federal register

Wednesday
December 8, 1999

Part III

Department of Energy

10 CFR Part 850

Chronic Beryllium Disease Prevention Program; Final Rule

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: Final rule.

SUMMARY: The Department of Energy (DOE) is today publishing a final rule to establish a chronic beryllium disease prevention program (CBDPP) to reduce the number of workers currently exposed to beryllium in the course of their work at DOE facilities managed by DOE or its contractors, minimize the levels of, and potential for, exposure to beryllium, and establish medical surveillance requirements to ensure early detection of the disease. This program improves and codifies provisions of a temporary CBDPP established by DOE directive in 1997.

EFFECTIVE DATE: This rule is effective January 7, 2000.

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.

SUPPLEMENTARY INFORMATION:

I. Introduction

This final rule implements a chronic beryllium disease prevention program (CBDPP) for the Department of Energy (DOE or the Department). This program will reduce the number of workers currently exposed to beryllium at DOE facilities managed by DOE or its contractors, minimize the levels of, and potential for, exposure to beryllium, establish medical surveillance requirements to ensure early detection of disease, and improve the state of information regarding chronic beryllium disease and beryllium sensitization.

On December 3, 1998, DOE published a Notice of Proposed Rulemaking (NOPR) for public comment in the **Federal Register** (63 FR 66940) proposing regulations for a chronic beryllium disease prevention program. The public comment period for the NOPR ended on March 9, 1999. DOE received 36 comment letters. In addition, public hearings were held on February 3, 1999, in Oak Ridge, Tennessee; February 9, 1999, in Golden, Colorado; and February 11, 1999, in Washington, DC. Comment letters were received from private individuals, DOE contractors, other federal agencies, trade associations, academia, public health and medical professionals, and attorneys.

On June 3, 1999, DOE published a notice of limited reopening of the comment period (64 FR 29811) to solicit public comments on options that DOE was considering for the criteria to be used for the release or transfer of equipment and other items previously used in DOE beryllium operations, either to other DOE facilities or to the public. In response to this reopening of the comment period, DOE received 15 additional comments.

DOE has carefully considered the comments and data from interested parties, as well as reference works, journal articles, and other information relevant to the subject of the rulemaking.

A. Background

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 melting, casting, grinding, and machine tooling of parts.

Inhalation of beryllium dust or particles can cause chronic beryllium disease (CBD) or 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 September 1999, among the 11,266 current and former DOE federal and contractor workers who were screened for the disease, 130 workers had been diagnosed with CBD, and another 277 workers had become sensitized to beryllium. DOE anticipates an increase in the number of workers who may be exposed to beryllium as DOE 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) in 1971 and codified in 29 CFR 1910.1000, Tables Z–1, Z–2 and Z–3 by reference to existing national consensus standards. DOE's predecessor agency, the Atomic Energy Commission (AEC), had previously established the same limit of 2 $\mu g/m^3$ for application at its facilities in 1949, and that limit has remained in effect at DOE's facilities up to the present. In 1977, the National Institute for Occupational Safety and Health (NIOSH), a federal agency, recommended to OSHA an exposure limit of 0.5 $\mu g/m^3$ for beryllium. NIOSH, at the same time, classified beryllium as a potential occupational carcinogen.

Between the 1970s and 1984, there appeared to be a significant reduction in the incidence rate of CBD. 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 1940s). However, the number of confirmed cases of CBD, more recent 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 (during decontamination and decommissioning activities) all indicate a need for more

aggressive workplace controls to minimize worker exposure to beryllium in the DOE complex.

In December 1998, the American Conference of Governmental Industrial Hygienists (ACGIH) published a Notice of Intended Change for its beryllium exposure limit. ACGIH is a professional organization that develops and publishes consensus occupational health standards. In the Notice, ACGIH proposed an 8-hour TWA of 0.2 μg/m^3 to help minimize the occurrence of CBD and sensitization. DOE's NOPR did not address ACGIH's proposed change because publication of the NOPR preceded ACGIH's announcement.

DOE has reviewed current technical information and is of the opinion that it is difficult to determine the exposure level that is necessary to eliminate the risk of contracting CBD. Until OSHA completes its rulemaking, DOE has decided to implement an aggressive, two-pronged exposure reduction and minimization program that is expected to further protect DOE federal and contractor workers from the hazards associated with exposure to beryllium. While DOE acknowledges that this rule may not eliminate the risk of contracting CBD, DOE believes that this rule will significantly decrease the number of workers exposed and the level of exposure to beryllium, and therefore, is expected to decrease disease. First, DOE is establishing an 8-hour TWA action level of 0.2 μg/m^3 that triggers certain workplace precautions and control measures. Second, DOE is requiring its contractors and any covered DOE employers to establish in their CBDPPs exposure reduction and minimization measures designed to reduce potential exposure to levels below the action level. This program will enhance and supplement existing worker protection programs established under DOE Order 440.1A, Worker Protection Management for DOE Federal and Contractor Employees.

This rulemaking initiative was preceded by several years of information gathering and data analysis. In 1996, DOE 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. 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. These estimates were updated in 1999 through a cost survey conducted by the Office of Environment, Safety and Health (1999 Environment, Safety and Health Cost Survey). In this survey, 14 DOE sites indicated that they would be affected by the proposed rule. These sites reported that 1,634 workers in more than 100 different job categories would be potentially exposed to beryllium and 1,236 of these workers (75.6 percent) would be potentially exposed at the proposed action level or PEL.

The 1996 survey also provided information on exposure levels experienced by workers at the surveyed sites. Although the exposure data were not comprehensive, the reported 8-hour TWA exposure data (personal breathing zone monitoring results) for these workers ranged from nondetectable to 25 μg/m^3. Most of these exposure levels were reported to be below the 2 μg/m^3 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. The survey showed that beryllium exposure controls varied considerably among the DOE facilities.

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 new DOE beryllium health standard (61 FR 68725). This was followed by two Beryllium Public Forums, one held in Albuquerque, New Mexico, and one held in Oak Ridge, Tennessee, in January 1997.

Acting on the information compiled from these various sources, and in view of the time needed to promulgate a rule, then-Secretary of Energy Pena 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 Secretary Pena and issued on July 15, 1997. This interim Notice established a CBDPP that enhanced and supplemented worker protection programs under DOE Order 440.1A.

Because of the complexity and significance of issues regarding the development of a DOE beryllium worker protection rule, Secretary Pena also established the Beryllium Rule Advisory Committee (BRAC) in June 1997 to advise DOE on issues pertinent to the proposed rulemaking. The BRAC, which consisted of a diverse set of stakeholders and recognized experts from DOE, other federal agencies, industry, labor, medicine, and academia, explored issues and generated recommendations for consideration in the development of a CBDPP rule.[1]

B. Chemical Identification and Use

Beryllium (atomic number 4) is a silver-gray, metallic element with a density of 1.85 g/cm^3 and a high stiffness. The second lightest of the metals, beryllium also has a high melting point (1285° C) and heat absorption capacity; a pound of beryllium will absorb as much heat as 5 pounds of copper.

Beryllium occurs naturally in the earth's surface in about 30 minerals found in rocks, coal and oil, soil, and volcanic dust. Beryllium used in industry begins as a silicate ($BeSiO_3$) in beryl and bertrandite ores. In very pure crystalline form, beryl takes the form of gems, such as blue-green aquamarine and green emeralds. Bertrandite is mined in Utah. The United States is the world's leading producer, processor, and consumer of beryllium products.

Beryllium, discovered in 1798, was not widely used in industry until the 1940s and 1950s. Beryllium can be used as a pure metal, mixed with other metals to form alloys, processed to salts that dissolve in water, and processed to form oxides and ceramic materials.

Beryllium metal has been produced for various industrial uses, especially in the aerospace and defense industries. Both structural and instrument grade materials are manufactured, including windshield frames and other structures in high-speed aircraft and space vehicles, aircraft and space shuttle brakes, satellite mirrors and space telescopes, inertial guidance systems and gyroscopes, neutron moderators or reflectors in nuclear reactors, X-ray windows, and nuclear weapons components.

