures to or below the PEL or STEL.
[4] Housekeeping efforts must maintain removable surface contamination at or below 3 μg/100 cm^2.
[5] Hazard communication training is required for all workers who could be potentially exposed.
[6] Counseling is required for beryllium workers diagnosed with CBD or beryllium sensitization.

A. Subpart A—General Provisions

Proposed section 850.1 emphasizes that the proposed CBDPP would enhance, supplement, and be integrated into existing worker protection program requirements for DOE Federal and contractor employees. The Department has structured the proposed rule this way for two main reasons: (1) To take advantage of existing and effective comprehensive worker protection programs that have been implemented at DOE facilities, and (2) 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 section 850.2(a)(1) specifies that the proposed rule would apply to DOE Federal employees with responsibilities for operations or activities involving exposure or the potential for exposure to beryllium at DOE-owned or -leased facilities. The Department recognizes that its 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 often must enter facilities where beryllium is handled. Federal workers are protected 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 (EO) 12196, ''Occupational Safety and Health Programs for Federal Employees.'' The Department's intent in proposed section 850.2(a)(1) 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.

Proposed section 850.2(a)(2) specifies that the proposed rule would also apply to DOE contractors with operations or activities involving exposure or the potential for exposure to beryllium. As clarified in the definition of DOE contractor (proposed section 850.3), the Department's intent is that the DOE contractors covered under this proposed rule would include any entity under contract to perform DOE activities at DOE-owned or -leased facilities, including contractors awarded contracts, integrating contractors, and subcontractors. This section further clarifies that the requirements of the CBDPP would apply only to contractors and subcontractors who work in areas or on DOE activities that involve the potential for worker exposure to beryllium. The Department's intent with this clarification is to focus DOE and contractor resources and efforts on areas and activities that present a real potential for worker exposure to beryllium and thus realize the most benefit from implementing the proposed CBDPP. DOE emphasizes this intent throughout the proposed rule by requiring that DOE contractors tailor their approach to implementing the CBDPP.

The Department's intent with the applicability provisions of proposed section 850.2(a)(1) and (a)(2) is that the proposed rule would apply only to exposures and potential exposures to beryllium that occur in connection with facility operations. This recognizes the fact that beryllium occurs naturally in soils and that the focus of the CBDPP should not be on naturally occurring beryllium but rather on the occupational exposures resulting from DOE operations.

Proposed section 850.2(b)(1) would exempt ''beryllium articles'' from the requirements of the proposed rule (see the discussion of the definition of ''beryllium article'' under proposed section 850.3). The Department recognizes that some beryllium-containing manufactured items may not pose beryllium hazards where they have been formed to specific shapes or designs and their subsequent uses or handling will not result in the release of beryllium. This exemption for beryllium articles is consistent with the approach taken by OSHA when defining hazardous materials subject to the Hazard Communication standard at 29 CFR 1910.1200.

Proposed section 850.2(b)(2) would establish that the rule does not apply to the DOE laboratory operations involving beryllium that are subject to the requirements of OSHA's Occupational Exposure to Hazardous Chemicals in Laboratories standard, 29 CFR 1910.1450, commonly called OSHA's laboratory standard. In establishing its laboratory standard, OSHA clarified its intent that 29 CFR 1910.1450 supersede all other OSHA regulations for bench-top laboratory-scale activities, noting that the provisions of the standard were more relevant and suitable to the unique characteristics of laboratory activities. The Department agrees with OSHA's approach and believes that the provisions of OSHA's laboratory standard are adequate to protect workers from beryllium exposures in facilities that fall within the scope of the standard.

Proposed section 850.3 would apply traditional industrial hygiene terminology to define key terms used throughout the proposed rule. In relying on such terminology and by using terms consistent with OSHA interpretations, DOE intends to signal the Department's increased emphasis on industrial hygiene compliance through the use of accepted occupational safety and health requirements and procedures. The following discussion defines and

explains each of the definitions in the proposed rule.

Accepted applicant is any person who has accepted an offer of employment in beryllium work at a DOE facility but who has not yet begun performing beryllium work. DOE intends for DOE contractors to provide such individuals with baseline medical evaluations before allowing them to begin employment as beryllium workers to ensure that they can safely perform work in areas that may present the potential for exposure to beryllium.

Action level means the level of airborne concentration of beryllium established pursuant to Subpart C, which, if exceeded, would require the implementation of certain provisions of the proposed rule. Using an action level to trigger certain provisions of the proposed rule is consistent with the approach applied in many of OSHA's substance-specific standards. This approach ensures that appropriate workplace precautions are taken and that training and medical surveillance are provided in cases in which worker exposures to beryllium could approach the permissible exposure limit. Additional discussion on the application of the action level in this proposed rule is provided in the discussion on proposed section 850.23, Action Level, and in the discussions of the individual provisions of the proposed rule that would be triggered by exceeding the proposed action level.

Authorized person means any person required by work duties to be in regulated areas. Authorized individuals are intended to be trained and experienced in the hazards of beryllium and in the means of protecting themselves and those around them against such hazards. Training requirements for all individuals working with beryllium are specified in proposed section 850.36 of the proposed rule. The concept of authorized persons is consistent with OSHA standards and with contractor practice in many facilities and is intended to ensure that the number of potentially exposed individuals is reduced to the lowest possible number and that workers who are granted access to regulated areas have the knowledge they need to protect themselves and other workers.

Beryllium means elemental beryllium and any insoluble beryllium compound or alloy containing 0.1 percent beryllium or greater that may be released as an airborne particulate. The Department has chosen this definition of beryllium because it clearly reflects that the focus of the proposed rule is on exposure to airborne levels of beryllium. DOE notes in this definition that OSHA uses the criterion for a carcinogenic mixture as one that contains a carcinogenic component at a concentration of 0.1 percent (or 1,000 parts per million [ppm]) or greater, by weight or volume.

Beryllium article means a manufactured item that is formed to a specific shape or design during manufacture and that has end-use functions that depend in whole or in part on the item's shape or design during use and that does not release beryllium or otherwise result in exposure to airborne concentrations of beryllium under normal-use conditions. The Department has included this definition of ''beryllium article'' to distinguish between forms of beryllium that could result in exposure and manufactured items containing beryllium that do not release beryllium or otherwise result in exposure to airborne concentrations of beryllium. This definition is consistent with the rationale employed by OSHA in formulating its definition of ''article'' in the Hazard Communication standard (29 CFR 1910.1200). The key concept is that an article does not have the potential to result in hazardous exposures; this definition of ''article'' also considers the item's intended use. For example, an item ceases to be an ''article'' when it is subjected to machining, cutting, or drilling. Similarly, if an item is manufactured for the purpose of being machined later, it is not considered an article.

Beryllium emergency means any occurrence such as, but not limited to, equipment failure, container rupture, or failure of control equipment or operations, that unexpectedly releases a significant amount of beryllium. 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 is based on OSHA's interpretation of the term as applied in 29 CFR 1910.120 and is intended to refer to any untoward event, such as a major spill of powdered beryllium or an unexpected, massive upset that releases a significant amount of airborne beryllium into the workplace atmosphere. The use of the term ''beryllium emergency'' in this proposed rule applies to proposed section 850.32, Emergencies, which requires DOE contractors to develop emergency procedures and training to address emergency scenarios. Such procedures and training must focus on emergency events that can reasonably be foreseen by an employer, such as a spill or a rupture of a pipe or a container.

Beryllium-induced lymphocyte proliferation test (Be-LPT) means an *in vitro* measure of the beryllium antigen-specific, cell-mediated immune response. This test measures the extent to which lymphocytes, a class of white blood cells, respond to the presence of beryllium by replicating in the laboratory. The Be-LPT is used by medical personnel to identify workers who have become sensitized to beryllium through their occupational exposure.

Beryllium worker means a current worker who is exposed or potentially exposed to airborne concentrations of beryllium at or above the action level or above the STEL or who is currently receiving medical removal protection benefits. This individual is a DOE Federal or contractor worker, a worker of a subcontractor to a DOE contractor, or a visitor who performs work for or with DOE or uses DOE facilities. This definition, through the phrase ''current worker who is exposed or potentially exposed to airborne concentrations of beryllium,'' clarifies the Department's intent that the proposed rule would apply only to current workers who are part of the at-risk population. The definition further clarifies that current workers who have been removed from beryllium exposure as part of the medical removal plan would continue to be considered as beryllium workers under the proposed rule. Former DOE workers who were potentially exposed to beryllium do not fall within this definition or the proposed rule. These workers will be addressed under a separate DOE initiative that is under development.

Breathing zone is 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 section 850.24, Exposure Monitoring, which would require DOE contractors to determine worker 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 practice and ensures that samples collected for personal exposure monitoring represent the air inhaled by workers while performing their duties in affected work areas.

DOE means the Department of Energy or Department.

DOE beryllium activity means an activity performed for, or by, DOE that can expose workers to airborne concentrations of beryllium. Activities within the scope of this definition

include design, construction, operation, maintenance, and decommissioning. The definition further explains that, to the extent appropriate, a ''DOE activity'' may involve one DOE facility or operation, a combination of facilities and operations, or possibly an entire site. This definition is broad enough to include such activities as repair work performed by support-service subcontractors who visit the site infrequently.

DOE contractor means any entity under contract (or its subcontractors) with DOE with responsibility for performing DOE activities at DOE-owned or -leased facilities. This does not apply to contractors or subcontractors who solely provide ''commercial items'' as defined under the Federal Acquisition Regulations (FAR). As explained in proposed section 850.10, subcontractors included in this definition who would be covered under the proposed rule would not necessarily be expected to produce their own written CBDPPs. However, these subcontractors should be included in the CBDPP that encompasses all beryllium-related activities at the site. See the discussion in proposed section 850.10 for further details on how the requirements of the proposed CBDPP would be extended to a subcontractor.

DOE facility means any facility owned or leased by DOE.

High-efficiency particulate air (HEPA) filter means a high-efficiency filter capable of trapping and retaining at least 99.97 percent of 0.3-micrometer monodisperse particles. Such filters are commonly used in heating and ventilating systems, respiratory protection equipment, local exhaust ventilation, and so on, to remove toxic or hazardous particulates like beryllium.

Immune response refers to the series of cellular events by which the immune system reacts to challenge a specific antigen. Types of immune responses include acquired immunity and sensitization. The body's immune response to beryllium is indicated by the results of the Be-LPT.

Medical removal protection benefits are employment rights established in proposed section 850.34 for beryllium workers who voluntarily accept temporary or permanent medical removal from regulated areas following medical evaluations that confirm beryllium sensitization or CBD. These provisions would ensure that contractors make reasonable efforts to find and offer alternate employment to beryllium workers who have suffered negative health effects due to exposure to beryllium. The definition of medical removal protection benefits and the requirements in proposed section 850.34 would ensure that such workers would suffer no reductions in wage rate, seniority, or other benefits for 2 years after medical removal. The 2-year period would allow the contractor to make a reasonable effort through job retraining and out-placement programs operated by many sites to locate alternate work placement for beryllium workers, either internally or with different employers.

Regulated area means an area established and managed by the contractor to demarcate locations where the airborne concentration of beryllium exceeds, or can reasonably be expected to exceed, the action level (see the preceding definition of ''action level''). Employees working in regulated areas must be authorized to do so by the contractor and trained and equipped with protective clothing and equipment. The purpose of such areas is to limit beryllium exposure to as few employees as possible. This is a standard definition used throughout DOE, particularly with regard to radiation protection, and is consistent with OSHA's expanded health standards that address toxic particulates.

Short-term exposure limit (STEL) means the level of airborne concentration established pursuant to Subpart C (calculated as a 15-minute TWA, measured in the worker's breathing zone by personal monitoring), which should not be exceeded for any 15-minute period at any time during the workday. Additional discussion on the application of the STEL in this proposed rule is provided in the discussion on proposed section, 850.22, Exposure Limits.

Site occupational medicine director (SOMD) means the physician responsible for the overall direction and operation of the site occupational medicine program. DOE's intent with this definition is to ensure that each site's occupational medicine program would be administered by a qualified medical professional.

Surface contamination means the presence of beryllium on exposed work surfaces, which may cause skin irritation upon contact or which may present an airborne hazard when reentrained into the workplace air. This definition of ''surface contamination'' is also important in addressing the maintenance, decontamination, and cleaning of facilities and equipment for recycling or for release for other uses. The Department recognizes that airborne respirable beryllium particles differ from surface contamination, which is not respirable until it is disturbed. Therefore, the rule provides separate definitions of ''beryllium'' and ''surface contamination.''

Worker means a person who performs work for or on behalf of DOE, including a DOE employee, an independent contractor, a DOE contractor employee, or any other person who performs work at a DOE facility. As clarified in the definition of DOE contractor, a contractor employee can be an employee of a covered subcontractor.

Worker exposure means the airborne concentration of beryllium in the breathing zone of the worker when the worker is not using respiratory protective equipment. This definition is consistent with accepted industrial hygiene practice and with OSHA's definition of the term ''employee exposure'' as applied in the OSHA expanded health standards.

Proposed section 850.3(b) references the standard definitions contained in the Atomic Energy Act and related rules under 10 CFR part 850 for other terms used throughout this proposed rule.

Proposed section 850.4 would establish enforcement provisions for the proposed rule. Like other Departmental regulations that apply to DOE contractors, this provision would allow DOE to employ contractual mechanisms, such as contract termination or fee reduction, when contractors fail to comply with the provisions of this proposed rule. These mechanisms help the Department ensure that beryllium workers receive an appropriate level of protection while performing Departmental activities that involve exposure or the potential for exposure to beryllium.

Proposed section 850.5 would provide the appropriate steps that the Department may take to enforce compliance with this proposed rule. The grievance-arbitration processes of collective bargaining agreements covering accepted applicants and beryllium workers employed by Department contractors would generally apply to disputes relating to implementation of this part. Therefore, proposed section 850.5 would provide that disputes arising under this part brought by beryllium workers and accepted applicants (or by labor organizations acting on their behalf) that are covered by grievance-arbitration processes should be resolved through such processes. This approach to dispute resolution would minimize the possibility of bypassing collective bargaining representatives or existing contractual grievance-arbitration processes and minimize the possibility of conflicting outcomes that would exist with multiple avenues for enforcing compliance with the rule.

However, where the individuals bringing such disputes are not covered by collective bargaining agreements or where such collectively bargained processes are not applicable, the proposed rule would provide that disputes brought by individuals may be resolved by the Department's Office of Hearings and Appeals (OHA). OHA is an established and impartial body that has experience in dealing with whistleblower, security, and other disputes brought by individual workers. The procedures in 10 CFR part 1003, Subpart C, shall apply to resolution of disputes by OHA.

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.

As owner or lessor of DOE-owned or -leased facilities, the Department has both a responsibility for overseeing the health and safety activities of its contractors and a partnership interest in achieving excellence in worker protection activities. Accordingly, *proposed section 850.10*(a)(1) would require DOE contractors who are responsible for DOE beryllium activities to prepare CBDPPs for their operations and submit the CBDPPs to the appropriate DOE Field Organization for approval. This section would establish a 90–day time frame from the effective date of the rule for contractor submission of the CBDPP to the appropriate DOE Field Organization. The Department is well aware of the burden of documentation that can be generated by new programs. However, most DOE contractors have already developed CBDPPs in response to the requirements of DOE Notice 440.1. The Department expects that the additional efforts that would be required to refine the existing CBDPPs to meet the requirements of the proposed rule would be minimal. The Department considers 90-days sufficient time for DOE contractors to examine their safety and health programs and make any changes necessitated by the rule.

Proposed section 850.10(a)(2) would require that a single written CBDPP be submitted to encompass all beryllium-related activities at a site. Because the Department recognizes that one site may encompass multiple contractors and numerous work activities, however, this proposed section clarifies that the CBDPP for a given site may include specific sections for individual contractors, work tasks, and so on. 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 contractors to update and submit for approval only the affected sections of the CBDPP. When multiple contractors are involved, the DOE contractor designated by the DOE Field Organization shall take the lead in compiling the overall CBDPP document and coordinating the input from various subcontractors or work activities. This section further clarifies that in such cases where multiple contractors are involved, the designated contractor would have to review and approve the CBDPPs of other contractors engaged at the site before a consolidated CBDPP would be submitted to the head of the cognizant DOE Field Organization for final review and approval.