In alloys, beryllium confers on metal specific properties of resistance to corrosion, wear, and fatigue; high electrical and thermal conductivity;

[1] Individual members and groups of members made BRAC recommendations. The recommendations 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.''

strength; and hardness. Beryllium-copper (BeCu) alloys usually contain about 2 percent beryllium, but vary greatly in composition to meet different industrial and consumer needs. Beryllium is also added to aluminum, nickel, zinc, and zirconium for some applications. Beryllium alloys are used for springs, switches, relays, and connectors in automobiles, computers, radar and telecommunications equipment, and other instruments; high-strength non-sparking tools; molds or casts to make metal, glass, and plastic items; sports equipment such as golf clubs and bicycle frames; and dental bridges and related applications.

Other beryllium materials include soluble salts and oxides. Beryllium soluble salts, such as beryllium fluoride, chloride, and sulfate, are used in nuclear reactors, in glass manufacture, and as catalysts for certain chemical reactions. Beryllium Oxide (BeO) is used to make ceramics for electronics, and other electrical equipment. Beneficial properties of BeO include hardness, strength, excellent heat conductivity, and good electrical insulation.

C. Health Effects

DOE received a number of comments (Exs. 2, 5, 14, 19, 20, 22, 23, 24, 26, 29, 30) [2] regarding the ''Health Effects'' section of the NOPR. DOE has carefully considered these comments and has revised the following health effects discussion as appropriate.

1. Chronic Beryllium Disease

Chronic beryllium disease (CBD) is a granulomatous lung disease that is caused by the body's immune system response (similar to an allergic reaction) to inhaled dust or fumes containing beryllium metal, alloys, beryllium compounds or mixtures, or insoluble beryllium salts. The body's immune system response to beryllium is often called beryllium sensitization. Beryllium sensitization precedes the development of CBD. Sensitization can occur quickly or many years after exposure to beryllium, progressing into disease at a rate of approximately 10 percent a year (ref. 1) [3].

It is hypothesized that 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 can occur at relatively low exposure levels and, in some cases, after relatively brief durations of exposure. The International Agency for Research on Cancer (IARC) and ACGIH classify beryllium as a human carcinogen.

Frequently reported symptoms include one or more of the following: dyspnea (shortness of breath) on exertion, cough, fever, night sweats, and chest pain and, less frequently, arthralgias (neuralgic pain in joints), fatigue, weight loss, or appetite loss. On physical examination, a doctor may find signs of CBD results, such as rales (changes in lung sounds), cyanosis (lack of oxygen), digital clubbing, or lymphadenopathy (enlarged lymph nodes). A radiograph (X-ray) of the lungs may show many small scars. Patients may also have an abnormal breathing test, pulmonary function test, and a blood test, the peripheral blood beryllium-induced lymphocyte proliferation test (Be–LPT). Examination of the 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. In advanced cases, there may be manifestations of right-sided heart failure, including cor pulmonale (enlarged right ventricle of the heart caused by blockage in the lungs).

The Be-LPT is highly specific for beryllium sensitivity and has a high predictive value for beryllium disease. It is the most definitive means of ruling out beryllium disease as the cause of non-specific lung and other symptoms. Therefore, this measurement of sensitization to beryllium identifies at-risk individuals, as well as individuals whose lung problems are not beryllium related (ref. 1). For individuals whose Be-LPT screening results exceed a certain threshold, an additional Be-LPT is conducted on cells washed from a segment of the lung. The presence of granulomata in the lung of an individual with a positive lung Be-LPT confirms the presence of CBD. In the absence of granulomata or other clinical evidence of CBD, individuals with a positive Be-LPT are classified as sensitized to beryllium.

The clinical course of CBD is highly variable. Some individuals deteriorate rapidly; most experience long, gradual deterioration. 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 physically impaired. Once sensitization has occurred, it is medically prudent to prevent additional exposure to beryllium. Individuals with CBD have a clinical illness varying from mild to severe. In severe cases, the affected individuals may be permanently and totally disabled. Mortality of the sensitized individuals directly attributable to CBD and its complications is estimated to be 30 percent (ref. 2). This estimate is based upon historical data reflecting both the higher levels of exposure that occurred in the workplace prior to regulation of workplace exposure in the late 1940s and a tracking of the medical history of subjects of CBD over several decades. DOE's more recent experience with improved diagnoses and treatments may result in a lower mortality rate for CBD cases.

2. Beryllium Exposures at DOE Operations

DOE's medical surveillance programs are discovering cases of CBD among workers who were first exposed after 1970, when DOE facilities were expected to maintain workers exposure to beryllium below the OSHA PEL. As of June 1999, 119 workers (88 at the Rocky Flats facility in Golden Colorado, 29 at the Y–12 Plant in Oak Ridge, Tennessee, and two at the Hanford facility in Richland, Washington) have been diagnosed with CBD, and another 258 workers (197 at the Rocky Flats facility, 59 at the Y–12 Plant, one at the Hanford facility, and one at the Mound facility in Miamisburg, Ohio) have been diagnosed as sensitized to beryllium from among approximately 10,000 current and former DOE federal and contractor workers who were screened for the disease.

A worker's exposure is measured by personal monitoring, which is accomplished by sampling the air within the breathing zone of the worker. 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, results from area monitoring 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

[2] A list of commenters is included as an appendix to the Section-by-Section Discussion of Comments and Rule Provisions in this Supplementary Information section.

[3] A listing of references is included as an appendix to this Supplementary Information section.

levels of beryllium exposure that 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 have occurred to date at the Rocky Flats facility, and at the Y–12 Plant. 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 were collected at the Oak Ridge Y–12 Plant (Table 1). These samples were taken at several different Y–12 operations associated with CBD, 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 for the sampling and analytical method used at Y–12.

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

	1980 to 1989	1990 to 1996
Number of Samples	148	1448
Estimated Arithmetic Mean Level of Exposure [1]	0.9 μg/m^3	0.3 μg/m^3
Percent of Samples Less Than 2 μg/m^3 [2]	94%	98%

[1] The arithmetic mean was estimated from the samples using linear regression.
[2] Samples were analyzed using flame spectroscopy with a detection limit of about 0.1 μg/m^3.

These Y–12 data are from beryllium operations where cases of CBD have been found. The facilities where these operations take place have not been remodeled since the 1970s. Thus the differences between sampling results measured before and after 1990 are attributed to changing work practices. For example, increased monitoring in the 1990s identified a greater number of exposures over the existing exposure limit. The investigations of these exposures resulted in changes to work practices that had contributed to the high exposures. This focus on operations with elevated exposure levels 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 then again in 1986 after extensive remodeling to the ventilation system illustrates the impact and effectiveness of engineering modifications to control exposure.

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

	1984 to 1985	1986
Number of Samples	99	279
Estimated Arithmetic Mean Level of Exposure [1]	1.19 μg/m^3 [1]	0.035 μg/m^3
Percent of Samples Less Than 2 μg/m^3 [2]	84%	99.6%

[1] The arithmetic mean was estimated from the samples using linear regression.
[2] Samples were analyzed using graphite furnace atomic absorption (AA) or Inductively Coupled Plasma (ICP) spectroscopy with a detection limit of about 0.01 μg/m^3.

The samples collected in 1984 and 1985 were the first personal samples collected in this shop following the discovery of a case of CBD in 1984. 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 ventilation hoods, operations performed outside of hoods were eliminated to the extent possible. The improved engineering controls in this shop reduced average exposure levels by a factor greater than 30, to levels approaching 1% of the existing PEL.

A final example, taken from personal sampling data collected during the decontamination of Rocky Flats Buildings 865 and 867 in 1995–1996, further demonstrates the low levels of beryllium exposure which can be achieved through the implementation of effective controls (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 TO 1996

Number of Samples	7,673
Arithmetic Mean Level of Exposure.	0.03 μg/m^3
Percent of Samples Less Than 2 μg/m^3.	99.8%

As can be seen from the foregoing examples, machining and D&D operations at Y–12 and Rocky Flats 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 future occurrences can be prevented.

3. Epidemiology

Epidemiology is the field of public health that examines relationships between disease in people, and exposures or events that are related to that disease. Occupational epidemiology is the study of the effects of workplace exposures on the frequency and distribution of diseases and injuries.