Proposed section 850.10(b) would require heads of DOE Field Organizations to review and approve CBDPPs. DOE believes that DOE review and approval are necessary to ensure that each contractor's CBDPP is consistent with best industry practices for industrial hygiene, the Department's exposure reduction and minimization philosophy, and the objectives of the CBDPP. Through these proposed sections, DOE hopes to establish clear lines of authority for review and approval of contractors' CBDPPs.

Proposed section 850.10(b)(1) would establish a 90-day period for DOE to review and either approve or reject the CBDPP. During its review, DOE could direct the contractor to modify the CBDPP, or it could modify the CBDPP itself. If DOE takes no action within 90 days, the initial CBDPP would be considered approved. The Department would establish this 90-day time frame to facilitate timely implementation of program elements by contractors and to ensure that DOE Field Organizations respond to contractors' submissions.

Proposed section 850.10(b)(2) would require that the written CBDPPs be furnished upon request to the DOE Assistant Secretary for Environment, Safety and Health or his or her designee; DOE program offices; affected workers; and designated worker representatives. This proposed requirement would be in addition to the provisions of this section that would require contractors to submit the CBDPP, or portions (e.g., the medical surveillance section) of it, to cognizant DOE offices. The Department's intent with this requirement is to facilitate implementation and enforcement of the proposed rule. In addition, this proposed section would ensure that workers and their representatives could access information that is related to the protection of their health during the performance of DOE activities.

Proposed section 850.10(c) would establish that updates to the written CBDPP be required under two circumstances: (1) Whenever a significant change or addition is made to the program and (2) whenever a contractor or subcontractor changes. DOE feels that such updates would be warranted to ensure that the CBDPP accurately reflects workplace conditions and appropriately addresses specific beryllium workplace exposure hazards.

This proposed section would also require that DOE contractors review their written CBDPPs at least annually and revise these programs as necessary to reflect any significant changes. Only sections of the CBDPP that require changes would have to be resubmitted to the head of the DOE Field Organization for approval. The Department considers the annual review cycle to be appropriate and necessary to ensure that CBDPPs remain up-to-date and accurately reflect workplace conditions and required control procedures.

Proposed section 850.10(d) was added to ensure that the CBDPP would be developed and implemented consistent with the requirements imposed by the National Labor Relations Act (NLRA) on employers in this context, and not to create obligations in excess of those that would be found in such circumstances under the NLRA.

Proposed section 850.11(a) specifies that the CBDPP would be expected to address all existing and anticipated operational tasks that fall within its scope. In addition, the section would require all DOE contractors to develop and implement a CBDPP that is integrated into the Department's existing worker protection program. This proposed requirement would reflect the Department's desire to develop and implement one comprehensive, consistent, and integrated worker protection program that addresses all DOE workplace hazards. By including this provision, DOE notes the importance of controlling beryllium hazards within the framework of the worker protection program established under DOE Order 440.1A (or, where applicable, under predecessor orders like DOE Orders 5483.1A, 5480.4, 5480.8A, and 5480.10) and related DOE health and safety initiatives. The existing industrial hygiene and occupational medicine programs, which were established in the comprehensive worker protection program and related initiatives, provide the basis needed to protect DOE federal

and contractor workers from health hazards like beryllium exposure. DOE believes that establishing a beryllium exposure control program outside the framework of this accepted program would create redundant and inconsistent requirements that would unnecessarily burden the regulated community and create an inefficient program.

Unlike the DOE orders listed above, the regulatory requirements of this proposed rule would by operation of law apply to DOE contracts. Accordingly, the application and enforcement of this proposed rule would not be subject to the Work Smart Standards Program or other related processes. DOE believes that this mandatory application of the proposed CBDPP requirements to all DOE beryllium activities is appropriate given the hazardous nature of beryllium-related work.

Proposed section 850.11(b) would require that contractors tailor the scope and content of their CBDPPs to the specific hazards associated with the DOE beryllium activities being performed. In addition, proposed section 850.11(b)(1) would require that these programs have to include formal plans outlining how DOE contractors would ensure that occupational exposures to beryllium are maintained at or below the PELs (8-hour TWA PEL of 2 $\mu g/m^3$ and 15-minute STEL of 10 $\mu g/m^3$).

Proposed section 850.11(b)(2) further specifies that a contractor's CBDPP must, at a minimum, address each requirement in Subpart C of the rule. Consistent with the performance-based nature of the proposed rule, DOE's intent with this requirement is that DOE contractors include in their CBDPPs those provisions necessary to protect workers from exposure to beryllium during the performance of DOE beryllium activities at the contractors' respective sites. Proposed section 850.11(b)(3) would clarify that the CBDPP provisions must focus on: (i) Minimizing the number of current workers exposed and potentially exposed to beryllium; (ii) minimizing the number of opportunities for workers to be exposed to beryllium; and (iii) setting challenging exposure reduction and minimization goals to facilitate the minimization of worker exposures. DOE believes that the establishment of exposure reduction and minimization goals is essential to the success of the CBDPP. With this catalyst to achieving further exposure reductions, DOE contractors would be encouraged to seek opportunities to provide enhanced worker protection, thereby assisting DOE in moving toward the ultimate goal of preventing CBD within the DOE complex.

DOE is sensitive to concerns that exist within the DOE community regarding the need to approach the Department's exposure reduction and minimization objectives in a responsible and realistic manner. Accordingly, proposed section 850.11(b)(3)(iii) would establish a performance-based requirement that would allow contractors to establish their own exposure reduction and minimization goals tailored to their unique workplace needs and conditions. DOE's intention with this proposed requirement is that DOE contractors would establish reasonable but challenging goals based on sound industrial hygiene principles and the specific circumstances for each affected workplace and location. DOE believes that relevant circumstances must be considered in establishing these goals. Those circumstances would include the current level of worker exposures, the number of workers exposed, the existing controls that are in place, the technical feasibility and exposure reduction potential of possible additional controls, and the cost and operational impact of the controls.

Proposed sections 850.12 (a) and (b) would require that DOE contractors manage and control beryllium exposures in all DOE beryllium activities in accordance with the approved CBDPP. This section would clarify that DOE and contractor personnel must follow applicable requirements of the rule and any resulting programs, plans, schedules, or processes, as well as requirements in other applicable Federal statutes and regulations.

Proposed section 850.12(c) would clarify the Department's position that tasks involving potential beryllium exposure that would not be covered under the CBDPP could not be initiated until the CBDPP has been updated to include them and has been approved by the appropriate DOE Field Organization. DOE provides an exception of this requirement for urgent and unexpected situations. In such cases, the task could proceed with the approval of the DOE Field Organization prior to revision and approval of the CBDPP.

Proposed section 850.12(d) would require that, depending on the circumstances of the work, other actions may be necessary to protect workers and that such actions are not to be limited by the provisions of the proposed rule. The Department recognizes that those individuals responsible for implementing CBDPP activities are accountable for using their professional judgment in protecting the health and safety of workers. Nothing in the proposed rule should be viewed as relieving these individuals of their professional responsibility to take whatever actions are warranted to protect the health and safety of the workforce.

Proposed section 850.13(a) would mandate that DOE activities involving beryllium comply with their respective CBDPP that has been approved by the cognizant DOE Field Organization, as appropriate. Through this provision, DOE recognizes that even the best CBDPP will not adequately protect workers if it is not followed at the site. Proposed section 850.13(b) further proposes that once the final rule takes effect, DOE contractors would have 2 years to fully implement all aspects of the program (written plans, schedules, and other measures). The Department intends to reduce the resource impacts on contractors by permitting them to phase in costly controls over the 2-year period. However, the Department would expect portions of the program to be implemented as soon as practical during the 2-year period.

Proposed section 850.13(c) would specify that the DOE contractor in charge of the activity involving a potential for beryllium exposure would be responsible for complying with the rule. When no contractor is responsible for the activity and Federal employees perform the activity, this section would require DOE to be responsible for compliance.

Subpart C—Specific Program Requirements

Subpart C of the proposed rule would establish performance-based requirements for the CBDPP. These proposed requirements focus on preventing CBD by reducing the number of workers who could be exposed to beryllium, minimizing the potential level of beryllium in the workplace atmosphere, and continually monitoring worker health to ensure that workplace controls are sufficiently protective. The Department's intent is that implementation of the rule will increase understanding of the development and course of chronic beryllium disease. Throughout the Department's pre-rulemaking activities, including the public forums in Albuquerque, NM, and Oak Ridge, TN, and the BRAC meetings, many interested parties advised DOE to adopt various hazard-specific programs to address DOE beryllium hazards. For instance, several public forum participants suggested that DOE control beryllium hazards through an ''as low as reasonably achievable (ALARA)''

approach, similar to that the Department applies to control radiation hazards. These participants believed the ALARA approach was warranted due to the continued occurrence of CBD among the DOE workforce and questions regarding whether any level of beryllium exposure should be considered safe. Other public forum participants argued that OSHA's expanded health standard for asbestos would provide a better model because it applies accepted industrial hygiene practices to remediation activities similar to the remediation activities that may be encountered in DOE cleanup operations that involve beryllium. DOE acknowledges that both the ALARA approach and the OSHA Asbestos standard (as well as other OSHA expanded health standards) include provisions that could be applied effectively in controlling beryllium hazards in the DOE workplace. Accordingly, DOE combined the relevant components of the Asbestos standard (and other OSHA expanded health standards) and the ALARA approach in DOE Notice 440.1 and continues this approach in the proposed rule.

Proposed section 850.20(a) would require that DOE contractors develop a baseline beryllium inventory to identify beryllium in DOE facilities and operations and to identify workers who are or may be potentially exposed to beryllium. Such baseline inventories would accomplish several functions that are critical to the success of the CBDPP, including: (1) The identification of locations and operations that should be physically isolated from other areas to prevent the spread of contamination, (2) the identification of areas in which worker access should be restricted to minimize the number of workers who could be exposed, (3) the identification of beryllium contamination in facilities scheduled for decontamination and decommissioning (D&D) operations to ensure the implementation of appropriate D&D control procedures, (4) the identification of beryllium contamination in facilities that are still used to determine the need for appropriate cleanup measures, and (5) the determination of which workers should be covered under the CBDPP.

Proposed sections 850.20(b)(1) through (4) would supplement the generic inventory requirement originally established in DOE Order 440.1A by requiring DOE contractors to conduct records reviews, employee interviews, and, if necessary, appropriate sampling procedures to determine and document the presence and locations of beryllium on DOE sites. These supplemental requirements are necessary because of the nature of past beryllium operations within the DOE complex, which were often conducted in open, uncontrolled work areas.

Because the results of records reviews and employee interviews alone may not suffice to confirm the presence of beryllium contamination in a specific location, proposed section 850.20(b)(4) would require that DOE contractors conduct sampling procedures to assess beryllium workplace hazards. DOE contractors should design such sampling protocols according to the specific workplace conditions and the suspected types and locations of beryllium contamination. Sampling techniques could include collecting area and wipe samples and/or collecting personal breathing zone samples.

Proposed section 850.20(c) would require contractors to ensure that the baseline beryllium inventory activities required under proposed section 850.20 are conducted by individuals with sufficient knowledge in industrial hygiene. The Department believes that this provision would be required to ensure that the inventory is accurate and complete and that the CBDPP provides protection to all affected workers. 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 various control measures must be employed, *proposed section 850.21* would require DOE contractors to conduct a beryllium hazard assessment to characterize workplace beryllium exposure hazards. This requirement would allow each site to determine the appropriate risk-based approach for assessing beryllium-related hazards in its worksites where the baseline beryllium inventory has established that beryllium is present.

The flexibility of proposed section 850.21 is particularly important because operations, conditions, and the potential for exposure may vary greatly from operation to operation and facility to facility. For instance, the hazard assessment required for a facility that houses current beryllium machining operations may be much more in-depth than that required for an inactive storage facility that stored a used beryllium lathe temporarily. In both cases, proposed section 850.21(a) would require a review of existing worksite conditions, exposure data, medical surveillance trends, and exposure potential of planned activities. In the beryllium machining operations example, however, this review would require an in-depth analysis of machining and other interrelated operations involving the performance of multiple tasks by multiple employees, each with varying exposure potentials. In this case, extensive medical surveillance and personal exposure monitoring data may already exist and may provide a sufficient basis for hazard assessment efforts. If the existing data do not suffice, however, the collection and analysis of additional personal breathing zone monitoring data for each task, operation, and work area may be necessary to accurately characterize potential beryllium exposure hazards.

For the inactive storage area, a review of existing wipe sampling data, collected according to proposed section 850.20(b)(4), may suffice to ascertain that no beryllium exposure hazard exists in the facility. However, if wipe sampling data from the facility indicate that beryllium contamination exists in the storage facility, a more in-depth analysis could be required to determine the extent of contamination, the potential for the contamination to become airborne, and the need for facility cleanup and/or related exposure control measures.

Proposed section 850.21(b) would require contractors to ensure that hazard assessments are conducted by individuals with sufficient knowledge in industrial hygiene. The Department believes that the establishment of such minimum personnel qualifications would be necessary to ensure the appropriate implementation of the provisions of the proposed rule and to ensure that the CBDPP provides protection to all affected workers.

Proposed section 850.22(a) would retain the OSHA 8-hour, TWA PEL for beryllium (2 ($\mu g/m^3$), as measured in the worker's breathing zone, or would adopt a lower 8-hour TWA PEL if such a PEL were established by OSHA through the rulemaking process. DOE is aware of viewpoints both for and against a lower DOE 8-hr TWA PEL for beryllium. Arguments in favor of lowering the PEL include the growing number of confirmed CBD cases (110 as of June 1998 among the 8,951 current and former DOE federal and contractor workers who have undergone medical screening) and the apparent low-level, incidental beryllium exposures received by some of the afflicted workers. Arguments against lowering the PEL include a lack of compelling scientific evidence that the current exposure limit is not protective.

There is scientific evidence (presented in the Health Effects discussion of this NOPR, Section IV) that suggests that the current exposure limit does not sufficiently protect worker health. However, existing scientific data does not currently

provide an adequate basis for determining an appropriate new DOE exposure limit. For this reason, DOE proposes to retain the existing OSHA 8-hr TWA PEL at this time and include in this proposed rule other provisions that are designed to minimize worker exposure in DOE facilities and to encourage continual monitoring of worker health to ensure an adequate level of protection. Chief among these provisions are the action level in proposed section 850.23, the exposure reduction and minimization requirements of proposed section 850.25, and the medical surveillance provisions of proposed section 850.33. Each is discussed below.

OSHA has placed beryllium on its regulatory agenda but has indicated that it will take several years for a new OSHA standard on beryllium to be promulgated. Through proposed section 850.22(a), DOE has clarified its intent to adopt the new OSHA permissible exposure limit upon promulgation.

Proposed section 850.22(b) would adopt the short-term exposure limit (STEL) established by the American Conference of Governmental Industrial Hygienists (ACGIH) of 10 μg/m^3, averaged over a 15-minute sampling period. According to the ACGIH Threshold Limit Value (TLV) and Biological Exposure Indices booklet, a worker's 15-minute TWA exposure must not exceed the STEL at any time during the workday even if the worker's full shift exposure is within the 8-hour TWA PEL. Exposures above the PEL-TWA must not be longer than 15 minutes and must not occur more than four times per day. The ACHIH TLV and Biological Exposure Indices booklet further indicates that if such exposures occur more than once a day, there must be at least 60 minutes between successive exposures in this range.

The ACGIH recently established this 10 μg/m^3 STEL for beryllium based on studies suggesting that acute beryllium disease did not appear in a group of workers exposed below 15 μg/m^3, and that CBD and lung cancer appear to be associated with exposure regimes in which short, high exposures occur. As noted in the ACGIH supporting rationale for the STEL, the 10 μg/m^3 STEL is in accord with the ACGIH's standard practice of recommending a generic excursion limit of 5 times the 8-hour TWA threshold limit value (TLV). The ACGIH 8-hr TWA TLV for beryllium is equal to OSHA's 8-hour TWA PEL of 2 μg/m^3.

DOE recognizes that the ACGIH 15-minute STEL is more protective than the OSHA acceptable maximum peak exposure for beryllium of 25 μg/m^3 for a duration of 30 minutes. DOE also notes that the adoption of the ACGIH STEL in this proposed rule is consistent with current DOE policy and with minimum standards already in effect throughout the Department. As specified in DOE Order 440.1A and its predecessor Orders, DOE contractors must comply with both the OSHA standards and with the ACGIH TLVs. These Orders further clarify that where a conflict exists between the OSHA and ACGIH exposure limits, the more protective standard shall apply.

DOE is aware of the continued occurrence of CBD among its workforce and intends to take every reasonable measure to minimize worker exposure to beryllium and to prevent the occurrence of CBD. One such measure is in *proposed section 850.23,* which would establish an 8-hour TWA action level of 0.5 μg/m^3, measured in the worker's breathing zone. Consistent with the worker protection practices employed in many of the OSHA expanded health standards, the action level would be used to trigger certain mandatory elements of the CBDPP: periodic exposure monitoring (proposed section 850.24(c)), regulated areas (proposed section 850.26), change rooms (proposed section 850.27), protective clothing and equipment (proposed section 850.29), and medical surveillance (proposed section 850.33).

In selecting the action level for the proposed rule, DOE considered: (1) OSHA's practice of establishing action levels; (2) the results of a 1996 survey of DOE facilities (presented in the draft DOE Beryllium Information Survey Report contained in the prerulemaking docket), which reported potential beryllium exposures and related control practices throughout the DOE complex; and (3) questions regarding the adequacy of the 8-hour TWA PEL. OSHA, in its expanded health standards, typically establishes action levels for hazardous and toxic substances at one-half the 8-hour TWA PEL. Applying this approach to beryllium would result in an 8-hour TWA action level of 1.0 μg/m^3. According to the results of the 1996 DOE survey, however, two DOE facilities (Pantex and Rocky Flats) had already employed an action level of 0.5 μg/m^3. One facility (Lawrence Livermore National Laboratory) reported the use of an ''administrative warning range'' of 0.2 to 2.0 μg/m^3, which triggered a requirement for an investigation, and six DOE facilities employed an action level of 1.0 μg/m^3. Consistent with the Department's decision to implement aggressive exposure minimization efforts DOE proposes adopting the lower of the existing action levels currently used within the DOE complex in proposed section 850.23 rather than following typical OSHA practice. DOE believes that the successful implementation of this action level at two DOE facilities, and the implementation of an even lower ''administrative warning range'' at a third facility, provide sufficient evidence of the feasibility of implementing the 0.5 μg/m^3 action level across the DOE complex. DOE does not intend for this action level to discourage efforts to reduce exposures below 0.5 μg/m^3 in a regulated area. In fact, proposed section 850.25 would require contractors to establish and implement appropriate exposure reduction and minimization goals to further reduce worker exposures to beryllium.

Proposed section 850.24 would establish CBDPP worker exposure monitoring requirements. Monitoring of breathing zone air space in areas where workers are potentially exposed is a well-recognized and widely accepted risk-management tool that is used to protect workers from exposure to airborne toxic substances. The proposed provisions in this section, which are also required under DOE Order 440.1A, are necessary to characterize worker exposures to a specific toxic substance and, based on these exposures, to determine the need for appropriate engineering or work-practice controls. In addition to this traditional compliance role, DOE proposes to expand the CBDPP's exposure monitoring element to provide continual feedback on the effectiveness of the program in preventing the occurrence of CBD. Such exposure monitoring results would help the Department to resolve uncertainties regarding the adequacy of the existing beryllium PEL and to refine the requirements of this rule as needed to protect worker health.

Proposed section 850.24(a) would require that exposure monitoring be conducted by individuals with sufficient knowledge in industrial hygiene. The Department believes that the establishment of such minimum personnel qualifications is necessary to ensure the appropriate implementation of the provisions of the proposed rule and ensure that the CBDPP provides protection to all affected workers.

Proposed section 850.24(b) would require that DOE contractors perform initial exposure monitoring for all workers who work in areas that may have airborne concentrations of beryllium as determined through the baseline beryllium inventory and hazard assessment. Such initial exposure

information is necessary to identify workers who must be enrolled in the medical surveillance program, determine the need for engineering and work practice controls, select appropriate personal protective clothing and respiratory protective equipment where needed, and identify the need to establish regulated areas. Because the proposed PELs include an 8-hour TWA PEL and a 15-minute STEL, proposed section 850.24(b)(1) would require that worker exposure be measured by personal breathing zone samples that represent each worker's (i) full-shift exposure (for 8-hour TWA exposure measurements) or (ii) 15-minute exposure at operations where exposures may be above the STEL.

DOE recognizes that many DOE contractors may have performed the required initial monitoring as part of their efforts to implement DOE Notice 440.1. DOE does not intend for DOE contractors to repeat these efforts. Accordingly, proposed section 850.24(b)(2) would allow contractors to use initial monitoring data collected within 12 months before the effective date of this rule to satisfy the rule's initial monitoring requirements.

Proposed section 850.24(c) would require DOE contractors to conduct periodic exposure monitoring to detect any workers who have been exposed to beryllium at or above the action level or above the STEL. DOE believes that such periodic monitoring is necessary to ensure the continued protection of worker health. This requirement would provide contractors the flexibility to determine the monitoring frequency that is needed to characterize worker exposures accurately. DOE believes that such flexibility is warranted due to the wide range of beryllium-related operations within the DOE complex. The Department recognizes that DOE contractors are best positioned to evaluate the potential variability of worker exposures in their operations and to tailor their periodic monitoring approaches as appropriate, based on existing exposure levels and the potential for these exposure levels to change. However, because slight process or procedural changes may go unnoticed over time and because equipment maintenance, aging, or deterioration can affect performance, DOE proposes in proposed section 850.24(c) a minimum exposure monitoring frequency requirement of 3 months (quarterly) for workers who are exposed to airborne concentrations of beryllium at or above the action level or above the STEL. DOE recognizes that the proposed minimum quarterly monitoring of workers exposed at or above the action level or above the STEL is more stringent than most OSHA expanded health standards. However, the Department feels this minimum monitoring frequency is necessary due to the uncertainties regarding the adequacy of the current PEL.

To supplement this periodic monitoring requirement, proposed section 850.24(d) would also require that DOE contractors perform additional exposure monitoring when beryllium-related operations or procedures change. In the case of procedural or operational changes, this additional monitoring is needed to quantify how changes affect worker exposure to airborne beryllium, to ensure the continued effectiveness of existing engineering and work-practice controls, and to identify the need for additional control measures to minimize worker exposure to beryllium.

To obtain accurate exposure monitoring results, proposed section 850.24(e) would require that DOE contractors use monitoring and analytical methods that have an accuracy, at a confidence level of 95 percent, of not less than plus or minus 25 percent for airborne concentrations of beryllium at exposure levels between the 8-hour TWA action level and the PEL. Proposed section 850.24(f) would further ensure the quality of monitoring results by requiring that all laboratory analyses of air sampling data be performed in a laboratory accredited for metals by the American Industrial Hygiene Association. These proposed accuracy and quality requirements would be consistent with similar requirements that appear in many of OSHA's expanded health standards for toxic substances. DOE believes that the quality and accuracy of exposure monitoring data are crucial to protecting workers from airborne toxic substances because monitoring results trigger the implementation of several critical elements of the worker protection program. Accordingly, effective implementation of the CBDPP and ultimately the health of affected beryllium workers would rest on the quality and accuracy of the collected exposure monitoring data.

Proposed section 850.24(g)(1) would establish requirements to notify affected workers of monitoring results. This section would require DOE contractors to make this notification in writing within 10 working days of receipt of the monitoring results. This section would also provide DOE contractors with two alternative methods of worker notification: (1) Provide written notification to each affected worker, or (2) post monitoring results in a location or locations readily accessible to affected workers. When the posting option is selected, DOE contractors would have to post the results in such a way as to protect the privacy of the affected workers.

Proposed section 850.24(g)(2) also contains a provision for cases in which monitoring results indicate that worker exposure levels exceed the action level or STEL. In such cases, the DOE contractor would be required to notify the SOMD of the results within 10 working days of receipt of the results. DOE believes that the SOMD must 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 section 850.25 would establish the exposure reduction and minimization provisions of the CBDPP that reflect the Department's goal of achieving aggressive reduction and minimization of worker exposures to airborne beryllium. DOE believes this is a prudent approach to worker protection in light of questions regarding the adequacy of the existing PEL and the relationship between beryllium worker exposure and disease.

Proposed section 850.25(a) would establish the baseline requirement that DOE contractors ensure that no worker is exposed to airborne beryllium at levels above the exposure limits established in proposed section 850.22. The section would further clarify that DOE contractors must apply the hierarchy of industrial hygiene controls as established in DOE Order 440.1A to achieve this minimum exposure control requirement. This hierarchy dictates that DOE contractors must implement feasible engineering controls, followed by administrative controls, in their efforts to reduce exposure levels. If these engineering and administrative controls do not reduce beryllium levels to the exposure limits, DOE contractors must supplement these controls with personal protective clothing and equipment as appropriate to reduce exposure levels to within the exposure limits.

Proposed section 850.25(b) would clarify the requirement to establish exposure reduction and minimization goals by requiring that DOE contractors include in their CBDPP, the rationale to support their exposure reduction and minimization goals. This section further requires that the CBDPP include a plan for meeting these goals as well as performance measures to be used to assess the contractor's status in achieving the goals. DOE considers this level of formality essential to the

establishment and implementation of meaningful goals, and to the use of these goals in achieving the exposure reduction and minimization objectives of the CBDPP. In addition, DOE believes that appropriate documentation of the supporting rationale for these goals is necessary to address concerns among the DOE community regarding overzealous DOE enforcement of the exposure reduction and minimization requirements of this proposed rule and to avoid second-guessing of contractor CBDPP efforts.

Proposed sections 850.25(b)(1) and (2) would establish the Department's minimum expectations for the implementation of exposure reduction and minimization efforts. DOE does not intend for these minimum requirements to stifle contractor innovation but intends for them to serve as a starting point in efforts to implement an effective exposure reduction and minimization program. Specifically, proposed section 850.25(b)(1) would require DOE contractors to include in their CBDPP strategies for the use of the action level to trigger actions to reduce or minimize worker exposures and the potential for exposures. Proposed section 850.25(b)(2) would clarify that CBDPP strategies shall also include use of the conventional hierarchy of industrial hygiene controls as a means of achieving exposure reduction and minimization goals. The intent of these provisions is to encourage contractors to (1) investigate opportunities for exposure reductions when worker exposures reach or could reach the action level (or at lower levels of exposure if appropriate) and (2) implement control measures that are feasible and consistent with sound industrial hygiene principles, the objectives of the CBDPP, and the contractor's own internal exposure reduction and minimization goals.

Proposed section 850.26 would establish the regulated area provisions of the CBDPP. These regulated areas, managed by the contractors, would help minimize the number of workers exposed to airborne beryllium by preventing or minimizing the spread of beryllium to clean work areas. Because most if not all DOE contractors that would be affected by this proposed rule have already implemented varying provisions to control access to areas and operations with a potential for worker exposures to beryllium (as reported in the draft 1996 DOE Beryllium Information Survey Report), DOE believes that the majority of the provisions of this proposed section would pose minimal additional burden on DOE contractors.

Proposed section 850.26(a) would require that DOE contractors establish regulated areas where airborne concentrations of beryllium are in excess of the action level or STEL. DOE selected the action level in lieu of the 8-hour PEL as the trigger for this proposed requirement in keeping with the Department's aggressive beryllium exposure reduction and minimization philosophy. The STEL is included as a trigger for this requirement to address workplace areas where full-shift exposure levels may be below the action level but operations or activities result in exposures above the STEL.

Proposed section 850.26(b) of the proposed section would require that DOE contractors adequately identify regulated areas so that workers are aware of the presence and boundaries of such areas. This requirement would allow contractors the flexibility to determine the most appropriate means of identifying each regulated area based on specific worksite conditions.

Proposed section 850.26(c) would require that DOE contractors limit access to regulated areas to authorized persons only. The contractor would determine which workers should have the authority to enter the work area and how the entry of unauthorized individuals will be prevented. DOE's intention is that only individuals who are essential to the performance of work in the regulated area would be granted entry authority. DOE contractors would have to evaluate the affected operation and determine which personnel (including managers, supervisors, and workers) are necessary for the performance of the work and thus must have entry authority. Methods for preventing unauthorized persons from entering a regulated area may range from, at a minimum, posting a sign indicating that only authorized persons may enter (as would be required by proposed section 850.37) to the use of locked access doors and other security measures on the basis of worksite conditions. DOE believes that contractors are best equipped to determine whether any access control methods are needed in addition to those already specified in proposed section 850.37.

Proposed section 850.26(d) would require that DOE contractors keep a record of all persons who enter 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 work performed. The function of these records within the framework of the CBDPP is clarified in proposed section 850.38, Recordkeeping. Specifically, DOE believes that these records are necessary to monitor the effectiveness of each contractor's regulated area efforts and to provide valuable information regarding each worker's history of potential exposures. This historical information would assist the contractor's occupational medicine staff in establishing appropriate medical surveillance protocols and would aid in the Department's efforts to establish links between working conditions and potential health outcomes.

Proposed section 850.27 would establish change room provisions for workers in regulated areas. These hygiene provisions are common in OSHA's expanded health standards, specifically in those standards designed to protect workers from exposures to hazardous particulates. Proposed section 850.27(a)(1) would require that change rooms used to remove beryllium-contaminated clothing and protective equipment be maintained under negative pressure or, located in a manner or area that prevents dispersion of beryllium contamination into clean areas. Proposed 850.27(a)(2) would require that separate facilities be provided 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 facility and into workers' private automobiles and homes. These provisions would 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 exposures.

Consistent with the goal of preventing the spread of contamination into adjacent work areas and into affected workers' homes, proposed section 850.27(b) would require that DOE contractors provide hand-washing and shower facilities for workers assigned to regulated areas. DOE recognizes that the installation of such facilities may take time in some cases. Accordingly, proposed section 850.13(b) would allow contractors 2 years to achieve full compliance with the requirements of the rule.

Proposed section 850.28 would establish the respiratory protection provisions of the CBDPP. Specifically, proposed section 850.28(a) would require that DOE contractors comply with the OSHA Respiratory Protection standard (29 CFR 1910.134). Proposed section 850.28(b) would require that

DOE contractors provide appropriate respiratory protective equipment for all workers exposed to airborne concentrations of beryllium above the PELs established in proposed section 850.22 and ensure that the workers use protective equipment. Proposed section 850.28(c) would require that DOE contractors select and use only National Institute for Occupational Safety and Health (NIOSH)-approved or DOE-accepted respiratory protective equipment as required by DOE Order 440.1A.

None of the provisions of this proposed section are new. For instance, DOE contractors have historically been subject to the OSHA standards, including 29 CFR 1910.134, through the provisions of DOE Order 440.1A and its predecessor orders, which incorporate the OSHA standards. DOE Order 440.1A require DOE contractors to provide, and DOE workers to use, appropriate respiratory protective equipment necessary to protect workers from exposures to hazardous substances, including airborne beryllium, at levels above established OSHA PELs. In addition, the provisions of 29 CFR 1910.134 include a requirement that employers select only NIOSH-approved respirators. In recognition of the unique nature of certain DOE operations, DOE Order 440.1A expanded this NIOSH-approval restriction to allow for the use of DOE-accepted respiratory protection when NIOSH-approved respiratory protection did not exist for a specific DOE task.

Proposed section 850.29 would establish the protective clothing and equipment provisions of the CBDPP. Proposed section 850.29(a) would require that DOE contractors provide workers who are potentially exposed to beryllium at or above the action level or above the STEL with protective clothing and equipment and ensure that the protective clothing and equipment are maintained and used as appropriate. Proposed section 850.29(a)(1) would clarify that appropriate protective clothing for work in areas where beryllium contamination is present includes full-body protective clothing and footwear (work shoes or booties). This section further stipulates that workers must exchange their personal clothing for this protective clothing before beginning work in regulated areas. As would be required under proposed section 850.27(a), this change from personal clothes into protective work clothing must occur in a change room that protects the worker's personal clothes and clean protective clothing from beryllium contamination. DOE believes that the use of full-body protective clothing in lieu of personal clothes in regulated areas is necessary to prevent the spread of beryllium contamination into adjacent work areas and to preclude the possible transport of beryllium into affected workers' private property.