Hardy and Tabershaw (ref. 3) reported the first evidence of the existence of CBD in a 1946 paper. The paper described ''delayed chemical pneumonitis'' among fluorescent lamp workers exposed to beryllium compounds. The differential diagnosis included sarcoidosis (an immune disease of unknown etiology) and tuberculosis.

There also are 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. 4). Likewise, a 1949 report described 11 patients with CBD who lived near a beryllium extraction plant (ref. 5). 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 of their CBD. Measurements of air concentrations of beryllium at various distances from the plant provided the basis for the Environmental Protection Agency's (EPA's) community permissible exposure limit (24-hour ambient air limit of 0.01 microgram of beryllium per cubic meter of air [μg/m^3]).

In addition, CBD has been reported among family members of beryllium workers who were presumably exposed to contaminated work clothing during the 1940s and 1950s (refs. 6, 7). The virtual disappearance of CBD caused by 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. 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 (ref. 8).

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. 7).

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 1960s, and ultimately was 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. 6). 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. 9).

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 upon examination of lung tissue or thoracic lymph nodes, (5) radiologic evidence of interstitial lung disease, and (6) decreased pulmonary function tests (ref. 10).

The beryllium-induced lymphocyte proliferation test (Be-LPT) in blood and bronchoalveolar lavage (BAL) fluid have allowed earlier identification of the disease. The BAL Be-LPT now is one of the criteria required for diagnosis (refs. 11–13). 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. 14). Current data suggest that the peripheral blood Be-LPT is a specific and sensitive method for testing beryllium sensitivity (ref. 11). The presence of granulomatous tissue in the lung along with a positive BAL Be-LPT is considered definitive evidence for diagnosis of CBD (ref. 12). When a worker has clear signs and symptoms of interstitial lung disease and a positive Be-LPT, CBD may be presumed only if performing a bronchoscopy on the worker is deemed to be too risky given the health status of that of that worker.

An article published by Cullen et al. in 1987 reported on an epidemiology study of CBD among precious-metal refinery workers (ref. 15). In 1993, researchers at the National Jewish Medical and Research Center (NJMRC) published two reports on epidemiology studies that were designed to determine the incidence of CBD among beryllium workers and the value of the Be-LPT in detecting CBD (refs. 16, 17). One of these two studies was conducted at DOE's Rocky Flats Environmental Technology Site (Rocky Flats). These three epidemiology studies showed that CBD incidence among exposed workers was the same as had been reported among workers exposed in the 1940s, when the disease was first recognized. This exposure limit was originally derived by analogy to other toxic metals (ref. 18). A decline in the number of reports of CBD in the 1970s and up to 1984 led to the assumption that the 2 μg/m^3 limit had been effective in preventing CBD (ref. 6). DOE recognizes that the 1980s–1990s studies used more effective screening and diagnostic methods than the earlier studies. Nevertheless, these 1980s–1990s studies provide strong evidence that adherence to the OSHA standard has not prevented new cases of disease.

In 1991, responding to NJMRC findings, DOE's 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 NJMRC studies. 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 THREE DOE SITES THROUGH DECEMBER 1997

	Rocky Flats	Y–12	Mound
Individuals Examined	6,257	1,949	632
Abnormal Be-LPT Number (percent)	221 (3.5%)	77 (4%)	1 [1]
Completed Diagnostic Exams	186	33	0

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

	Rocky Flats	Y–12	Mound
CBD Number (percent)[2]	79 (1.3%)[3]	25 (1.3%)[4]	0

[1] The one Mound employee who was found to be consistently positive declined 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 cases through the 1987–1991 NJMRC study, and 6 cases 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 cases 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 who were provided the Be-LPT.

In 1996, three studies reported on exposure to beryllium associated with CBD and immunologic sensitization to beryllium (refs. 19–21). Two of the studies reported on cases of CBD at Rocky Flats (refs. 19, 20). The third reported on an epidemiology study of a private sector beryllium ceramics fabrication plant that began operating in 1981 (ref. 21). Both Rocky Flats and the ceramics plant were extensively monitored for compliance with the current OSHA 8-hour TWA exposure standard of 2 μg/m^3. The authors concluded that exposures among the highest exposed groups in the plants were, on average, below the 2 μg/m^3 limit. At both plants, cases of CBD and sensitization to beryllium were found not only among the highest exposed workers, but also among the lowest exposed workers, including administrative and other personnel who did not work directly with beryllium.

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. 19). 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 one order of magnitude. Extensive air monitoring data were available for machinists, which were one of the highest exposed groups.

Barnard and colleagues completed an extensive analysis of the monitoring data associated with machining operations at Rocky Flats (ref. 20). 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 μg/m^3 limit, and that excursions above the limit were common.

Kreiss and colleagues studied CBD occurring in a beryllium oxide ceramic manufacturing plant (ref. 21). 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, ''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. 5). 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	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

Cases of CBD have occurred in machinists who worked in the Y–12 beryllium ceramic machine shop, where levels have been quite low. Only a small percentage of samples there have detected beryllium. Continuous area air monitors have operated in the shop throughout its existence. One area sample indicated levels above 2 μg/m^3 when a machine tool was operated with an exhaust duct that was disconnected. No other area measurements above 2 μg/m^3 were recorded, and the median measurement was at the level of detection.

Kreiss (ref. 22) describes the relative hazards in sectors of the beryllium industry, and risk factors for CBD and sensitization related to work processes in a beryllium manufacturing plant that produced pure metal, oxide, alloys, and ceramics. Employees in the pebble plant (producing beryllium metal) had the highest prevalence of CBD (6.4%) compared with other workers (1.3%). The pebble plant was not associated with the highest gravimetric industrial hygiene measurements, indicating that total beryllium was probably not a good indicator for hazard surveillance. The

report indicates that particle size or other characteristics may be more important contributors to risk than the total mass of breathing zone particles, that daily-weighted averages are poor estimates of personal exposure, and that methods of exposure assessment may poorly reflect actual exposures from accidents.

Several authors have highlighted the uncertainty that exists in the exposure assessments (refs. 20, 21, 23). 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 measurable airborne beryllium is capable of reaching the regions of the lung where health effects occur. 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. 20, 23).

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 μg/m^3 limit have occurred in all groups studied for which exposure data is available. 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. 24), producing the beryllium ion that elicits an immune response (ref. 25). The persistent presence of the beryllium ion in the lung makes CBD a chronic disease (ref. 26). Both intermittent high and continual low exposures to insoluble forms of beryllium can create and maintain a lung burden that will not clear for many years, if at all (ref. 27).

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. 28).

Differences in individual susceptibility have made it difficult to understand the relationship between exposure and CBD. Early epidemiology 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 one month and those who had unrecognized or seemingly trivial exposure. However, the NJMRC 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 1940s	Estimated exposed	Cases	Estimated incidence per 100 exposed	Estimated level of exposure μg/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	1,000
Painesville, Ohio	200	0	0.0	1,000
Reading, Pennsylvania	4,000	51	1.3	1,000
Exposed from the 1970s to the 1980s	**Study participants**	**Cases**	**Incidence per 100 exposed**	**Estimated level of exposure μg/m^3**
Beryllia Ceramics Plant [2]	505	9	1.8	NA
The DOE Rocky Flats Plant [3]	895	15	1.7	1
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/m^3,'' Am. J. Ind. Med., Vol. 30, pp 16–25, 1996.

TABLE 7.—BERYLLIUM SENSITIZATION AND DISEASE RATES AT ROCKY FLATS [1]

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	6	4.7
Trepanning	3	77	3.9
Band Sawing	4	67	6.0

TABLE 7.—BERYLLIUM SENSITIZATION AND DISEASE RATES AT ROCKY FLATS [1]—Continued

Beryllium process title	Workers sensitized	Workers doing process	Sensitization rate (percent)
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

[1] 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. 29) consolidated the previous epidemiology 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/m^3 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) the inadequacy of area monitoring in reflecting actual exposure; (3) the effect of chemical composition, size, and shape on the bioavailability of the inhaled particles; (4) inadequate monitoring of the chemical beryllium composition, size, and shape of inhaled particles; and (5) the effect of genetic predisposition on developing beryllium sensitization and CBD. As a result, the existing literature does not point to a specific tolerance level for exposure to beryllium.