Because direct contact with beryllium can cause contact dermatitis and possibly conjunctivitis, proposed section 850.29(a)(2) would require that DOE contractors provide workers with additional protective gear where skin or eye contact with powdered or liquid forms of beryllium is possible. This additional protective gear could include face shields, goggles, gloves, and gauntlets, depending on the nature of the operation and the related skin and eye exposure hazards involved. DOE recognizes that the potential for the development of contact dermatitis or conjunctivitis is mainly associated with contact with soluble forms of beryllium compounds. Nevertheless, DOE believes that the provisions of proposed section 850.29(a)(2) represent prudent industrial hygiene measures for work with all forms of beryllium, particularly in light of the fact that both soluble and insoluble forms of beryllium have been shown to cause chronic ulcerations if introduced into or below the skin via cuts or abrasions.

As clarified in the definition of beryllium in proposed section 850.3, soluble beryllium compounds would not be covered by the proposed rule. DOE omitted soluble beryllium compounds from the definition of beryllium based on information provided by the DOE field offices indicating that soluble beryllium compounds were not used within the DOE complex.

The Department's objective is to prevent the spread of beryllium contamination, thereby reducing the number of workers exposed and the opportunities for potential exposures. In keeping with this objective, proposed sections 850.29(b) through (e) would establish provisions to control the handling, maintenance, cleaning, and disposal of beryllium-contaminated protective clothing and equipment. Specifically, proposed section 850.29(b) would require DOE contractors to ensure that workers do not take contaminated clothing or equipment from the change room or worksite unless specifically authorized to do so for the purposes of cleaning, maintenance, or disposal. Where workers are authorized to remove contaminated clothing and equipment from the change-room or worksite, proposed sections 850.29(b)(1) and (b)(2) stipulate that such materials must be placed in sealed impermeable containers that bear warning labels to clearly identify the contents and appropriate handling precautions. Such warning labels would help ensure appropriate subsequent handling of beryllium-contaminated materials and in preventing inadvertent exposures that could result if laundry, maintenance, or disposal personnel are not aware of the presence of beryllium contamination.

Proposed section 850.29(c) would require that DOE contractors clean, launder, repair, and replace protective clothing and equipment as needed to ensure its continued effectiveness in protecting workers. This section would allow contractors some flexibility in determining the required frequency for laundering protective clothing based on specific work conditions and the potential for contamination. Because DOE believes that certain minimal laundering frequencies must be maintained to ensure that the protective clothing does not contribute to worker exposures, the proposed paragraph stipulates a minimal laundering frequency of at least once a week.

To reduce and minimize the potential for exposures to beryllium during laundering operations, proposed section 850.29(d) would require that DOE contractors launder contaminated clothing using methods that would prevent the release of airborne beryllium in excess of the action level or STEL. DOE would provide DOE contractors the flexibility to determine the most appropriate means to launder contaminated clothes based on their own specific worksite conditions. DOE has, however, included in this section one specific requirement designed to prevent the dispersion of beryllium particles into the workplace atmosphere: proposed section 850.29(e) would prohibit the use of blowing, shaking, or any other means of cleaning that could disperse beryllium particles into the air. This is a well-recognized and accepted industrial hygiene control employed to minimize exposures to airborne particulates.

Proposed section 850.30 would establish the housekeeping provisions of the CBDPP. Good housekeeping practices are necessary in areas where beryllium is used or handled to prevent the accumulation of beryllium-containing dusts on surfaces throughout the workplace. Such accumulations, if not controlled, may lead to reentrainment of beryllium particles into the atmosphere. This potential for beryllium accumulations to become reentrained into the atmosphere increases potential beryllium exposure hazards in locations where beryllium

dusts were originally generated and introduces the potential for such exposures in other work areas. In addition, the uninhibited accumulation of beryllium-containing dust on equipment in the workplace increases the potential for worker exposure to beryllium during the performance of equipment maintenance, handling, and disposal tasks. Accordingly, the housekeeping program focuses on the prevention of accumulation of beryllium-containing dust in the workplace. Because the performance of housekeeping tasks can, in and of itself, lead to worker exposures to beryllium-contaminated dust, the provisions of this housekeeping section also focus on preventing the reentrainment of dust during the performance of housekeeping activities.

Proposed section 850.30(a) would require that DOE contractors conduct routine surface sampling to ensure the effectiveness of housekeeping efforts. Surface sampling has become an accepted method for providing qualitative information on chemical contamination of work surfaces. Unfortunately, surface sampling procedures have not reached the stage of development that would allow an industrial hygienist to predict a personal exposure or a potential airborne concentration of reentrained contaminants. Such sampling, however, can identify the presence of beryllium contamination and thus can provide an indication of the effectiveness of housekeeping efforts. Accordingly, this proposed requirement is intended only as a housekeeping performance measure and should not be interpreted as a proposed mechanism for measuring, predicting, or controlling airborne concentrations of beryllium. In addition, this proposed requirement would only apply to removable or loose surface contamination which could become reentrained into the workplace atmosphere.

Affected sites throughout the Department have already established beryllium surface contamination levels to ensure the effectiveness of their housekeeping procedures. According to representatives from these sites, existing surface contamination limits employed throughout the DOE complex range from 1 to 5 μg/100 cm^2, with the majority of the sites using approximately 3 μg/100 cm^2 (e.g., Pantex, Lawrence Berkeley National Laboratory, Y–12, Rocky Flats). Accordingly, DOE has adopted the 3 μg/100 cm^2 level in the proposed rule.

The use of diverse sampling methods (differences include type of sample media, type of solvent (if any) on the sample media, area sampled, etc.) may easily lead to the reporting of inconsistent or incorrect results. To reduce the variability in reported surface contamination across the DOE complex, DOE recommends the use of a single sampling method: NIOSH method 9100 (NIOSH Manual of Analytical Methods (NMAM), 4th Edition, August 15, 1994, Lead in Surface Wipe Samples). This method may have to be modified for surfaces smaller than 100 cm^2 using a procedure such as that described in Appendix D of 10 CFR part 835.

Proposed sections 850.30(b) and (c) would establish provisions for the use of housekeeping methods that will prevent or minimize the reentrainment of beryllium particulates into the workplace atmosphere. Specifically, proposed section 850.30(b) would require the use of wet methods or vacuuming for the cleaning of beryllium-contaminated floors and other surfaces, and prohibit the use of compressed-air or dry methods for such activities. Proposed 850.30(c) would require the use of HEPA filters in all vacuuming operations for contaminated or potentially contaminated surfaces and would further require filter replacement as needed to maintain the capture efficiency of the vacuum. The use of wet methods for reducing or minimizing the dispersal of dust during general housekeeping tasks such as sweeping is a common industrial hygiene practice, as is the use of HEPA filters, which prevent the spread of dust by effectively collecting the dust as it is vacuumed or brought into a hood.

As discussed in earlier sections of this analysis, the movement of contaminated or potentially contaminated equipment from a regulated area to a nonregulated area may result in the spread of beryllium contamination. To prevent this potential spread of contamination in the performance of housekeeping activities that would be required under this rule, proposed section 850.30(d) would require that cleaning equipment used in areas where surfaces are contaminated or potentially contaminated with beryllium be labeled, controlled, and not used in other clean areas of the facility. These procedures are similar to those required under OSHA's Asbestos standard for any equipment used during cleanup or removal of asbestos from buildings.

Proposed section 850.31 would establish the waste disposal provisions of the CBDPP. Like many of the regulated area, protective clothing and equipment, and housekeeping provisions of the proposed rule, the waste disposal provisions of this section focus on minimizing the spread of beryllium contamination throughout the facility. As mentioned throughout this NOPR, such contamination control measures are necessary to achieve the Department's objectives of reducing the number of workers exposed to beryllium and minimizing the opportunities for beryllium exposures.

DOE believes that the most effective way to control the spread of contamination resulting from waste disposal activities is to first prevent or minimize the generation of beryllium waste. Accordingly, proposed section 850.31(a) would require that DOE contractors control the generation and disposal of beryllium waste through good housekeeping practices, the performance of appropriate hazard analyses for operations with the potential to generate waste, and the application of waste minimization principles. Good housekeeping practices aid in this effort by continually removing beryllium dust accumulations from work surfaces, thereby reducing the potential for, and significance of, contamination of workplace equipment. The performance of hazard analyses on operations with the potential to generate wastes can help DOE contractors identify potential sources of wastes and evaluate possible controls that could be implemented to prevent or reduce waste generation. Other waste minimization practices, such as minimizing the equipment and material that is exposed to beryllium contamination, will also assist in reducing the amount of material that must be disposed of as beryllium or beryllium-contaminated waste, thus reducing the potential beryllium exposure hazards associated with waste disposal activities.

Proposed section 850.31(b) would require that DOE contractors dispose of all waste, scrap, debris, bags, containers, small equipment, and clothing contaminated with beryllium in sealed impermeable bags or other closed impermeable containers that are labeled in accordance with section 850.37. DOE believes these waste disposal provisions are necessary to prevent the reentrainment of beryllium contamination into the workplace atmosphere. Warning labels are necessary to ensure that workers are aware that containers or bags contain beryllium contamination so that they can take appropriate precautions.

Proposed section 850.32 would establish the beryllium-related emergency provisions of the CBDPP. Such provisions are particularly important in light of suggestions made by several participants in the public forums that a single, high-level beryllium exposure may have been the

cause of CBD occurring among several workers thought to have no exposure or only incidental, low-level exposures to beryllium.

Proposed section 850.32(a) would require that DOE contractors develop and implement procedures to address potential beryllium emergency situations for each facility engaged in beryllium operations. The Department's intent is for DOE contractors to evaluate their respective beryllium-related operations to determine possible emergency scenarios. Then, based on these facility- and operation-specific scenarios, the contractors would fashion procedures to specifically address the types of emergencies that could be encountered at the facility. DOE believes that this tailored approach would provide workers the best opportunity to be prepared in the event of an emergency, enabling them to respond in an appropriate and safe manner and to remedy site conditions with minimal potential for additional exposures to themselves or other personnel in the facility.

Proposed section 850.32(a)(1) would require that DOE contractors establish procedures to alert workers in the event of a beryllium emergency. By ensuring that workers are continually aware of how they are expected to respond in the event of an emergency and by ensuring that they receive prompt notification or warning when an emergency situation has developed, DOE contractors would enable workers to quickly implement the actions needed for protection while bringing an emergency situation under control.

Proposed section 850.32(a)(2) would require DOE contractors to ensure that workers engaged in the cleanup of emergency spills of beryllium, or in handling other emergency situations involving beryllium contamination, are provided with and wear protective clothing and equipment as specified in this proposed rule. DOE believes that such protective equipment is necessary to adequately protect workers from exposures to beryllium. DOE feels that this protection is even more critical when responding to uncontrolled situations where airborne levels of beryllium may not be adequately characterized and may exceed the PEL.

Because even the best emergency response procedures will be ineffective if personnel required to implement the procedures are not aware of them, DOE has included in proposed section 850.32(b) a requirement that contractors train affected workers on required emergency procedures.

Proposed section 850.33 would establish the medical surveillance provisions of the CBDPP. Proposed sections 850.33(a) and (b) propose that DOE contractors and Field Organizations designate a SOMD to be responsible for administering the respective contractor and federal medical surveillance programs required by this rule. Proposed section 850.33(c) would also require that the written medical surveillance program that is required for inclusion in the CBDPP be submitted and reviewed by the DOE Office of Environment, Safety and Health and approved by the head of the cognizant DOE Field Organization. DOE review and approval authority is necessary to ensure that contractor medical surveillance requirements are consistent with the intent of the CBDPP and that these programs are applied uniformly across the DOE complex.

Proposed section 850.33(d) would require DOE contractors to establish and implement a medical surveillance program for all beryllium workers exposed at or above the action level or above the STEL. Under this program, DOE would offer medical evaluations to affected beryllium workers. Once an employee is enrolled in the program, he or she would remain enrolled for the duration of employment at that site. The program would have two purposes: (1) Ensure the prompt identification and proper treatment of workers who become sensitized to beryllium or develop CBD, and (2) evaluate and ensure the effectiveness of the CBDPP in preventing CBD by determining the incidence of CBD in the workforce and by identifying risk factors associated with the development of CBD and beryllium sensitization.

Proposed section 850.33(e) would require that DOE contractors provide the SOMD with the information needed to administer the medical surveillance program. This information would include, but may not be limited to, the baseline beryllium inventory, hazard assessment, and exposure monitoring data, as well as information regarding the identity and nature of activities or operations on the site that are covered under the CBDPP, the related duties of beryllium workers, and the types of personal protective equipment employed in the performance of these duties.

Proposed section 850.33(f) would require the SOMD to establish and maintain a list of beryllium workers in the medical surveillance program based on records and other information regarding the identity of beryllium workers. Current employees who are at risk for CBD because of past beryllium operations would not be included on this list or covered under this proposed rule. Rather, they would be identified and offered medical surveillance under a separate, directly funded program.

The Department views medical surveillance as a primary tool for determining the extent of CBD risk in an employee population. The list developed under section 850.33(f)(1) would establish the population of beryllium workers who may be eligible for medical surveillance. The Department's expectation is that SOMDs will use inclusive criteria for identifying beryllium workers to be covered under medical surveillance. In addition, proposed section 850.33(f)(2) clarifies DOE's intention that SOMDs refine the list of beryllium workers based on subsequent analyses of medical surveillance results required under proposed section 850.33(k). For example, the results of Be-LPTs would be used to determine risk factors that appear to be associated with CBD. Based on the apparent risk factors, the SOMD would adjust the surveillance program to better identify workers at risk of developing CBD.

Proposed section 850.33(g) would require the SOMD to provide the examining physician with (1) a copy of this rule, (2) a description of the workers' relevant duties as they pertain to beryllium exposure, (3) records of the workers' beryllium exposure, (4) a description of personal protective and respiratory protective equipment in current or anticipated use, and (5) any relevant information from previous medical examinations of the workers that is not otherwise available to the examining physician. The Department believes that this information is necessary to ensure that the physician can make informed decisions regarding the required content of the medical evaluation and the subsequent development of recommendations related to each beryllium worker's work.

Proposed section 850.33(h)(1) would clarify that DOE contractors must provide required medical examinations and procedures to beryllium workers and accepted applicants at no cost to the workers and accepted applicants at a time and place convenient to them. In addition to minimizing the financial burden on affected workers, DOE believes that this provision will encourage DOE contractors to minimize the levels of beryllium exposures in the workplace and the number of workers exposed or potentially exposed to beryllium. DOE also believes that this provision will help ensure that workers obtain proper medical evaluations.

Proposed section 850.33(h)(2) would specify that DOE contractors must provide baseline medical evaluations to

beryllium workers who qualify for medical surveillance. DOE believes that such baseline medical evaluations are necessary to ensure that beryllium workers can safely perform assigned duties in areas that may present the potential for exposure to beryllium. In addition, DOE believes that the proper evaluation and documentation of each worker's health status is essential for determining whether future health problems may be related to occupational exposure to beryllium.

Proposed section 850.33(h)(3) would supplement the baseline medical evaluation requirement of proposed section 850.33(h)(2) by requiring that DOE contractors offer annual medical evaluations to beryllium workers who qualify for medical surveillance. Such annual evaluations shall be offered as long as the beryllium workers work in areas where beryllium is present at levels at or above the action level or above the STEL. DOE believes that such periodic medical evaluations would be critical to ensuring the early identification and treatment of beryllium sensitization and CBD. This proposed section further clarifies that in cases where beryllium workers no longer work in areas where beryllium is present at levels at or above the action level or above the STEL, the requirement for annual medical evaluations may be reduced to once every 3 years. DOE believes that this continued surveillance is warranted due to the extended latency period associated with the development of CBD.

Both proposed sections 850.33(h)(2) and (h)(3) would also establish the minimum required content of the baseline and periodic medical evaluations, respectively. Among these minimum requirements for both types of evaluations is the need to conduct a Be-LPT. The Be-LPT is the only available laboratory test for determining individual immune response to beryllium *in vitro*. Its use in a surveillance program would permit detection of beryllium-related health effects at a preclinical stage. A positive Be-LPT would indicate the need for further evaluation to determine the presence of CBD. The use of the Be-LPT as an evaluation tool would not only allow the earliest opportunity for diagnosis and treatment of CBD, but would also assist in identifying unhealthy working conditions or operations and deficiencies in the CBDPP.

In addition to the Be-LPT, some medical experts recommend that a chest radiograph (X-ray) and spirometry be obtained prior to exposure to beryllium to establish a baseline for possible comparison with future test results. Spirometry involves measuring the amount of air entering and leaving the lungs. Accordingly, proposed section 850.33(h)(2) would further specify that baseline evaluations also include a chest radiograph (X-ray) and spirometry. However, because neither chest radiography nor spirometry has proven to be any more predictive in identifying the presence of CBD than symptom questionnaires, these additional tests would not be mandated as a part of the periodic evaluation required under proposed section 850.33(h)(3). Instead, the need for these tests would be left to the discretion of the examining physician. DOE believes that the examining physician is in the best position to determine the need for such additional tests based on the unique circumstances associated with each worker's exposure scenarios and health status.

Proposed section 850.33(h) would not establish a requirement for termination evaluations. DOE believes termination evaluations for beryllium workers who are reassigned to non-beryllium work would not be needed because periodic evaluations will continue for as long as the worker is employed by the DOE contractor. Termination evaluations for beryllium workers who resign or retire from employment with DOE contractors would also not be necessary because the Department intends to establish a separate, directly funded program that offers medical examinations to former employees at risk for developing CBD. DOE recognizes that many sites already have an internal requirement to provide termination medical evaluations to workers upon their separation from employment. Nothing in this proposed rule would preclude the SOMD from continuing this practice.

Proposed section 850.33(h)(4) would require that DOE contractors ensure that all medical evaluations and procedures be performed by or under the supervision of a licensed physician who is familiar with the health effects of beryllium. Conducting a medical surveillance program for beryllium workers requires specialized medical knowledge and crucial clinical decision-making. DOE believes that a licensed physician with specialized knowledge of the health effects of beryllium is the most appropriate medical professional to provide medical evaluations. A physician is also needed to answer health-related questions and to discuss and interpret abnormal clinical findings with the affected worker.

Proposed section 850.33(i) would establish requirements for referrals for additional diagnostic evaluation. Specifically, beryllium workers who have two or more positive Be-LPTs or other signs and symptoms of CBD, would be referred by the examining physician for diagnostic evaluation. Such an evaluation would be performed by a pulmonary medicine, occupational medicine, or other clinic with the specialized equipment and examination protocols required to definitively differentiate between CBD and other lung disease. DOE believes that this proposed referrals provision is warranted due to the unusual nature of CBD and the fact that not all physicians are familiar with the evaluation of beryllium-exposed patients.

Proposed section 850.33(j) would establish requirements for physicians' written reports and recommendations. Proposed section 850.33(j)(1) would ensure that employees and accepted applicants are informed of the results of their medical evaluations and tests within 15 days of completion of the evaluations. In addition, proposed section 850.33(j)(2) would specify that within this same 15 day time period, the DOE contractor obtain a copy of a limited version of the physician's report. This limited version must include any recommendations for restricting the employee from working with beryllium, or for wearing protective equipment.

Proposed section 850.33(k) would establish the requirement for a routine and systematic analysis of medical, job, and exposure data. The purpose of this requirement is to establish a program that would follow the public health model for disease surveillance programs. Information would be collected and analyzed so that the prevalence of disease could be accurately described and conclusions could be reached on causes or risk factors for the disease. This data analysis would provide an effective performance measurement mechanism for use in correction and improvement of the CBDPP. Proposed section 850.33(k)(1) would require that the results of these analyses be used by the SOMD to determine which workers should be offered medical surveillance and the need for additional exposure controls. In addition, proposed section 850.33(k)(2) would require that the SOMD provide copies of the data analyses to the contractor for performance feedback information.

Proposed section 850.34 would establish medical removal requirements. Specifically, this section would require that upon recommendation of the SOMD, DOE contractors shall give workers with two positive Be-LPTs or a

diagnosis of CBD the option of: (1) placement in another position without occupational exposure to beryllium, or (2) continued employment in the current position with actual or potential exposure to beryllium.

Proposed section 850.34(a) would require that, with the written consent of the worker, DOE contractors remove a beryllium worker from exposure to beryllium or postpone an accepted applicant's start of active duty as a beryllium worker if the SOMD recommends such actions due to confirmed CBD, two or more positive Be-LPTs results, or while other signs or symptoms are being evaluated for their relation to CBD. Proposed section 850.34(a)(1) would further require that DOE contractors provide the affected beryllium worker a follow-up medical examination to determine whether the worker may be returned to his or her beryllium work or whether the worker should be permanently removed from working in beryllium areas.

Proposed section 850.34(a)(2) would provide affected beryllium workers and accepted applicants with the option to decline the medical removal or restriction by signing an informed consent waiver. DOE notes that prudent medical practice suggests that workers with two or more positive Be-LPTs or diagnosis of CBD should avoid additional exposure to beryllium however, since no medical evidence exists to suggest that removal from exposure will alter the course of disease, DOE believes that it is ultimately the affected worker's decision whether to remain in a job with potential or actual beryllium exposure.

For beryllium workers or accepted applicants who choose to accept restriction from continued work with beryllium, proposed section 850.34(a)(3) would require DOE contractors to make reasonable efforts to find and offer alternative employment. This section clarifies that the contractor is not required to displace an existing worker in order to create a vacancy, nor is the contractor required to promote the affected worker or accepted applicant or pay for job placement training costs in excess of $6,000.00. The contractor is also not required to provide training that takes longer than 6 months to complete.

Proposed section 850.34(b) would establish the requirement for medical removal protection benefits for beryllium workers who choose to accept a physician's recommendation to be removed from working with beryllium. Specifically, proposed section 850.34(b) would establish a requirement to protect an employee's base pay, benefits, and seniority should that worker accept restriction from working with beryllium. The Department's intent with this provision is that DOE contractors would offer sensitized employees and employees with CBD placement in a job that does not involve exposure to beryllium and that provides base pay and benefits comparable to their current job. Under this provision, if no such job exists within the contractor's organization, DOE contractors may offer the affected workers out-placement assistance to find suitable alternative employment.

Proposed section 850.34(b) would further clarify that DOE contractors would be required to protect the pay and benefits of affected workers for a two-year period. DOE believes that the establishment of a two-year period of protected pay and benefits is fair and would provide sufficient incentive for DOE contractors to put forth the level of job placement effort necessary to find suitable alternative employment that would be acceptable to the affected worker.

One of the main goals of the medical surveillance program is to minimize the disability associated with CBD. The Department believes that the establishment of the medical removal protection benefits of proposed section 850.34(b) is critical to achieving this goal for two reasons: (1) removal from exposure and effective job-placement efforts coupled with early diagnosis and treatment would allow affected workers to continue as productive members of the workforce, and (2) providing beryllium workers with a reasonable level of assurance that a finding of sensitization or diagnosis of CBD would not lead to the loss of their employment would further encourage worker participation in the medical surveillance program.

Proposed section 850.35 would establish the medical consent provisions of the proposed rule. Because DOE intends worker participation in medical surveillance to be voluntary, the provisions of this section would be necessary to ensure that beryllium workers receive the information they need to make an informed decision regarding their participation in the program.

Proposed section 850.35(a) would require that DOE contractors provide beryllium workers with information on the benefits and risks of the medical tests and examinations offered as part of medical surveillance. This information must be provided at least one week prior to any examinations or tests. In addition to providing this information, the Department also believes that DOE contractors should take reasonable efforts to ensure that workers understand the material. Accordingly, proposed section 850.35(a) would further clarify that workers shall have the opportunity to ask questions and have their questions answered prior to the performance of a medical evaluation.

Proposed section 850.35(b) would also require that DOE contractors provide beryllium workers and accepted applicants with a summary of the medical surveillance program, information explaining the purpose of the data, the type of data needed to be collected, how the data will be maintained, and the confidentiality of medical records will be protected. This information must also be provided at least one week prior to any examinations or tests.

Proposed section 850.35(c) would require DOE contractors to use the informed consent form approved by the Assistant Secretary for Environment, Safety and Health (EH–1) to obtain the signed consent of a beryllium worker prior to performance of a medical examination. The signature of the beryllium worker is intended to document that he or she consented to being tested. The signature of the examining physician is intended to document the commitments made to the beryllium worker. An example of the consent form can be found in Appendix A to Part 850.

Proposed section 850.35(d) would ensure that a beryllium worker or accepted applicant who develops a beryllium-related health effect, such as beryllium sensitization or CBD, would be given the information by the contractor that he or she needs to make an informed decision whether to accept medical removal. As clarified in this section, this information would include, at a minimum, information on opportunities for alternative placement with the contractor, out-placement benefits if no suitable positions exist within the contractor's organization, and any available long-term medical and disability insurance benefits for which the worker may qualify. The goal of this provision is to provide the worker with detailed information on the risks and benefits of accepting or rejecting medical removal to assist the worker in making the best possible decision.

Proposed section 850.35(e) would clarify that the SOMD must first provide the affected worker or accepted applicant the opportunity to ask questions and have their questions answered prior to obtaining the workers agreement to medical removal or before

having the worker sign a medical removal waiver.

Proposed section 850.36 would establish requirements for training and counseling regarding worker exposure to beryllium and the potential health effects associated with such exposure. DOE believes that such worker training is necessary because the appropriate implementation of the required workplace procedures of the CBDPP would ultimately rest upon the front-line workers who will actually be performing work on, with, or near beryllium or beryllium-contaminated materials. If these workers are not aware of the required procedures or if they do not fully appreciate the significance of these procedures, they cannot be expected to implement the procedures. For this reason, DOE believes that the ultimate success of the proposed CBDPP and the realization of the Department's goal to prevent future occurrences of CBD within the DOE complex depend to a great extent on the training and knowledge of the beryllium workers.

Proposed section 850.36(a) would require contractors to develop and implement a worker training program for all workers who are exposed or potentially exposed to airborne concentrations of beryllium and ensure their participation in the program. DOE recognizes that OSHA's Hazard Communication standard (29 CFR 1910.1200) already requires that DOE contractors provide their workers with similar training regarding the risks associated with all hazardous materials in the workplace. DOE does not intend that contractors would implement two separate and redundant training and information programs to comply with this proposed rule and the Hazard Communication standard. Accordingly, proposed section 850.36(a)(1) would require that DOE contractors' CBDPP training and information programs comply with the Hazard Communication standard as well as address the contents of the CBDPP. Through this provision, DOE intends for its contractors to integrate their CBDPP training and information efforts into their existing Hazard Communication training program, thus minimizing the burden on contractors and providing for a consistent approach to worker training and the communication of workplace hazards.

Proposed section 850.36(a)(2) would require that training be provided to workers prior to initial assignment and at least annually thereafter to ensure that workers are appropriately prepared to recognize the hazards and risks of working with beryllium. The initial training requirement of the paragraph is important to ensure that workers have the information they need to protect themselves before they are actually subject to exposure or potential exposure hazards. Annual training is necessary to reinforce 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 would establish this frequency as a minimum requirement, noting that changes in workplace operations, controls, or procedures, or the availability of new or updated information regarding the health risk associated with exposures to beryllium, may warrant the need for more frequent training.

In addition, proposed section 850.36(a)(3) would require that the training include information regarding beryllium health risk, exposure reduction, safe handling of beryllium and medical surveillance. This proposed section does not limit the contractor from providing training in additional areas.

All training must be conducted in a manner easy to understand so that workers can effectively translate CBDPP training into safe work practices. Training material should be appropriate in content and vocabulary to the education level, literacy, and language background of affected workers. Such targeted training would ensure that all workers, regardless of cultural or educational background, would have the requisite knowledge necessary to reduce and minimize their exposure to beryllium.

To provide additional support to affected workers, proposed section 850.36(b) would establish the requirement for the development and implementation of a worker counseling program that would assist beryllium-sensitized workers and workers diagnosed with CBD. The purpose of the counseling program would be to help communicate to workers the information that they will need to make important health- and work-related decisions and to facilitate the performance of required administrative activities, such as filing workers' compensation claims. Proposed section 850.36(b) would require the communication of information regarding the availability of: the medical surveillance program; medical treatment options; work practices aimed at limiting worker exposure to beryllium; the risk of continued exposure after sensitization; medical benefits; workers' compensation claims; and medical, psychological, and career counseling for workers with CBD or with positive results on Be-LPTs.

Proposed section 850.37 would require DOE contractors to post warning signs and labels to ensure that the presence of and dangers associated with beryllium and beryllium-contaminated materials or areas are communicated to workers.

Proposed section 850.37(a) would require the posting of warning signs at all entranceway locations where regulated areas have been established. This proposed section further requires that these signs bear the following warning:

DANGER
BERYLLIUM CAN CAUSE LUNG DAMAGE
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY

The purpose of these signs would be to minimize the number of persons in a regulated area by warning workers prior to entry. The signs would also alert workers to the fact that they must have the appropriate authorization from their supervisor to enter the 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 exposures to beryllium and thus may not be appropriately equipped for or aware of the need to protect themselves from potential exposures. Warning signs would also serve as a constant reminder to those who work in regulated areas that the potential for exposure to beryllium exists in the area and that appropriate controls must be used.

Proposed sections 850.37(b)(1) and (2) would require that DOE contractors label all containers of beryllium, beryllium compounds, or beryllium-contaminated clothing, equipment, waste, scrap, or debris in accordance with OSHA's Hazard Communication standard (29 CFR 1910.1200). Ensuring that the content and format of the warning labels are consistent with those of OSHA's Hazard Communication standard would provide DOE and its contractors with a consistent and comprehensive approach to alerting workers to beryllium's potential to cause serious disease. The use of such warning labels would also ensure that all those who come in contact with labeled containers are aware of the containers' contents and of the need to implement special handling precautions. Because the effectiveness of the warning labels in achieving these objectives is greatly dependent upon the visibility, accuracy, and understandability of the content of the

labels, proposed section 850.37(a)(2) would further 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 section 850.38 would address requirements for the establishment and maintenance of accurate records to demonstrate effective implementation of the program. Proposed section 850.38(a) would require the collection and maintenance of all beryllium inventory information, hazard assessments, exposure measurements, controls, and medical surveillance data. The Department feels that accurate and retrievable records are essential to the assessment of the adequacy of worker protection programs. Proposed section 850.38(b) would require that records required by this part be maintained in an electronic, easily retrievable format that can be easily transmitted to DOE headquarters when requested. This supplemental requirement would be necessary to facilitate timely, efficient, and cost-effective transfer and analysis of exposure monitoring and medical surveillance data.

Although the Department does not at this time mandate any specific methods or types of records system in the proposed rule, DOE contractors are already required to keep records of beryllium inventory information (29 CFR 1910.1200, Hazard Communication) and hazard assessment, exposure measurement, and medical surveillance data (29 CFR 1910.1020, Access to Employee Exposure and Medical Records). DOE contractors would be encouraged to take advantage of existing recordkeeping systems to minimize the implementation burden.

Proposed section 850.38(c) would also require that DOE and contractors create links between data sets on working conditions and health outcomes to serve as a basis for understanding the beryllium health risk. This linkage of data will assist DOE and contractors in identifying unsafe work practices and defining the exposure-response relationship.

The establishment and maintenance of useful, linked, and easily retrievable records would directly support and be an integral part of successful performance feedback, as described in proposed section 850.40. Combining data facilitates analyses that might be impossible to perform in smaller populations. Combined analyses can identify associations between CBD prevalence and risk factors that might otherwise be missed, and can lead to the development of conclusions based on the predictive value of medical tests used earlier in the analysis process.

Proposed section 850.38(d) specifically states that medical information generated by the CBDPP may only be maintained as a part of the site beryllium workers' medical records. This section further states that the medical information must be maintained separately from other personnel records and in conformity with the Americans with Disabilities Act, the Privacy Act and other applicable laws.