4. Value of Early Detection

Early detection of a disease is of value if it leads to earlier treatment and a better prognosis for the individual being tested. Screening for CBD with the Be-LPT can provide earlier detection than is possible with other tests. In some cases this has led to treatment of CBD to reduce lung damage that would not have been possible if the CBD remained undiagnosed by other tests, such as chest X-ray. Researchers at the NJMRC compared the lung functions of patients with CBD who had been identified through abnormal chest X-rays or clinical symptoms to those of patients whose CBD had been identified through positive Be-LPTs (ref. 30). Twelve out 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.

DOE's experience is consistent with this conclusion. The 79 cases of CBD diagnosed among Rocky Flats workers showed a range of severity. 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. Clinical evaluations using computer aided tomography (CAT) scan, bronchoalveolar lavage-BeLPT (BAL Be-LPT), transbronchial biopsy, and gas diffusion studies of workers confirmed the presence of CBD in these workers.

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 (ref. 27). Additionally, members of the work force who are consistently positive on the Be-LPT are those most likely to eventually develop CBD. Treating physicians generally recommend that these individuals receive more frequent and more extensive pulmonary function testing so that the lung damage associated with CBD can be minimized through early detection and treatment. Sensitized and early CBD patients can be removed from jobs with beryllium exposure.

Finally, beryllium sensitization found through screening with the Be-LPT is the earliest indication that working conditions and work practices are affecting the health of exposed workers. This allows for an earlier opportunity to initiate corrective actions and possibly to prevent cases of CBD. Early detection enhances the contribution of medical surveillance to the management of the CBDPP.

II. Legal Authority and Relationship to Other Programs

Today's rule, which establishes minimum requirements for the protection of beryllium-associated workers, is promulgated pursuant to DOE's authority under section 161 of the Atomic Energy Act of 1954 (AEA) to prescribe such regulations as it deems necessary to govern any activity authorized by the AEA, specifically including standards for the protection of health and minimization of danger to life or property (42 U.S.C. 2201(i)(3) and (p)). Additional authority for the rule, insofar as it applies to DOE Federal employees, is found in section 19 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 668) and Executive Order 12196, ''Occupational Safety and Health Programs for Federal Employees,'' (5 U.S.C. 7902 note), which require Federal agencies to establish comprehensive occupational safety and health programs for their employees.

DOE intends this final rule to be integrated with the existing worker protection management program for DOE Federal and contractor employees established by DOE Order 440.1A. The requirements in this final rule will supersede any conflicting provisions of DOE Order 440.1A on the effective date of the rule. On that date the rule also

will supersede DOE Notice 440.1, ''Interim Chronic Beryllium Disease Prevention Program,'' established by then-Secretary Pena on July 15, 1997.

Some comments on the NOPR raised questions about the effect of the rule on collective bargaining and grievance-arbitration processes established by collective bargaining agreements. One union urged (Ex. 22) DOE to clarify whether the terms of this rule are subject to negotiation between a union and a contractor.

DOE has concluded that there is a compelling need for the CBDPP requirements in this final rule in order for DOE to meet its obligation under the AEA to protect the health of its employees and other workers at DOE facilities. The regulatory requirements of this rule will by operation of law apply to DOE contracts. Therefore, the application and enforcement of this rule are not subject to the Work Smart Standards Program or other related processes. DOE believes that this mandatory application of the CBDPP requirements to all DOE beryllium activities is appropriate given the hazardous nature of beryllium-related work.

While the minimum requirements in the rule are non-negotiable and may not be waived, the rule does not preclude all collective bargaining on matters related to beryllium exposure protections. Some rule provisions, such as the requirement for a beryllium exposure reduction and minimization provision in an employer's CBDPP, are performance-based and allow for negotiation between the employer and employee representatives. Other rule requirements, however, are stated in specific terms that do not permit any change. For example, section 850.24(e) of the rule specifies the accuracy that must be achieved by exposure monitoring of workers: not less than plus or minus 25 percent, with a confidence level of 95 percent, for airborne concentrations of beryllium at the action level. DOE's objectives of controlling worker exposure to airborne beryllium and obtaining better exposure data would be defeated if accuracy of monitoring were a subject of collective bargaining. Although today's rule may incidentally affect collective bargaining, it is neutral with respect to the balance of bargaining power of organized labor and management. The rule applies to all DOE contractors whether or not they are involved in collective bargaining.

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

III. Overview of the Final Rule

The final rule strengthens the worker protection program established under DOE Order 440.1A, Worker Protection Management for DOE Federal and Contractor Employees (or DOE Orders 5483.1B, 5480.4, 5480.8A, and 5480.10 for operations not covered by DOE Order 440.1A), by supplementing the general worker protection program requirements with provisions that are specifically 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,'' but a number of provisions have been modified as a result of DOE's consideration of comments received in the rulemaking.

Consistent with DOE Notice 440.1, this final rule establishes a CBDPP that is designed to reduce the occurrence of CBD among DOE federal and contractor workers and any other individuals who perform work at DOE facilities. The CBDPP will accomplish this disease-reduction mission through provisions that: (1) Reduce the number of current workers who are exposed to beryllium by clearly identifying and limiting worker access to areas and operations that contain or utilize beryllium; (2) minimize the potential for, and levels of, worker exposure to beryllium by implementing engineering and work practice controls that prevent the release of beryllium into the workplace atmosphere and/or capture and contain airborne beryllium particles before worker inhalation; (3) establish medical surveillance to monitor the health of exposed workers and ensure early detection that makes possible early treatment of disease; and (4) establish continual monitoring of the effectiveness of the program in preventing CBD and implementing program enhancements as appropriate. Another key purpose of the rule is the collection of consistent data, which will improve the information available to better understand the cause of CBD.

DOE has made numerous changes in the final rule after considering the public comments on the proposed rule. The principal changes are as follows:

- The final rule requires responsible employers to assign a qualified individual, such as a Certified Industrial Hygienist, to manage and supervise beryllium inventories, hazard assessments, and exposure monitoring.

- The final rule establishes the airborne beryllium concentration action level, which in this rule triggers key worker protection measures, at 0.2 $\mu g/m^3$, instead of 0.5 $\mu g/m^3$ as proposed. The STEL has been deleted, because the proposed STEL would not provide any added protection for workers given that the new action level of 0.2 $\mu g/m^3$ would be exceeded in less than 15 minutes where exposure levels are at 10$\mu g/m^3$.

- The final rule provides that responsible employers must require workers to use respirators in areas where the beryllium exposure level is at or above the action level, rather than at or above the PEL as proposed in the NOPR, and must provide a respirator to any worker exposed to beryllium who requests one, regardless of the concentration of airborne beryllium.

- The final rule includes criteria and requirements to govern the release of beryllium-contaminated equipment and other items at DOE sites for use by other DOE facilities or the public.

- The final rule requires responsible employers to offer medical surveillance to any ''beryllium-associated worker,'' defined to include any current worker who is exposed through beryllium work or who had past exposure or potential exposure to beryllium at a DOE facility.

- The final rule contains medical removal protection and multiple physician review provisions that are modeled on provisions of three of OSHA's expanded health standards.

The provisions of the rule are presented in three subparts. Subpart A 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 provisions requiring responsible employers to develop and maintain a CBDPP and to perform all beryllium-related activities according to the CBDPP. Subpart C establishes requirements for the content and implementation of the CBDPP. Some of the provisions of Subpart C apply only when it is determined that the airborne concentration of beryllium in a specific workplace or operation rises above a specified limit. Table 8 summarizes these provisions and indicates the levels of beryllium at which the provisions apply.

TABLE 8.—LEVELS AT WHICH THE PROVISIONS OF THE CBDPP APPLY

Provision	Worker exposure or potential exposure levels (8–Hour TWA)		
	Be operations/locations [1]	≥Action level (0.2 μg/m^3)	≥PEL (8-hr TWA) (2.0 μg/m^3)
Baseline 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[2]	X[3]	X[4]
Regulated Areas (850.26)		X	
Hygiene Facilities and Practices (850.27)		X	
Respiratory Protection (850.28)	X[5]	X	
Protective Clothing and Equipment (850.29)	X[6]	X	
Housekeeping (850.30)	X[7]		
Release Criteria (850.31)	X[8,9]		
Medical Surveillance (850.34)	X[10]		
Training and Counseling (850.37)	X[11]		
Warning Signs (850.38)		X	

[1] Applies to beryllium operations and other locations where there is a potential for beryllium contamination.
[2] Responsible employers must implement actions for reducing and minimizing exposures, if practicable.
[3] Responsible employers must establish a formal exposure reduction and minimization program, if practicable.
[4] Responsible employers must reduce exposures to or below the PEL.
[5] Responsible employers must provide respirators when requested by the worker.
[6] Responsible employers must provide protective clothing and equipment where surface contamination levels are above 3 μg/100 cm^2.
[7] Housekeeping efforts must maintain removable surface contamination at or below 3 μg/100 cm^2 during non-operational hours.
[8] Removable contamination on equipment surfaces must not exceed 0.2 μg/100 cm^2 when released to the public or for non-beryllium use.
[9] Removable contamination on equipment surfaces must not exceed 3 μg/100 cm^2 when released to other beryllium handling facilities.
[10] Responsible employers must provide medical surveillance for all beryllium-associated workers.
[11] Training is required for all workers who could be potentially exposed. Counseling is required for beryllium-associated workers diagnosed with CBD or beryllium sensitization.

IV. Section-by-Section Discussion of Comments and Rule Provisions

This section of the Supplementary Information responds to significant comments on specific proposed rule provisions. It also contains explanatory material for some final rule provisions in order to provide interpretive guidance to DOE offices and DOE contractors that must comply with this rule. All substantive changes from the notice of proposed rulemaking (NOPR) are explained in this section. However, some non-substantive changes, such as the renumbering of paragraphs and changes to clarify the meaning of rule provisions, are not discussed.

DOE has determined that the requirements set forth in this final rule are those which, based on currently available data, are necessary to provide protection to workers who may be exposed to beryllium.

A. Subpart A—General Provisions

Section 850.1—Scope

The CBDPP required by this rule will enhance, supplement, and be integrated into existing worker protection program requirements for DOE Federal and contractor employees. DOE has structured the 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 protect workers from hazards of exposure to airborne beryllium.

Section 850.2—Applicability

As in the proposed rule, section 850.2 specifies that this rule applies to DOE offices and DOE contractors with responsibility for operations or activities that involve present or past exposure, or the potential for exposure, to beryllium at DOE facilities. It also applies to any current DOE employee, DOE contractor employee, or any other current worker at a DOE facility who is or was exposed or potentially exposed to beryllium at a DOE facility, regardless of which organization currently employs the worker.

Except at the few DOE-operated facilities, DOE federal workers are not usually directly involved in production tasks or other activities in which they would be exposed to airborne beryllium. However, in performing management and oversight duties, DOE federal workers may enter facilities where beryllium is handled. Federal agencies are required to ensure the protection of federal workers under the health and safety provisions of 29 CFR Part 1960, ''Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters,'' as well as Executive Order (EO) 12196, ''Occupational Safety and Health Programs for Federal Employees.'' DOE's intent in 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.

Section 850.2(a)(2) specifies that the rule also applies to DOE contractors with operations or activities involving exposure or the potential for exposure to beryllium. As clarified in the definition of ''DOE contractor'' (section 850.3), DOE's intent is that the contractors covered under this rule include any entity under contract to perform DOE activities at DOE-owned or -leased facilities, including contractors awarded management and operating contracts, integrating contractors, and subcontractors. This section further clarifies that the requirements of the CBDPP apply only to contractors and subcontractors who work in areas or on DOE activities that involve the potential for worker exposure to beryllium.

The provisions of this rule do not apply to former DOE workers; to activities at DOE facilities that do not involve exposure or potential exposure to beryllium; or to activities not

conducted at a DOE facility, such as the off-site laundering of beryllium-contaminated protective clothing from a DOE site.

Section 850.2(b) exempts ''beryllium articles'' from the rule (see the definition of ''beryllium article'' under section 850.3). DOE 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 airborne beryllium. This exemption for beryllium articles is consistent with the approach taken by OSHA in regulating hazardous materials under the Hazard Communication standard at 29 CFR 1910.1200.

Section 850.2(c) establishes 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. Three commenters (Exs. 30, 31, 32) opposed this exemption, stating that lesser protection would be afforded to laboratory workers than to those workers covered by the rule. One commenter (Ex. 30) suggested that laboratory exposures are difficult to predict and that a lack of sampling resulting from the perception that little hazard is present in laboratory settings may lead to incomplete exposure characterizations.

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. DOE 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.

DOE notes the laboratory exemption only applies in instances where relatively small quantities of beryllium are used in a non-production activity. In addition, OSHA's Laboratory standard has specific provisions to ensure that protective laboratory practices are followed. Many of the provisions in OSHA's Laboratory standard are the same as, or similar to, those in this final rule. For instance, OSHA's Laboratory standard establishes provisions for identifying the presence of hazardous chemicals (baseline inventory), establishing a chemical hygiene plan (hazard assessment), performing periodic monitoring at the action level, implementing exposure reduction measures at the PEL, training employees on related hazards, and providing employees the opportunity for medical consultation and examination. In part because each of these aspects of the beryllium rule is already included in the OSHA Laboratory standard, DOE has retained the laboratory operations exemption in section 850.2(b)(2).

Section 850.3—Definitions

Commenters on the proposed rule's ''Definitions'' section typically requested clarification or modification of the proposed definitions.

New terms. In response to public comment, the following additional terms have been defined in section 850.3: ''beryllium-associated worker,'' ''Head of DOE Field Element,'' ''removable contamination,'' ''responsible employer,'' and ''unique identifier.'' A discussion of each term is included in the alphabetical listing of definitions provided below.

Terms and definitions deleted. In response to public comment, the following definitions in the NOPR are deleted in the final rule: ''accepted applicant,'' ''short term exposure limit (STEL),'' and ''surface contamination.'' The deletions are explained in the section-by-section discussion of the rule provisions in which the terms were previously used.

Section 850.3 defines key terms using traditional industrial hygiene terminology and terminology used by OSHA in its regulations. The use of such terminology is consistent with DOE's increased emphasis on industrial hygiene compliance through the use of accepted occupational safety and health requirements and procedures. The following discussion explains the definitions in the rule. Although some of these terms are commonly used, DOE believes that these definitions will help ensure that their meaning as used in the context of the rule is clear.

Action level means the level of airborne concentration of beryllium established pursuant to Subpart C, which, if met or exceeded, requires the implementation of certain specified provisions of the rule. Using an action level to trigger certain provisions of the rule is consistent with the approach applied in many of OSHA's substance-specific standards. The word ''exceeded'' was amended to read ''met or exceeded'' in the final rule to clarify DOE's intent that worker protection provisions must be implemented in cases where worker exposure levels are measured at, as well as above, the action level.

Authorized person means any person required by work duties to be in regulated areas. The concept of authorized person is consistent with OSHA standards and with contractor practice in many DOE facilities, and is intended to ensure that the population of potentially exposed individuals is reduced to the lowest possible number and that workers who are granted access to regulated areas have the knowledge they need to protect themselves and other workers. Under this rule, authorized individuals are to be trained in the hazards of beryllium and in the means of protecting themselves and those around them against such hazards. Training requirements for individuals working with beryllium are specified in section 850.37 of the rule. DOE did not receive any comments on this definition, which remains unchanged in the final rule.

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. This definition of beryllium reflects the focus of this rule on worker exposure to airborne beryllium. One commenter (Ex. 26) questioned whether exposure to naturally occurring beryllium compounds in excess of 0.1 percent was covered by the DOE program. However, as correctly noted by the same commenter, sections 850.2(a)(1) and (2) provide that the rule only applies to exposures and potential exposures to beryllium that occur in connection with facility operations. Another commenter (Ex. 10) suggested that 0.1 percent beryllium was too inclusive, and suggested that a level of 0.5 percent be used instead. DOE notes, however, that the concentration specified in the definition is consistent with the criterion that OSHA uses for a carcinogenic mixture, i.e., 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. Therefore, DOE has not changed the definition in the final rule.