Proposed section 850.39(a) would require that DOE contractors develop and maintain a separate electronic beryllium registry that includes all beryllium workers. This beryllium registry would serve as a repository for collecting and maintaining information on workers who are exposed to long term, low and moderate levels of beryllium. The results of beryllium sensitization testing and/or CBD status of exposed workers will be added to the registry as that information becomes available. As information accrues over time, the disease status of workers as it relates to past beryllium exposure would be determined. The goals of the registry would be to provide early guidance as to the effectiveness of exposure control mechanisms and intervention programs and assess the burden of health effects related to beryllium exposure. The beryllium registry would also facilitate the conduct of epidemiologic studies to better understand the development of the disease and better identify those at risk.

Section 850.39(b) would specify the required content of the registry and establish that the registry and subsequent updates be forwarded electronically on a semi-annual basis to the Office of Environment, Safety and Health, Office of Epidemiologic Surveillance. For most sites, the electronic transfer of data would be similar to that used for the existing Epidemiologic Surveillance program. The Office of Epidemiologic Surveillance would be responsible for the administration and policy decisions related to the beryllium registry. This office would also provide technical support to the SOMD as required.

The SOMD would provide demographic data, exposure data, and medical screening results. Personal identifying information would be required to link exposure data to an individual and to eliminate duplicate reports for each worker. This information would be collected pursuant to and contained within DOE Record System 88 ''Epidemiologic and Other Studies, Surveys, and Surveillance.''

Proposed section 850.39(c) would require that information contained in the beryllium registry be disclosed only in a manner consistent with applicable legal requirements, such as the Privacy Act. Use of records under this act is governed by specific routine uses.

DOE believes that the existence of a Department-wide registry of beryllium workers and CBD and sensitization cases would facilitate future research on improved diagnostic tests and treatments for the disease.

Proposed section 850.40 would establish the performance feedback provisions of the CBDPP. Performance feedback mechanisms are essential to ensure that the effectiveness of the CBDPP is evaluated on a continual basis and that the necessary changes are made to ensure the protection of worker health. This section would mandate the use and analysis of the data collected through the reporting requirements in proposed section 850.38 to maintain and improve each element of the CBDPP.

Proposed section 850.40(a) would require that DOE contractors conduct periodic analysis and assessment of monitoring results, hazards identified, medical surveillance results, attainment of exposure reduction and minimization goals, and occurrence reporting data. The Department believes that the analysis of these data would be important to the continuous improvement of the program. In addition, this information would provide insights to better understand and manage program implementation through the use of performance measures developed on a site-by-site basis.

To ensure that all workers have the necessary information to safely perform their assigned tasks, proposed section 850.40(b) would require that results of performance assessments conducted in accordance with this part be provided to line managers, planners, worker protection staff, workers, medical staff, and others. This requirement would improve communication among employees, managers, and others to more effectively evaluate and monitor program implementation and effectiveness.

VII. Procedural Requirements

A. Review Under Executive Order 12866

Today's 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, today's 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 the NOPR.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, requires that an agency prepare an initial regulatory flexibility analysis for any rule 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.

DOE obtained information for 15 potentially affected sites to determine if the proposed rule, if promulgated, would have a significant economic impact on small entities. This information indicates that no small businesses currently would be affected by the proposed rule. A more detailed account of this information appears in the Economic Analysis prepared under the requirements of Executive Order 12866. Furthermore, DOE expects that any potential economic impact of this rule on small businesses would be minimal because businesses at DOE sites perform work under contracts to DOE or the prime contractor at the site. Increased funding may be available under this contractual arrangement to offset much of the impact that the rule would impose. In addition, many of the requirements of this part would apply to prime contractors and not subcontractors. Currently none of the prime contractors at affected DOE sites are small businesses.

For the foregoing reasons, DOE certifies that today's proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. DOE invites public comment and information on this certification.

C. Review Under the Paperwork Reduction Act

The proposed collections of information in this proposed rule have been submitted to the Office of Management and Budget (OMB) for review and approval under section 3507(d) of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number assigned by OMB.

This section describes the collections of information in the proposed rule and provides estimates of the annual burden on respondents. The burden estimates include the total time, effort, and financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for DOE. DOE invites public comment on: (1) Whether the proposed collections are necessary for the performance of DOE's functions, including whether the information will have practical utility; (2) the accuracy of DOE's estimates of the burden of the proposed collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collections of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments should be addressed to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, OMB, 725 17th Street, NW, Washington, DC 20503. Persons submitting comments to OMB also are requested to send a copy to the contact person at the address given in the **ADDRESSES** section of this notice. Requests for a copy of the Department's Paperwork Reduction Act Submission to OMB should be directed to the contact person.

Title: Reporting and recordkeeping requirements for the Chronic Beryllium Disease Prevention Program.

Abstract: The proposed rule would require DOE contractors at sites where beryllium is present to: develop and submit an initial CBDPP to DOE for approval (§ 850.10); periodically revise the CBDPP (§ 850.10); conduct a baseline inventory of beryllium at the site (§ 850.20); notify workers of exposure monitoring results (§ 850.24); develop and maintain a registry of beryllium workers (§ 850.39); require workers to sign a consent form for beryllium work and medical surveillance (§ 850.35); establish and maintain records related to the beryllium inventory and hazard assessment, exposure monitoring, workplace controls and medical surveillance (§ 850.38); and establish a performance feedback process for continually evaluating and improving the CBDPP (§ 850.40). DOE has determined that these collections of information are necessary for implementation of an effective CBDPP.

The burden of compliance with the collections of information in this rule will depend upon the nature of each requirement and the number and type of respondents. DOE estimates that DOE contractors at 15 facilities would be required to develop and submit CBDPPs to DOE for approval and, thereafter, implement the CBDPPs including the collections of information. Approximately 1,057 workers at the 15 facilities may be exposed to beryllium and, therefore, may be subject to certain of the information collection requirements.

DOE estimates the total startup costs at $348,781. Initial CBDPPs were required from all of the affected facilities by DOE Notice 440.1. DOE estimates that 2,549 professional hours and 637 clerical hours were required to prepare and submit the initial CBDPPs, at a total cost of $112,220. DOE estimates that the baseline inventory of beryllium will require 5,026 professional hours and 2,417 clerical hours, for a total cost of $234,631. Development of the beryllium registry is expected to cost $1,930, which represents 168 hours of clerical time.

DOE estimates the total recurring, annual paperwork burden at $318,860. This includes 3,498 professional hours ($142,047) and 15,375 clerical hours ($176,812). Recordkeeping would impose the largest recurring monetary cost (an estimated 10,993 clerical hours). Other recurring paperwork burdens are attributable to submitting performance feedback reports, worker notification of exposure monitoring, obtaining signed medical consent forms from workers, maintenance of the beryllium registry, revising the CBDPP plan on an annual basis, obtaining written reports from physicians regarding the results of medical exams, and performing analyses of medical data.

DOE estimates the total annualized cost of paperwork burdens for the Chronic Beryllium Disease Prevention Program would be $368,518.

D. Review Under the National Environmental Policy Act

DOE is reviewing the promulgation of 10 CFR part 850 under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality regulations for implementing NEPA, and DOE's NEPA implementing

procedures (10 CFR part 1021). DOE has prepared a draft Environmental Assessment (EA) (DOE/EA 1249) to support a decision on whether to issue a finding of no significant impact or to prepare an environmental impact statement for this proposed rule. Requests for copies of the draft EA and any comments on the EA should be submitted to the address indicated in the **ADDRESSES** section of this NOPR. Copies of the draft EA may also be downloaded from the ''Chronic Beryllium Disease Prevention Program'' home page on the Internet. The address is *http://tis.eh.doe.gov/be/* DOE will consider any comments on the draft EA and the proposed rule before completing the NEPA process.

E. Review Under Executive Order 12612

Executive Order 12612, 52 FR 41685 (October 30, 1987), requires that regulations, rules, legislation, any other policy actions be reviewed for any substantial, direct effects on states, on the relationship between the national government and the states, or in the distribution of power and responsibilities among various levels of government. If there are sufficient substantial, direct effects, then the Executive Order requires a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action.

This proposed rule, if promulgated as a final rule, would apply only to DOE facilities. It would not have a substantial direct effect on the institutional interests or traditional functions of the states.

F. 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 final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each federal agency to prepare a written assessment of the effects of any federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year. It also requires a federal agency to develop an effective process to permit timely input by elected officers of State, local, and tribal governments on a proposed ''significant intergovernmental mandate,'' requires an agency to develop a plan for giving notice and opportunity to timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. The proposed rule published today does not contain any federal mandate. Thus, these requirements do not apply.

VIII. Public Comment Procedures

A. Written Comments

Interested individuals are invited to participate in this proceeding by submitting data, views, or arguments with respect to this proposed rule. To help the Department review the submitted comments, commentors are requested to reference the paragraph(s) (e.g., 850.3[a]) to which they refer where possible.

Ten copies of written comments should be submitted to the address indicated in the **ADDRESSES** section of this notice. Comments should be identified on the outside of the envelope and on the documents themselves with the designation ''Beryllium Rule, Docket No. EH–RM–98–BRYLM.'' Should anyone wishing to provide written comments be unable to provide ten copies, alternative arrangements can be made in advance with the Department.

All submitted comments will be available for public inspection as part of the administrative record on file for this rulemaking, which is in the DOE Freedom of Information Office Reading Room at the address indicated in the **ADDRESSES** section of this NOPR.

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 one complete copy of the document, as well as two copies, if possible, from which the information has been deleted. The Department will make its own determination as to the confidentiality of the information and treat it accordingly.

B. Public Hearings

Public hearings will be held at the times, dates, and places indicated in the **DATES** and **ADDRESSES** sections 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 number in the **DATES** section of this NOPR. The person should provide a daytime phone number where he or she may be reached. Persons requesting an opportunity to speak will be notified as to the approximate time they will be speaking. Each presentation is limited to 10 minutes. Persons making oral presentations should bring ten copies of their statements to the hearing and submit them at the registration desk.

DOE reserves the right to select the persons 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 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 transcript of each hearing will be made available to the public. DOE will retain the record of the full hearing, including the transcript, and make it available for inspection in the DOE Freedom of Information Office, at the address provided in the **ADDRESSES** section of this NOPR. Transcripts may be purchased from the court reporter.

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

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List of Subjects in 10 CFR Part 850

Hazardous waste, Occupational safety and health, Reporting and recordkeeping requirements, Safety.

Issued in Washington, DC on October 30, 1998.

Bill Richardson,

Secretary of Energy.

For the reasons set forth in the preamble, Title 10, Chapter III of the Code of Federal Regulations is proposed to be amended by adding Part 850 to read as set forth below.

PART 850—CHRONIC BERYLLIUM DISEASE PREVENTION PROGRAM

Subpart A—General Provisions

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850.1 Scope.
850.2 Applicability.
850.3 Definitions.
850.4 Enforcement.
850.5 Dispute resolution.

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850.29 Protective clothing and equipment.
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850.33 Medical surveillance.
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850.38 Recordkeeping and use of information.
850.39 Beryllium registry.
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Appendix A to Part 850—Chronic Beryllium Disease Prevention Program Informed Consent Form

Appendix B to Part 850—Questions and Answers Concerning the Beryllium-Induced Lymphocyte Proliferation Test (Be-LPT), Medical Records, and the DOE Beryllium Registry

Authority: 42 U.S.C. 2201.

Subpart A—General Provisions

§ 850.1 Scope.

This part establishes a chronic beryllium disease prevention program (CBDPP) that supplements and is integrated into existing worker protection programs that are established for Department of Energy (DOE) employees and DOE contractor employees.

§ 850.2 Applicability.

(a) This part applies to:

(1) DOE offices responsible for DOE beryllium activities and DOE employees exposed or potentially exposed to beryllium at DOE-owned or -leased facilities; and

(2) DOE contractors and contractor employees with operations or activities involving exposure or the potential for

exposure of employees to beryllium at DOE-owned or -leased facilities.

(b) This part does not apply to:

(1) Beryllium articles; and

(2) DOE laboratory operations involving beryllium that are subject to the requirements of 29 CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories.

§ 850.3 Definitions.

(a) As used in this part:

Accepted applicant means a person who has accepted an offer of employment in beryllium work at a DOE facility but who has not begun performing beryllium work.

Action level means the level of airborne concentration of beryllium established pursuant to § 850.23 of this part that, if exceeded, requires the implementation of worker protection provisions specified in that section.

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

Beryllium means elemental beryllium and any insoluble beryllium compound or alloy containing 0.1 percent beryllium or greater that may be released as an airborne particulate.

Beryllium article means a manufactured item that is formed to a specific shape or design during manufacture that has end-use functions that depend in whole or in part on its shape or design during end use and that does not release beryllium or otherwise result in exposure to airborne concentrations of beryllium under normal conditions of use.

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 facility.

Beryllium-induced lymphocyte proliferation test (Be-LPT) is an in vitro measure of the beryllium antigen-specific, cell-mediated immune response.

Beryllium worker means a current worker who is exposed or potentially exposed to airborne concentrations of beryllium at or above the action level or above the STEL or who is currently receiving medical removal protection benefits.

Breathing zone is defined as a hemisphere forward of the shoulders, centered on the mouth and nose, with a radius of 6 to 9 inches.

DOE means the U.S. Department of Energy.

DOE beryllium activity means an activity taken for, or by, DOE that can expose workers to beryllium, including but not limited to design, construction, operation, or decommissioning. The activity may involve one DOE facility or operation or a combination of facilities and operations.

DOE contractor means any entity under contract (or its subcontractor) with DOE with responsibility to perform beryllium activities at DOE facilities.

DOE facility means any facility operated by or for DOE.

High-efficiency particulate air (HEPA) filter means a filter capable of trapping and retaining at least 99.97 percent of 0.3 micrometer monodispersed particles.

Immune response refers to the series of cellular events by which the immune system reacts to challenge by an antigen.

Medical removal protection benefits are employment rights established by § 850.34 of this part for beryllium workers who are removed temporarily from work in regulated areas or who voluntarily accept permanent medical removal from regulated areas following tests that confirm beryllium sensitivity or CBD.

Regulated area means an area or physical location demarcated by the contractor in which the airborne concentration of beryllium exceeds, or can reasonably be expected to exceed, the action level or the STEL.

Short term exposure limit (STEL) means the short term exposure limit established pursuant to § 850.22(b) of this part.

Site occupational medicine director (SOMD) means the physician responsible for the overall direction and operation of the site occupational medicine program.

Surface contamination is the presence of beryllium on work surfaces, which may cause skin irritation by direct contact with damaged skin or which may present an airborne hazard when reentrained into the workplace air.

Worker means a person who performs work for or on behalf of DOE, including a DOE employee, an independent contractor, a DOE contractor employee, or any other person who performs work at a DOE facility.

Worker exposure means the exposure to airborne beryllium that would occur if the worker were not using respiratory protective equipment.

Terms used in this part that are undefined but that are defined in the Atomic Energy Act shall have the same meaning as under the Atomic Energy Act.

§ 850.4 Enforcement.

DOE may take appropriate steps under its contracts with DOE contractors to ensure compliance with this part, including contract termination or reduction in fee.

§ 850.5 Dispute resolution.

Disputes arising under this part that are brought by beryllium workers and accepted applicants shall be resolved through applicable grievance-arbitration processes or, where such processes are not available, through referral to the Department's Office of Hearings and Appeals. The procedures in 10 CFR part 1003, subpart G, shall apply to resolution of disputes by the Office of Hearing and Appeals.

Subpart B—Administrative Requirements

§ 850.10 Development and approval of the CBDPP.

(a) Preparation and Submission of Initial CBDPP to DOE. (1) DOE contractors responsible for DOE beryllium activities at DOE facilities shall ensure that a CBDPP is prepared for their respective facility and submitted to the appropriate DOE Field Organization before beginning beryllium activities, but no later than [90 days after the effective date of the final rule] of this part.

(2) Where there are separate sections addressing the activities of particular contractors at the facility, the DOE contractor designated by the DOE Field Organization shall review and approve those sections so that a single consolidated CBDPP for the facility is submitted to the DOE Field Organization for review and approval.

(b) DOE Review and Approval. Heads of DOE Field Organizations shall review and approve the CBDPPs.

(1) The initial CBDPP and any updates shall be considered approved 90 days after submission if not approved or rejected by DOE earlier.