Beryllium activity means an activity performed for, or by, DOE at a DOE facility that can expose workers to airborne concentrations of beryllium. Activities within the scope of this definition may involve design, construction, operation, maintenance, and decommissioning. The definition further explains that a ''beryllium activity'' may involve one DOE facility or operation, or a combination of facilities and operations. This definition

is broad enough to include activities such as repair work performed by support-service subcontractors who visit the site infrequently. DOE did not receive comments on this proposed definition. However, DOE modified the language to clarify that maintenance operations are within the scope of the term.

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 the item's shape or design, and that does not release beryllium or otherwise result in exposure to airborne concentrations of beryllium under normal use conditions. DOE has included this definition of ''beryllium article'' to distinguish between forms of beryllium that may result in exposure to airborne beryllium and manufactured items containing beryllium that do not release beryllium or otherwise result in exposure to airborne concentrations of beryllium. All of the persons (Exs. 9, 26, 30, 31) commenting on this definition agreed that exempting beryllium articles from the program is a logical approach. Two of these commenters (Exs. 9, 26) stated that an item destined for machining should be considered a beryllium article up to the time of that machining. In response to these comments DOE notes that the beryllium article definition is consistent with the approach 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, if used as intended, does not have the potential to result in hazardous exposures. However, an item ceases to be an ''article'' when it is subjected to machining, cutting, drilling, or similar action other than its intended end use. Similarly, if an item is manufactured for the purpose of being machined later, it is not considered an article. Another commenter (Ex. 31) suggested that examples of activities that could release beryllium, such as burning, grinding and chipping, be included in a parenthetical listing in the definition. DOE recognizes that there are many activities that could lead to a release, and is concerned that providing examples could be interpreted to exclude other activities. To avoid such confusion, DOE believes that examples should not be included in the definition, but rather should be included in a companion implementation guide for the rule.

Beryllium-associated worker means a current worker who is or was exposed or potentially exposed to airborne concentrations of beryllium at a DOE facility. This individual may be a DOE Federal or contractor worker, an employee of a subcontractor to a DOE contractor, or a visitor who, pursuant to a DOE-approved arrangement, performs work at a DOE facility. This definition clarifies DOE's intent that the rule applies only to current workers. The definition further clarifies that current workers who have been removed from beryllium exposure as part of the medical removal plan are beryllium-associated workers under the rule, but they are not ''beryllium workers'' (see definition of ''beryllium worker'').

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 ''emergency'' as applied in 29 CFR 1910.120 and refers to any untoward event, such as a major spill of powdered beryllium or an unexpected upset that releases a significant amount of beryllium into the workplace atmosphere. Two commenters (Exs. 24, 31) expressed concern that the term ''significant release'' was open to too much interpretation and needed further clarification. Emergency situations, by their very nature, are difficult to anticipate and describe. DOE believes that the examples listed provide a general indication as to what constitutes a significant release. The use of the term ''beryllium emergency'' is used in section 850.33, which requires DOE contractors to develop emergency procedures and training to address emergency scenarios.

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. Medical personnel use the Be-LPT to identify workers who have become sensitized to beryllium through their occupational exposure. DOE did not receive any comments on this proposed definition, which remains unchanged in the final rule.

Beryllium worker means a current worker who is regularly employed in a DOE beryllium activity. Section 850.3 of the NOPR defined ''beryllium worker'' as ''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 proposed definition included DOE Federal or contractor workers, workers employed by a subcontractor to a DOE contractor and visitors performing work at DOE facilities. Consistent with other provisions of the proposed rule, DOE intended this definition to apply only to current workers. DOE specifically stated in the NOPR that former workers would not be included in the proposed ''beryllium worker'' definition, but instead would be addressed under a separate initiative.

DOE received eight comments on the definition of ''beryllium worker'' in the proposed rule. Five commenters (Exs. 2, 14, 16, 17, 28) stated that the term beryllium worker was too limiting. These commenters argued that the proposed definition of beryllium worker should not be limited to those workers exposed to levels of beryllium at or above the action level, but rather should include all workers with the potential for beryllium exposure. Three commenters (Exs. 2, 14, 28) supported this position by noting that current scientific evidence does not suggest a ''safe'' level of beryllium exposure, and that CBD has been identified in individuals thought to have only low or incidental exposure to beryllium. DOE shares this concern, and has omitted the reference to the action level from the definition of ''beryllium worker'' in the final rule. DOE has revised the definition in the final rule to apply to each ''current worker who is regularly employed in a DOE beryllium activity.''

These same five commenters (Exs. 2, 14, 16, 17, 28) also argued that medical surveillance should be offered to all individuals with beryllium exposure and that the beryllium worker definition, therefore, should be expanded to include reassigned and former workers with prior beryllium exposure. These commenters were concerned that restricting medical surveillance to ''beryllium-workers,'' as defined in section 850.3 of the proposed rule, would exclude workers with incidental beryllium exposure who also may be at risk of contracting CBD.

Two commenters (Exs. 2, 28) questioned the need for separate medical surveillance programs for former and current beryllium workers. These two commenters raised the issues of increased cost, lack of continuity, and the added confusion to participants associated with maintaining separate surveillance programs.

In response to these comments, DOE added the term ''beryllium-associated worker,'' which is more inclusive than the term ''beryllium worker.'' (See definition of ''beryllium-associated worker.'') The term ''beryllium-associated worker'' is used in provisions of the rule where DOE has determined that coverage should not be limited to workers regularly employed in DOE beryllium activities. Use of the term ''beryllium-associated worker'' clarifies DOE's intent that current employees with past beryllium exposures or potential exposures, as well as current individuals who are exposed to airborne beryllium at DOE facilities, be included under the following rule provisions: 850.5 (dispute resolution), 850.10 (development and approval of the CBDPP), 850.33 (medical surveillance), 850.34 (medical removal), 850.35 (medical consent), 850.36 (training and counseling) and 850.39 (beryllium registry).

DOE, however, has not expanded the definition to include former workers. DOE previously established the Former Beryllium Workers Medical Surveillance Program and offers medical examinations to former (retired and separated) workers who are at risk for developing CBD due to their work at DOE. The elements of the Former Beryllium Workers Medical Surveillance Program are: (1) identification of beryllium workers who have retired or separated from employment; (2) notifying workers of their eligibility to participate in the program, and general announcements to provide former workers an opportunity to self-identify as a former beryllium worker; (3) informed consent on the risks and benefits of participating in the program; (4) screening for CBD using the Be-LPT, a standardized questionnaire on respiratory symptoms, and a chest radiograph if indicated by responses to the questionnaire; (5) an offer of diagnostic medical examinations to individuals found to have either a positive Be-LPT or signs or symptoms of CBD; (6) periodic medical monitoring; (7) funds for medical care that is not covered by insurance; and (8) epidemiologic surveillance to identify high risk operations where additional primary preventative actions are needed.

One commenter (Ex. 23) took issue with the phrase ''potentially exposed'' in the proposed definition of ''beryllium worker,'' arguing that it is too vague and could allow too much room for individual interpretation. DOE believes that limiting the definition to workers with actual personal exposure monitoring results at or above a specified airborne level would unnecessarily limit responsible employers' options for meeting the exposure monitoring requirements of this rule. For instance, if the phrase ''potentially exposed'' were removed from the definition, the use of representative sampling would no longer be an acceptable option for meeting the exposure monitoring requirements in the rule. Employers would be required to determine actual exposures for all workers to determine whether the workers are beryllium-associated workers. DOE believes that such an inflexible requirement would be burdensome and inconsistent with sound industrial hygiene practices and the provisions of section 850.21 of the rule, which requires qualified industrial hygienists to apply their professional knowledge and experience in the performance of beryllium hazard assessments. Accordingly, the final rule (in the definitions of ''beryllium-associated worker'' and ''beryllium activity'') requires responsible employers to consider potential exposures in identifying beryllium workers.

Another commenter (Ex.16) stated that the proposed definition of ''beryllium worker,'' as applied in determining a worker's eligibility to participate in the medical surveillance program, could be too narrow in some respects and too broad in others. This commenter favored including current workers no longer working with beryllium and those with exposures below the action level in the definition of ''beryllium worker.'' This commenter recommended allowing the industrial hygiene and medical staff to use a ''graded approach'' to determine which workers received medical surveillance, based on the needs of the individual and ''common sense judgement about cost and benefit.'' DOE agrees that current workers no longer working with beryllium and those with exposures below the action level should be eligible for medical surveillance and, thus, has included such individuals in the final rule's definition of ''beryllium-associated workers.'' DOE does not agree, however, that determining whether a worker should receive medical surveillance should be left to the discretion of the industrial hygiene and medical staff. DOE believes that such discretionary application of medical surveillance will result in an inconsistent level of protection for workers across the DOE complex. Therefore, section 850.34 of the final rule requires responsible employers to develop and implement a medical surveillance program for all beryllium-associated workers (see discussion of section 850.34).

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 is used principally in section 850.24, Exposure Monitoring, which requires DOE contractors to determine worker exposures to beryllium by monitoring for the presence of contaminants in the worker's personal breathing zone. One commenter (Ex. 9) stated that this proposed definition was imprecise. DOE disagrees and views this definition as being consistent with sound and accepted industrial hygiene practice. It will ensure that samples collected for personal exposure monitoring represent the air inhaled by workers while performing their duties in affected work areas. Therefore, DOE has not revised this definition in the final rule.

DOE means the Department of Energy.

DOE contractor means any entity under contract with DOE, including a subcontractor, with responsibility for performing DOE activities at DOE-owned or -leased facilities. This term does not apply to a contractor or subcontractor who provides only ''commercial items'' as defined under the Federal Acquisition Regulations (FAR). Such contractors would not be performing DOE beryllium activities. As explained in the discussion of section 850.10, subcontractors who are covered under the rule normally will not be designated to prepare the written CBDPP for a site. However, these subcontractors will be included in the CBDPP that encompasses all beryllium-related activities at the site.

DOE facility means any facility operated by or for DOE, whether owned or leased by DOE.

Head of DOE Field Element is the high-level DOE official in a DOE field or operations office who has the responsibility for identifying the contractors and subcontractors covered by this part and for ensuring compliance with this part.

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, etc., to remove toxic or hazardous particulates like beryllium.

Immune response refers to the series of cellular events by which the immune system reacts to a specific antigen. Types of immune responses include acquired immunity and sensitization.

The body's immune response to beryllium is sensitization and is indicated by the results of the Be-LPT.

Medical removal protection benefits are employment rights established in section 850.35 for beryllium-associated workers temporarily or permanently subject to medical removal from working in regulated areas following medical evaluations. These provisions give contractors an incentive to make reasonable efforts to find and offer alternate employment to workers who have suffered negative health effects due to exposure to beryllium. The definition of medical removal protection benefits and the requirements in section 850.35 ensure that such workers would suffer no reductions in total earnings, seniority, or other worker rights and benefits for two years after permanent medical removal. The two-year period for medical removal protection benefits after permanent removal will allow the contractor to make a reasonable effort to find alternate employment for a removed worker or, through job retraining and out-placement programs operated by many sites, to locate alternate outside employment for the worker.

Regulated area means an area demarcated and managed by the responsible employer where the airborne concentration of beryllium exceeds, or can reasonably be expected to exceed, the action level (see the definition of ''action level.''). Employees working in regulated areas must be authorized to do so by the responsible employer, and must be trained and equipped with protective clothing and equipment. The purpose of such areas is to limit potential exposure to beryllium to as few workers as possible. Regulated areas are commonly used throughout DOE, particularly with regard to radiation protection, and their use is consistent with OSHA's expanded health standards for toxic particulates.

Removable contamination means beryllium contamination that can be removed from surfaces by nondestructive means, such as casual contact, wiping, brushing, or washing. This term was adopted from DOE's Radiological Control Manual, April 1994. One commenter (Ex. 23) stated that ''surface contamination'', a term defined in the proposed rule, should refer to contamination that is removable, not simply beryllium on surfaces. DOE agrees with this commenter that only removable surface contamination can become airborne and inhaled by workers, and has replaced the term ''surface contamination'' with ''removable contamination.''

Responsible employer means the DOE contractor office that is directly responsible for the safety and health of DOE contractor employees while performing a beryllium activity or other activity at a DOE facility; or for DOE employees, the DOE office that is directly responsible for the safety and health of DOE Federal employees while performing a beryllium activity or other activity at a DOE facility; and any person acting directly or indirectly for such office with respect to terms and conditions of employment of beryllium-associated workers. This definition is added to clarify DOE's intent that provisions of the final rule apply to both DOE Federal and contractor workers at DOE facilities.

Site Occupational Medical Director (SOMD) means the physician responsible for the overall direction and operation of the site occupational medicine program. DOE intends, through this definition, to ensure that a physician administers each DOE facility's occupational medicine program.

Unique identifier means a number or alphanumeric code used to identify each worker individually and distinctively while protecting the worker's privacy. Unique identifiers are used in DOE's health surveillance program to help identify the exposures each worker has experienced in the course of his or her work in a DOE facility without personally identifying the worker. The unique identifiers will allow DOE to link worker's exposure and occupational health data.

Worker means a person who performs work at a DOE facility including (but not limited to) a DOE employee, an independent contractor, or a DOE contractor employee. As clarified in the definition of ''DOE contractor,'' an employee of a covered subcontractor is a contractor employee under this part.

Worker exposure means the airborne concentration of beryllium in the breathing zone of the worker that would occur if the worker were 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.

Section 850.4–Enforcement

DOE proposed that enforcement of the CBDPP requirements in Part 850 would be through contractual remedies, including contract termination or reduction in fee. Section 850.4 of the final rule adheres to this approach. This section provides that DOE may take appropriate steps under its contracts to ensure compliance with this rule, including (but not limited to) contract termination or reduction in fee.

One union commented (Ex. 22) that the proposed enforcement provision would be inadequate because DOE is not likely to terminate a prime contractor's contract for failure to comply with health and safety requirements, and because award fee reductions are only useful if the contracting officer is aware of, and qualified to investigate, noncompliance. The union requested that the rule be enforced under DOE's nuclear safety requirement enforcement procedures in 10 CFR Part 820 or pursuant to section 3131 of the National Defense Authorization Act for Fiscal Years 1992 and 1993 (42 U.S.C. 7274d). The union also suggested that while awaiting a compliance officer, a worker should have the right to shut down the job without loss of pay.

DOE has not adopted the commenter's recommendation to enforce this rule under 10 CFR Part 820 or section 3131 of the National Defense Authorization Act for Fiscal Years 1992 and 1993. Part 820, ''Procedural Rules For DOE Nuclear Activities,'' contains procedures for enforcement of DOE nuclear safety requirements. Beryllium is not normally considered a nuclear material, and, therefore, enforcement of this rule would not fall within the scope of Part 820. DOE also cannot enforce this rule under section 3131 of the National Defense Authorization Act because that section's scope is limited, authorizing only the imposition of civil penalties against a DOE contractor for failing to train or certify to DOE the adequacy of employee training in hazardous substance response or emergency response (42 U.S.C. 7274d(b)).

In DOE's view, the existing mechanisms and contractual remedies available for enforcing DOE contractor worker protection programs are adequate for enforcement of this rule. For instance, under DOE Order 440.1A, DOE and, to the extent incorporated into contracts, DOE contractors are required to implement worker protection programs that ensure compliance with applicable health and safety requirements. The worker protection program must provide workers with certain rights, including, among other things, the right to accompany DOE worker protection personnel during workplace inspections on official time; the right to express concerns related to worker protection; to decline to perform an assigned task based on a reasonable belief that the task poses an imminent risk of death or serious bodily harm

when there is insufficient time to obtain redress through normal reporting and abatement procedures; the right to observe monitoring or measuring of hazardous agents and have access to the results of exposure monitoring; the right to be notified if monitoring results indicate they were overexposed to hazardous materials; and the right to receive results of inspections and accident investigations upon request. These provisions of DOE Order 440.1A continue to apply under the CBDPP.