(2) DOE contractors shall furnish a copy of the approved CBDPP, upon request, to the DOE Assistant Secretary for Environment, Safety and Health or designee, DOE program offices, and affected workers or their designated representatives.

(c) Update. DOE contractors shall submit an update of the CBDPP to the appropriate DOE Field Organization for review and approval whenever a significant change or significant addition to the CBDPP is made or a change in contractor or subcontractor occurs. CBDPPs shall be reviewed at least annually and updated as necessary.

(d) Labor Organizations. If a DOE contractor employs beryllium workers who are represented for collective bargaining agreements by labor

organizations, the contractor must give those organizations timely notice of the development and implementation of the CBDPP and any updates thereto and must, upon timely request, bargain concerning implementation of this part, consistent with the National Labor Relations Act.

§ 850.11 General CBDPP requirements.

(a) The CBDPP shall specify the existing and planned operational tasks that are within the scope of the CBDPP. The CBDPP shall augment and be integrated, to the extent feasible, into the existing worker protection programs that cover activities at the facility.

(b) The detail, scope, and content of the CBDPP for DOE beryllium activities shall be commensurate with the hazard of the activities performed, but in all cases the CBDPP shall:

(1) Include formal plans and measures for maintaining exposures to beryllium at or below the permissible exposure levels (PELs);

(2) Satisfy each requirement in subpart C of this part;

(3) Contain provisions for:

(i) Minimizing the number of current workers exposed and potentially exposed to beryllium;

(ii) Minimizing the number of opportunities for workers to be exposed to beryllium; and

(iii) Setting specific exposure reduction and minimization goals that are appropriate for the DOE activities covered by the CBDPP to further reduce exposure below the exposure limits prescribed in section 850.22.

§ 850.12 Implementation.

(a) DOE contractors shall manage and control beryllium exposures in all DOE beryllium activities consistent with the approved CBDPP.

(b) No DOE worker or DOE contractor worker shall take or cause any action inconsistent with the requirements of:

(1) This part,

(2) An approved CBDPP or any other program, plan, schedule, or other process established by this part,

(3) Any other Federal statute or regulation concerning the exposure of workers to beryllium at DOE facilities.

(c) No task involving potential beryllium exposure that is outside the scope of the existing CBDPP shall be initiated until an update of the CBDPP is approved by the DOE Field Organization, except in the event of an unexpected situation and, then, only upon approval of the DOE Field Organization.

(d) Nothing in this part shall be construed as precluding a DOE contractor from taking any additional protective action that it determines to be necessary to protect the health and safety of workers.

§ 850.13 Compliance.

(a) DOE contractors shall conduct activities in compliance with their respective CBDPP, as approved by the DOE Field Organization.

(b) DOE contractors shall achieve compliance with all elements of their respective CBDPP no later than [2 years from the effective date of the final rule].

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

Subpart C—Specific Program Requirements

§ 850.20 Baseline beryllium inventory.

(a) DOE contractors shall develop a baseline inventory of beryllium operations and other locations of potential beryllium contamination, and identify the workers exposed or potentially exposed to beryllium at those locations.

(b) In conducting the baseline inventory, DOE contractors shall:

(1) Review employee records;

(2) Interview employees;

(3) Document the presence and locations of beryllium at the facility; and

(4) Conduct sampling to identify the presence of beryllium.

(c) DOE contractors shall ensure that the individuals assigned to this task have sufficient industrial hygiene knowledge to perform such activities properly.

§ 850.21 Hazard assessment.

(a) If the baseline inventory establishes the presence of beryllium, DOE contractors shall conduct a beryllium hazard assessment that includes an analysis of existing conditions, exposure data, medical surveillance trends, and the exposure potential of planned activities.

(b) DOE contractors shall ensure that the individuals assigned to this task have sufficient industrial hygiene knowledge to perform such activities properly.

§ 850.22 Exposure limits.

(a) Eight-Hour Time-Weighted Average (TWA) Permissible Exposure Limit (PEL). DOE contractors shall not expose any worker to an airborne concentration of beryllium over 2 $\mu g/m^3$, calculated as an 8-hour TWA exposure, as measured in the worker's breathing zone by personal monitoring, or a more stringent TWA PEL that may be promulgated by the Occupational Safety and Health Administration as a health standard.

(b) Short-Term Exposure Limit (STEL). DOE contractors shall not expose any worker to an airborne concentration of beryllium over 10 $\mu g/m^3$, averaged over a sampling period of 15 minutes, as measured in the worker's breathing zone by personal monitoring. Exposures above the PEL-TWA up to the STEL must not be longer than 15 minutes and must not occur more than four times in a day. If such exposures occur more than once a day, there must be at least 60 minutes between successive exposures in this range.

§ 850.23 Action level.

(a) DOE contractors shall include in their CBDPP an action level that, if met or exceeded, shall require the implementation of §§ 850.24(c) (periodic monitoring), 850.26 (regulated areas), 850.27 (change rooms), 850.29 (protective clothing and equipment), and 850.33 (medical surveillance).

(b) The provision enumerated in paragraph (a) of this section shall also be implemented if the STEL is exceeded.

(c) The action level established under paragraph (a) of this section shall not exceed 0.5 $\mu g/m^3$, calculated as an 8-hour TWA exposure, as measured in the worker's breathing zone by personal monitoring.

§ 850.24 Exposure monitoring.

(a) General. DOE contractors shall ensure that the individuals assigned to the monitoring tasks of this section have sufficient industrial hygiene knowledge to perform such activities properly.

(b) Initial Monitoring. DOE contractors shall perform initial monitoring for all workers in areas that may have airborne concentrations of beryllium, as shown by the baseline inventory and hazard assessment.

(1) DOE contractors shall determine each worker's exposure by conducting personal breathing zone sampling:

(i) To determine the 8-hour TWA exposure level.

(ii) To determine if exposure is above the STEL.

(2) Exposure monitoring results obtained within the 12 months preceding the effective date of this part may be used to satisfy this requirement if the measurements were made as provided in paragraph (b)(1) of this section.

(c) Periodic Exposure Monitoring. DOE contractors shall conduct periodic

monitoring of all workers who work in areas where airborne concentrations of beryllium are at or above the action level or above the STEL. The monitoring shall be conducted in a manner and at a frequency necessary to represent worker exposures as specified in their respective CBDPP, but in no case shall sampling be conducted at intervals greater than every 3 months (quarterly).

(d) Additional Exposure Monitoring. DOE contractors shall perform additional monitoring if operations or procedures change.

(e) Accuracy of Monitoring. DOE contractors shall use a monitoring method that has an accuracy (to a confidence level of 95 percent) of not less than plus or minus 25 percent or better for airborne concentrations of beryllium at the action level.

(f) Analysis. DOE contractors shall have all samples collected to satisfy the monitoring requirements of this part analyzed in a laboratory accredited for metals by the American Industrial Hygiene Association.

(g) Notification of Monitoring Results. (1) DOE contractors shall, within 10 working days after receipt of any monitoring results, notify the affected workers, and any labor organizations representing such workers, of monitoring results in writing. This notification shall be made personally to the affected workers or representatives, or in a posted form in location(s) that are readily accessible to affected workers, but in a manner that does not identify individual workers.

(2) If the monitoring results indicate that worker exposure is at or above the action level or STEL, DOE contractors shall also notify the SOMD of these results within 10 working days after receipt.

§ 850.25 Exposure reduction and minimization.

(a) DOE contractors shall ensure that no worker is exposed above the exposure limits prescribed in § 850.22, using the conventional hierarchy of industrial hygiene controls (i.e., engineering and administrative controls, and personal protective equipment).

(b) DOE contractors shall include in the CBDPP the rationale for reduction and minimization goals, strategies for achieving those goals, and the specific measures that will be used to assess the attainment of those goals. Strategies for achieving the exposure reduction and minimization goals shall include, but are not limited to:

(1) Using the action level to initiate actions to reduce or minimize worker exposure, and the potential for exposure, to beryllium; and

(2) Implementing work and contamination control strategies to reduce exposure to CBDPP goal levels using the conventional hierarchy of industrial hygiene controls.

§ 850.26 Regulated areas.

(a) If airborne concentrations of beryllium in areas in DOE facilities are at or above the action level or above the STEL, DOE contractors shall establish regulated areas for those particular areas.

(b) Regulated areas shall be demarcated from the rest of the workplace in a manner that adequately alerts workers to the boundaries of such areas.

(c) DOE contractors shall limit access to regulated areas to authorized persons.

(d) DOE contractors shall keep records of all individuals who enter regulated areas. These records shall include the name, date, time in and time out, and work activity.

§ 850.27 Change rooms.

(a) DOE contractors shall provide change rooms for workers who work in regulated areas.

(1) The change rooms that are used to remove beryllium-contaminated clothing and protective equipment shall be maintained under negative pressure or located so as to minimize dispersion of beryllium into clean areas; and

(2) Separate facilities shall be provided for workers to change into, and store, personal clothing, and clean protective clothing and equipment.

(b) DOE contractors shall provide handwashing and shower facilities for workers who work in regulated areas.

§ 850.28 Respiratory protection.

(a) DOE contractors shall comply with the respiratory protection requirements of 29 CFR 1910.134, Respiratory Protection.

(b) DOE contractors shall provide respirators to, and ensure that they are used by, all workers who are exposed to an airborne concentration of beryllium at or above the PEL.

(c) DOE contractors shall select for use by beryllium workers respirators approved by the National Institute for Occupational Safety and Health (NIOSH) or those DOE has accepted for use for DOE employees.

§ 850.29 Protective clothing and equipment.

(a) Where exposure monitoring has established airborne concentrations of beryllium at or above the action level or above the STEL, DOE contractors shall provide protective clothing and equipment to their beryllium workers and ensure its appropriate use and maintenance.

(1) DOE contractors shall ensure that beryllium workers exchange their personal clothing for full-body protective clothing and footwear before they begin work in regulated areas.

(2) DOE contractors shall provide beryllium workers with, and ensure the use of, additional protective equipment, such as face shields, goggles, gloves, and gauntlets, where skin or eye contact is possible from powdered or liquid forms of beryllium.

(b) DOE contractors shall ensure that no worker takes beryllium-contaminated protective clothing and equipment from the site, except for workers authorized to launder, clean, maintain, or dispose of the clothing and equipment.

(1) DOE contractors shall ensure that contaminated protective clothing and equipment, when removed for laundering, cleaning, maintenance, or disposal, is stored in sealed, impermeable containers or other closed, impermeable containers that are designed to prevent the dispersion of beryllium dust.

(2) DOE contractors shall ensure that the bags or containers of contaminated protective clothing and equipment that are to be removed from the change room areas or the site for laundering, cleaning, maintenance, or disposal shall bear labels according to section 850.37 of this part.

(c) DOE contractors shall ensure that protective clothing and equipment is cleaned, laundered, repaired, or replaced as needed to maintain effectiveness.

(d) DOE contractors shall inform any individual who launders or cleans beryllium-contaminated protective clothing or equipment that exposure to beryllium is potentially harmful, and that clothing and equipment should be laundered or cleaned in a manner prescribed by the contractor to prevent the release of airborne beryllium at or above the action level or above the STEL.

(e) DOE contractors shall prohibit the removal of beryllium from protective clothing and equipment by blowing, shaking, or other means that may disperse beryllium into the air.

§ 850.30 Housekeeping.

(a) Where beryllium is present at DOE facilities, DOE contractors shall conduct routine surface sampling to determine housekeeping conditions. Surfaces contaminated with beryllium dusts and waste shall not exceed a removable surface contamination level of 3 μg/100 cm^2.

(b) Where beryllium is present at DOE facilities, DOE contractors shall clean beryllium-contaminated floors and surfaces using a wet method or vacuuming. Compressed-air or dry methods shall not be used for such cleaning.

(c) DOE contractors shall equip the portable or mobile vacuum units that are used to clean beryllium-contaminated areas with HEPA filters, and change filters as often as necessary to maintain their capture efficiency.

(d) DOE contractors shall ensure that the cleaning equipment that is used to clean beryllium-contaminated surfaces is labeled, controlled, and used in no other areas.

§ 850.31 Waste disposal.

(a) DOE contractors shall control the generation and disposal of waste that contains beryllium through good housekeeping, hazard analysis, and the application of waste minimization principles.

(b) Beryllium-contaminated waste, containers, small equipment, and clothing shall be disposed of in sealed, impermeable bags or containers. The bags and containers that are used to dispose of beryllium-contaminated waste or articles shall be labeled according to § 850.37.

§ 850.32 Beryllium emergencies.

(a) DOE contractors shall develop and implement procedures for handling beryllium emergencies at DOE facilities engaged in beryllium operations.

(1) DOE contractors shall establish procedures to alert and protect workers in the event of an emergency.

(2) DOE contractors shall ensure that workers who are engaged in cleanup related to a beryllium emergency are provided with, and wear, protective equipment and clothing.

(b) DOE contractors shall provide beryllium emergency procedure training to workers who are assigned to handle beryllium emergencies.

§ 850.33 Medical surveillance.

(a) General. DOE contractors shall designate a SOMD who shall be responsible for administering a medical surveillance program for contractor beryllium workers.

(b) Heads of DOE Field Organizations shall designate a SOMD who shall be responsible for administering a medical surveillance program for federal employees who are beryllium workers.

(c) The written medical surveillance program shall be reviewed by the Office of Environment, Safety and Health and approved by Heads of DOE Field Organizations.

(d) DOE contractors shall establish and implement a medical surveillance program under the direction of the SOMD for all beryllium workers exposed at or above the action level or above the STEL.

(e) DOE contractors shall provide the SOMD with the information needed to operate and administer the medical surveillance program, including the baseline inventory, hazard assessment and exposure monitoring data, identity and nature of activities or operations on the site that are covered under the CBDPP, related duties of beryllium workers, and type of personal protective equipment used.

(f) The SOMD shall establish and maintain a list of beryllium workers that is based on records and other information regarding the identity of beryllium workers.

(1) The list shall establish the population of beryllium workers who may be eligible for protective measures under this part.

(2) The list shall be adjusted on the basis of periodic evaluations of beryllium workers performed under paragraph (h)(3) of this section.

(g) Information provided to the examining physician. The SOMD shall provide the following information to the examining physician:

(1) A copy of this rule;

(2) A description of the beryllium worker's duties as they pertain to beryllium exposure;

(3) Records of the beryllium worker's beryllium exposure;

(4) A description of the personal protective and respiratory protective equipment in past, present, or anticipated use; and

(5) Relevant information from the beryllium worker's previous medical examinations that is not otherwise available to the examining physician.

(h) Medical evaluations. (1) DOE contractors shall provide medical examinations and procedures to beryllium workers and accepted applicants at no cost and at a time and place that is reasonable and convenient to them.

(2) DOE contractors shall offer a baseline medical evaluation to beryllium workers who qualify for medical surveillance. This evaluation shall include:

(i) A medical and work history;

(ii) A physical examination with special emphasis on the respiratory system;

(iii) A chest radiograph (posterior-anterior, 14 × 17 inches) interpreted by a National Institute for Occupational Safety and Health (NIOSH) B-reader or a board-certified radiologist (unless a baseline chest radiograph is already on file);

(iv) Spirometry;

(v) A Be-LPT; and

(vi) Any other tests deemed appropriate by the examining physician for evaluating beryllium-related health effects.

(3) Periodic evaluations. DOE contractors shall offer beryllium workers who qualify for medical surveillance under this section annual medical evaluations for as long as the beryllium worker performs beryllium work at a DOE site. DOE contractors shall offer beryllium workers who have been reassigned to non beryllium DOE work an evaluation every three years. Such periodic evaluations shall include:

(i) A respiratory symptoms questionnaire;

(ii) A physical examination;

(iii) A Be-LPT; and

(iv) Any other medical evaluations deemed appropriate by the examining physician for evaluating beryllium-related health effects.

(4) The SOMD shall ensure that all medical evaluations and procedures that are required by this section are performed by, or under the supervision of, a licensed physician who is familiar with the health effects of beryllium.

(i) Referrals. Beryllium workers who have two or more positive Be-LPTs, or other signs and symptoms of CBD, shall be referred by the examining physician for further diagnostic evaluation.

(j) Physician's written report and recommendation. (1) DOE contractors shall ensure that each beryllium worker or accepted applicant receives, within 15 calendar days after the completion of a medical evaluation performed under this section, a physician's written report containing the results of all medical tests or procedures, an explanation of any abnormal findings, and any recommendations that the worker be referred for additional testing for evidence of CBD.

(2) DOE contractors shall, within 15 calendar days after the completion of a medical evaluation performed under this section, obtain a copy of the physician's written report, that is limited to the following information: any recommendations that the beryllium worker's exposure to beryllium be precluded or that the accepted applicant's start of beryllium work be postponed, either temporarily or permanently, and any recommendation on the use of respiratory or other protective equipment.

(k) Data analysis. The SOMD shall routinely and systematically analyze medical, job, and exposure data with the

aim of identifying individuals or groups of individuals potentially at risk for CBD and working conditions that are unduly contributing to that risk.

(1) Results of these analyses shall be used by the SOMD in determining which workers should be offered medical surveillance, and the need for additional exposure controls.

(2) The SOMD shall provide copies of the data analyses to the DOE contractor for the performance feedback required in section 850.40.

§ 850.34 Medical removal.

(a) Medical removal plan. With the express written consent of the beryllium worker or accepted applicant, as indicated on the consent form, DOE contractors shall remove a beryllium worker from exposure to beryllium, or postpone an accepted applicant's start of beryllium work, if the SOMD recommends that the beryllium worker or accepted applicant do so due to two or more positive Be-LPT results, confirmation of CBD, or the detection of other signs or symptoms that require evaluation for their relationship to CBD.

(1) DOE contractors shall offer a beryllium worker removed from beryllium work a follow-up medical examination that the examining physician shall use to decide whether the beryllium worker may return to beryllium work.

(2) Beryllium workers and accepted applicants with two or more positive Be-LPTs or confirmed CBD shall have the option at any time after testing, diagnosis, or the appearance of CBD-related symptoms to decline the medical removal or restriction and, after signing an informed consent waiver, resume working in a beryllium area.

(3) DOE contractors shall make reasonable efforts to offer alternative employment to beryllium workers and accepted applicants who test positive on two or more Be-LPTs, or who are confirmed with CBD. The reasonable efforts to offer alternative employment required under this section shall not require the contractor: to displace any other worker in order to create a vacancy for the beryllium worker or accepted applicant; to promote the beryllium worker or accepted applicant; or to provide the beryllium worker or accepted applicant with training that costs in excess of $6,000.00, or requires longer than 6 months to complete.

(b) Medical removal protection benefits. DOE contractors shall provide beryllium workers who are removed from beryllium work and placed in other jobs with the contractor employing them, protection against a reduction in base pay, seniority, or other benefits for a total period of two years after removal.

§ 850.35 Medical consent.

(a) DOE contractors shall provide beryllium workers and accepted applicants with information on the benefits and risks of the medical tests and examinations available to them at least one week prior to any such examination or test. The examining physician shall provide beryllium workers and accepted applicants an opportunity to have their questions answered and shall obtain their signed consent before performing medical evaluations.

(b) DOE contractors shall also provide beryllium workers and accepted applicants with a summary of the medical surveillance program, the type of data that will be collected, how the data will be collected and maintained, the purpose for which the data will be used, and how confidential data will be protected. This information shall be provided at least one week prior to the first medical examination or test, or at any time requested by the beryllium worker or accepted applicant.

(c) DOE contractors shall use the form approved by the Assistant Secretary for Environment, Safety and Health to obtain the signed consent of a beryllium worker before performing a medical examination.

(d) DOE contractors shall provide beryllium workers or accepted applicants information that will facilitate informed decisions on whether to accept medical removal offered by the SOMD. This information shall include information on opportunities for alternative placement within their organization, available out-placement benefits, and long-term medical and disability insurance benefits for which they may qualify.

(e) The SOMD shall provide a beryllium worker or an accepted applicant with an opportunity to have his or her questions answered before obtaining the worker's agreement to medical removal or a signed waiver of an offer of medical removal protection.

§ 850.36 Training and counseling.

(a) DOE contractors shall develop and implement a beryllium training program for workers who may be exposed to beryllium, and ensure their participation.

(1) The information and training provided shall be in accordance with 29 CFR 1910.1200, Hazard Communication.

(2) Training shall be provided before or at the time of initial assignment and at least annually thereafter.

(3) Training shall include, but not be limited to, beryllium health risk, exposure reduction, safe handling of beryllium, and medical surveillance.

(b) DOE contractors shall develop and implement a beryllium worker counseling program to assist workers who are diagnosed by the SOMD to be sensitized to beryllium or to have CBD. This program shall include communicating with beryllium workers concerning the availability of: the medical surveillance program; medical treatment options; medical, psychological, and career counseling for workers with positive Be-LPT results or confirmed CBD; medical benefits; worker compensation claims; work practice procedures limiting worker exposure to beryllium; and the risk of continued exposure after sensitization.

§ 850.37 Warning signs and labels.

(a) Warning signs. DOE contractors shall post warning signs at all entranceways to regulated areas with the following information:

DANGER
BERYLLIUM CAN CAUSE LUNG DAMAGE
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY

(b) Warning labels. (1) DOE contractors shall affix warning labels to all containers of beryllium, beryllium compounds, or beryllium-contaminated clothing, equipment, waste, scrap, or debris.

(2) Labels shall be in accordance with 29 CFR 1910.1200, Hazard Communication, and shall contain the following information:

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

§ 850.38 Recordkeeping and use of information.

(a) DOE contractors shall establish and maintain accurate records of all beryllium inventory information, hazard assessments, exposure measurements, controls, and medical surveillance.

(b) DOE contractors shall maintain all records required by this part in an electronic, easily retrievable form for transmittal to DOE Headquarters on request.

(c) DOE contractors shall link data sets on working conditions and health outcomes to serve as a basis for understanding the beryllium health risk.

(d) Medical information generated by the CBDPP shall be maintained by the contractor as part of the beryllium worker's site medical records. Such medical information shall be maintained separately from other

personnel records. This information must be kept confidential and used or disclosed by the contractor only in conformance with any applicable requirements imposed by the Americans with Disabilities Act, the Privacy Act of 1974, and any other requirements under applicable law.

§ 850.39 Beryllium registry.

(a) DOE contractors shall establish and maintain a separate electronic beryllium registry that includes the name, social security number (SSN), date of birth, gender, site, job history, medical screening test results, and results of referrals for specialized medical evaluation. This data shall be submitted for all beryllium workers employed by them and all accepted applicants, subject to the requirements of § 850.38.

(b) DOE contractors shall transmit the beryllium registry information electronically to the Office of Environment, Safety and Health, Office of Epidemiologic Surveillance, semi-annually.

(c) Information in the beryllium registry maintained by DOE under paragraph (a) of this section may be disclosed only in a manner consistent with the Privacy Act of 1974 and any other applicable legal requirements.

§ 850.40 Performance feedback.

(a) DOE contractors shall conduct periodic analyses and assessments of monitoring efforts, hazards, medical surveillance, exposure reduction and minimization, and occurrence reporting data.

(b) To ensure that information is available to maintain and improve all elements of the CBDPP continuously, results of periodic analyses and assessments shall be given to the line managers, planners, worker protection staff, workers, medical staff, and labor organizations representing beryllium workers who request such information.

Appendix A to Part 850—Chronic Beryllium Disease Prevention Program Informed Consent Form

I have carefully read and understand the attached information about the Be-LPT and other medical tests. I have had the opportunity to ask any questions that I may have had concerning these tests.

I understand that I am free to withdraw at any time from all or any part of the medical surveillance program. I understand that if the results of any test suggest a health problem, the examining physician will discuss the matter with me, whether or not the result is related to my work with beryllium.

I understand that the results of my tests and examinations may be published in reports or presented at meetings, but that I will not be identified.

I understand that the results of my medical tests for beryllium will be included in the Beryllium Registry maintained by DOE. The confidentiality of identified information maintained by DOE is protected under the Privacy Act of 1974. Personal identifiers will not be published in any reports generated from the DOE Beryllium Registry. All medical information relative to the tests performed on me retained by my employer will be maintained in segregated medical files separate from my personnel files, treated as confidential medical records, and used or disclosed only as provided by the Americans with Disability Act, the Privacy Act of 1974, or as required by a court order or DOE directive.

I consent to having the following medical evaluations:

☐ Physical examination concentrating on my lungs and breathing
☐ Chest X-ray
☐ Spirometry (a breathing test)
☐ Blood test called the beryllium-induced lymphocyte proliferation test or Be-LPT
☐ Other test(s). Specify:_____

I understand that, if the results of one or more of these tests indicate that I have a health problem that is related to beryllium, additional examinations will be recommended. If additional tests indicate I do have a beryllium sensitization or CBD, I may be advised to stop working with beryllium. Every effort will be made to offer me a job of equivalent grade and base pay for which I am qualified. I also may continue working in the job with beryllium exposure if I so choose. I understand that continuing to work with beryllium may increase the chance that I will develop chronic beryllium disease (CBD).

☐ I decline to participate in any part of the medical surveillance program at this time. If I change my mind, I may participate in the program by contacting my supervisor.

Name of Participant:
SSN:
Signature of Participant:
Date:

I have explained and discussed any questions that the above employee expressed concerning the Be-LPT, physical examination, and other medical testing as well as the implications of those tests.

Name of Examining Physician:
Signature of Examining Physician:
Date:

Appendix B to Part 850—Questions and Answers Concerning the Beryllium-Induced Lymphocyte Proliferation Test (Be-LPT), Medical Records, and the DOE Beryllium Registry

What is the Be-LPT blood test?

In the Be-LPTs, disease-fighting blood cells that are normally found in the body, called lymphocytes, are examined in the laboratory and separated from your blood. Beryllium and other test agents are then added to small groups of these lymphocytes. If these lymphocytes react to beryllium in a specific way, the test results are ''positive.'' If they do not react with beryllium, the test is ''negative.''

Experts believe that the Be-LPT shows positive results in individuals who have become sensitive or allergic to beryllium. It is unclear what this sensitivity means. Studies have shown it to be an early sign of chronic beryllium disease (CBD) in many individuals. In others, sensitivity might simply mean that the person was exposed to beryllium and that his or her body has reacted. It might mean that an individual is more likely than others to get CBD. You are being offered the Be-LPT because doctors believe it is useful in detecting cases of CBD early or cases that might otherwise be missed or diagnosed as another type of lung problem. Once CBD is identified, doctors can determine the treatment that is needed to minimize the lung damage CBD causes.

As in any other medical test, the Be-LPT sometimes fails or provides unclear results. The laboratory calls these results ''uninterpretable.'' Even when the test appears successful, it may appear positive when it is not. This is called a ''false positive'' result. It is also possible that the test will show ''negative'' results when a person is actually ''sensitized'' to beryllium. This is a ''false negative'' result. If you have a ''uninterpretable'' blood Be-LPT result, you will be asked to provide another blood sample so the test can be repeated. If you have ''positive'' results, you will be offered further medical tests to confirm or rule out CBD. Remember, you may refuse further tests at this point or at any point during your medical evaluations.

It is important for you to know that if the physical examination or the results from other tests you are receiving suggest that you have CBD, you may be offered further medical tests. These medical tests may be offered even if your Be-LPT is ''negative.''

Some individuals with confirmed ''positive'' Be-LPTs but no other signs of CBD have developed the disease. The likelihood of this happening will only be known after large groups of potentially exposed individuals have had their blood tested, have had further medical tests, and are studied for many years.

What will happen if I decide to have the Be-LPT blood test?

A small amount of your blood will be drawn from a vein in your arm and sent to a laboratory. There is little physical risk in drawing blood. Slight pain and bruising may occur in a few individuals. Rarely, the needle puncture will become infected. Other routine medical evaluation tests may be offered when you have the Be-LPTs including a physical examination, a chest X-ray, and breathing tests that help find signs of CBD, if they exist.

Other diseases may resemble CBD. Different medical tests can help a physician decide if a person has CBD or another disease. If the examining physician suspects that you have CBD, he or she will recommend additional medical tests to help confirm a diagnosis. Separate information regarding these additional medical tests will be given to you if they are recommended. Your consent will be requested when the extra tests are given. You can always refuse

additional tests, if you so choose. All tests will be paid for by your employer.

When will I receive the results of my Be-LPT blood test?

It could take 2 to 4 weeks for you to receive a letter informing you of your test results. The test itself usually takes 8 days to perform. The testing laboratory reports results to the physician who examined you and he or she will notify you.

Could a positive Be-LPT blood test affect my job assignment?

Yes, but only if you elect to accept a change in your job assignment. If you have a positive Be-LPT or have been diagnosed with CBD, it may be advisable for you to stop working with beryllium. If you are working with beryllium at this time, every effort will be made to offer you another job that you are qualified to perform with your employer. This job will be of comparable responsibilities, base pay and benefits, and will not expose you to beryllium. If a comparable position cannot be found with your employer, you will be offered the choice of continuing to work for your employer with beryllium or assistance for a period of 2 years in finding employment with another employer, but in that case there can be no promise of continued base pay and benefits. If you become physically unable to continue working, you may be eligible for workers' compensation and other benefits.

Will I lose any pay or any other benefits by having the examination during normally scheduled working hours?

No. Your examination will be scheduled during normal work hours. You will not be required to take leave to have the examination, nor will you lose pay or any other benefits.

What will happen to the records of the medical examination results?

The results of your tests and examinations will be available to the physicians and nurses in this clinic, and possibly to scientists conducting health studies. The test results will be entered in your medical records, which will be kept in specially secured files under the supervision of physicians and nurses in the clinic, separate from other personnel records. Your test results will be medically confidential data and will not be released to anyone other than those listed in the following, unless you provide written permission. The following groups will have direct access to this information:

1. Clinic staff members
2. Medical specialists who will provide or arrange for additional medical treatment or tests, if necessary.
3. U.S. Department of Energy Beryllium Registry staff.
4. The Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health officials may require direct access to records that identify you by name for health studies.

If information about you is used in reports or a published health study, your identity will be disguised. You will not be identified in any published report or presentation. The results of your Be-LPT and other screening tests will be made available to you and, upon your request, to your physician. The information also will become part of your medical record, which the clinic keeps.

What is the DOE beryllium registry?

Your health and the health of all workers is a major concern to the Department. There is a need to learn more about chronic beryllium disease and what causes some individuals to react more strongly than others. A DOE beryllium registry has been established to collect and maintain information on workers who are exposed to long term, low and moderate levels of beryllium. This registry is a tool which will be used in health studies to better understand the nature of the disease. With it we can measure the burden of health effects related to beryllium exposure. The registry will also be used to evaluate the effectiveness of exposure control programs.

In addition to information about your beryllium related exposures, the results of beryllium sensitization testing and/or CBD status collected by your employer will be added to the registry. Your employer must treat this information as confidential medical information and can only use or disclose of this information in conformance with the Privacy Act of 1974, the Americans with Disabilities Act, or any other applicable law. Personal identifying information (such as your name and social security number) is required to link exposure data to the results of the medical testing and to eliminate duplicate reports for each worker. At no time will your name or other personal identifying information be published in any report. The confidentiality of identified information in DOE records is protected under the Privacy Act of 1974.

What laws protect me if I consent to participating in the screening program?

State medical and nursing licensing boards enforce codes of ethics that require doctors and nurses to keep medical information confidential. The Privacy Act prevents unauthorized access to your DOE records without your permission. The information in records kept by your employer must be handled in accordance with the Americans with Disabilities Act and the Privacy Act of 1974. The consent form you sign also provides additional protection.

Can my privacy and the confidentiality of my medical records be guaranteed?

No. Access to or release of records could be required under court order, or DOE directive, but it is unlikely. If you apply for another job or for insurance, you may be requested to release the records to a future employer or an insurance company. If, for medical reasons, it is recommended that you transfer to an area where you will not contact beryllium, and you elect to do so, the personnel department and your supervisor will be notified. They will not be told the specific results of your tests but, because of the restrictions, they may assume that your Be-LPT results were positive.

Do I have to have the Be-LPT done?

No. Your participation in the medical surveillance program is strictly voluntary. You may refuse any of the tests offered to you including the Be-LPT. If you change your mind, you are free to participate in the program at any time. Talking with your family, your doctor, or other people you trust may help you decide. The physicians in the clinic that provide the tests can also help answer any questions that you might have.

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