Additionally, a contractor employee is protected from retaliation for a refusal to work under certain circumstances, as specified in an interim final rule that DOE promulgated on March 15, 1999, which substantially revises 10 CFR part 708, DOE Contractor Employee Protection Program (64 FR 12862 as amended at 64 FR 37396). An employee of a contractor (or a subcontractor) may file a complaint under the ''whistleblower'' regulations if he or she is subject to retaliation for refusing to participate in an activity based on a reasonable fear of serious injury (10 CFR 708.5(c)).

Section 850.5–Dispute Resolution

In the NOPR, DOE proposed that disputes arising under this part that are brought by beryllium workers be resolved through applicable grievance-arbitration processes or, if such processes are not available, through referral to the DOE's Office of Hearings and Appeals.

A union commented (Ex. 22) that the proposal to relegate a worker to the grievance and arbitration provision of the collective bargaining agreement would be inadequate because it erroneously assumes that an arbitrator would find a final rule to be part of the collective bargaining agreement. The union stated that unless DOE required employers to propose this rule, and unions accepted it as a contract condition, an arbitrator would decline to enforce this rule. The same commenter asked that DOE clarify in the final rule that an employee representative may file grievances under a collective bargaining agreement or seek other remedies under the labor laws to compel contractor compliance or deter contractor retaliation for seeking enforcement of the rule.

A DOE contractor (Ex. 23) expressed concern that proposed section 850.5 might interfere with existing dispute resolution processes, or might violate Federal law by imposing an obligation on the employment relationship between a DOE contractor and its employees who are subject to the terms of a collective bargaining agreement.

In proposing section 850.5, DOE sought to avoid creating opportunities for workers represented by labor organizations to circumvent collective bargaining agreement procedures for resolving disputes concerning terms and conditions of employment. Thus, DOE proposed that workers use available grievance-arbitration procedures for resolution of disputes related to the subject of this rule. However, DOE agrees with the comment that an arbitrator deciding a grievance under a collective bargaining agreement might not look beyond the collective bargaining agreement in making a decision. Because this rule establishes minimum requirements that are independent of collective bargaining agreements, available grievance-arbitration procedures may not in some cases be sufficient to ensure compliance with the rule.

DOE, therefore, has modified the text of section 850.5 to permit any adversely affected person to refer a dispute regarding compliance with the rule to the Office of Hearings and Appeals for resolution, but employees who are represented by a labor organization are required first to exhaust any grievance-arbitration procedure that is available for resolving disputes over terms and conditions of employment. This is the approach DOE took in its interim final rule for the DOE Contractor Employee Protection Program, 10 CFR part 708 (64 FR 12862, March 15, 1999). Consistent with section 708.13(a) of the Contractor Employee Protection Program rule, DOE has revised section 850.5 in the final rule to provide that a worker will be deemed to have exhausted all applicable grievance-arbitration procedures if 150 days have passed after the filing of a grievance and a final decision on it has not been issued.

B. Subpart B—Administrative Requirements

Subpart B of the final rule establishes general and administrative requirements to develop, implement, and maintain a CBDPP and to perform all beryllium-related activities according to the CBDPP.

Section 850.10—Development and Approval of CBDPP

Section 850.10 establishes the procedures for the development and approval of the CBDPP. Section 850.10(a)(1) requires a responsible employer in charge of DOE beryllium activities to prepare a CBDPP for its operations and submit the CBDPP to the appropriate Head of DOE Field Element for approval. This section establishes a 90-day time frame from the effective date of the rule for responsible employers' submission of the CBDPP to the appropriate Head of DOE Field Element. DOE is aware of the burden of documentation that can be generated by new programs. However, most responsible employers have already developed CBDPPs in response to DOE Notice 440.1. DOE expects the additional effort required to refine the existing CBDPPs to meet the requirements of the rule will be minimal.

Section 850.10(a)(2) requires that a single CBDPP be submitted to encompass all beryllium-related activities at a site. Because DOE recognizes that one site may encompass multiple contractors and numerous work activities, this section clarifies that the CBDPP for a given site may include specific sections for individual contractors, work tasks, etc. DOE believes that this allowance for a segmented CBDPP structure will minimize the burden associated with the CBDPP update and approval requirements because it allows individual contractors to update and submit for approval only the section of the CBDPP pertaining to their specific activities. If multiple contractors are involved, the DOE contractor designated by the Head of DOE Field Element must take the lead in compiling the overall CBDPP and coordinating the input from various other contractors, subcontractors or work activities. This section further clarifies that in such cases the designated contractor must review and approve the CBDPPs of other contractors engaged at the site before a consolidated CBDPP can be submitted to the Head of DOE Field Element for final review and approval.

One commenter (Ex. 31) stated that the rule did not clearly designate an ''ultimate authority'' responsible for designating physical areas covered by the rule. DOE notes that in sections 850.20 and 850.21, the responsible employer is assigned the responsibility of developing a baseline beryllium inventory and, where appropriate, conducting a beryllium hazard assessment. The actions effectively determine which areas of the facility are covered by the rule. DOE believes that the responsible employer is the most familiar with activities and operations that occur on a given DOE site and, thus, is best equipped to make this determination through the performance of the baseline beryllium inventory and hazard assessment.

Section 850.10(b) requires Heads of DOE Field Elements to review and approve CBDPPs. DOE believes that its review and approval is necessary to

ensure that each contractor's CBDPP is consistent with the requirements and objectives of this final rule. Through these sections, DOE hopes to establish clear lines of authority for review and approval of contractors' CBDPPs. One commenter (Ex. 23) was concerned that local approval of the CBDPPs by DOE field offices could lead to uneven enforcement and increased cost of compliance. DOE does not agree with this assessment, and believes that the Head of DOE Field Element is not only responsible for operations within his or her jurisdiction, but is also familiar with the operations and any related special circumstances or unique situations that may affect implementation or effectiveness of the CBDPP. Thus, DOE believes the Head of DOE Field Element is the most appropriate DOE approval authority for CBDPPs. DOE notes, however, that mechanisms exist to provide independent oversight of DOE's field organizations. Specifically, the Office of Oversight within the Office of Environment, Safety and Health is charged with providing information and analysis needed to ensure that DOE's top management officials, Congress and the public have an accurate and comprehensive understanding of the effectiveness, vulnerabilities, and trends of DOE's environment, safety, health, nuclear safeguards, and security policies and programs. DOE believes that this independent oversight will help assure consistency among CBDPPs across the complex.

Section 850.10(b)(1) establishes a 90-day period for DOE to review and either approve or reject the CBDPP. During its review, DOE may direct the contractors to modify the CBDPP. If DOE takes no action within 90 days, the initial CBDPP is considered approved. DOE established this 90-day time frame to facilitate timely implementation of program elements by responsible employers and to ensure that Heads of DOE Field Elements respond to responsible employers' submissions.

One commenter (Ex.18) stated that labor organizations should receive initial and updated CBDPPs. DOE notes that proposed section 850.10(b)(2) would require contractors to give interested DOE offices, affected workers, and designated worker representatives a copy of the CBDPP, upon request. This provision is retained in section 850.10(b)(2) of the final rule. This section ensures that workers and their representatives have access to information that is related to the protection of their health during the performance of DOE activities.

Section 850.10(c) requires responsible employers to update the written CBDPP in two circumstances: (1) whenever a significant change or addition is made to the program, and (2) whenever a contractor or subcontractor changes. DOE believes that such updates are warranted to ensure that the CBDPP accurately reflects workplace conditions and appropriately addresses specific workplace beryllium exposure hazards.

This section also requires that responsible employers review their written CBDPPs at least annually and revise these programs as necessary to reflect any significant changes. Only those sections of the CBDPP that require a change will have to be resubmitted to the Head of DOE Field Element for approval. DOE considers the annual review cycle to be appropriate and necessary to ensure that CBDPPs remain up-to-date and that they accurately reflect workplace conditions and required control procedures.

Section 850.10(d) ensures that CBDPPs are developed and implemented consistent with the requirements imposed by the National Labor Relations Act (NLRA), 29 U.S.C. 141 *et seq.*, on employers in this context, and not to create obligations in excess of those that would be found in such circumstances under the NLRA.

Section 850.11–General CBDPP Requirements

Section 850.11 establishes the general requirements of the CBDPP. Section 850.11(a) specifies that the CBDPP must address all existing and anticipated operational tasks that fall within its scope. In addition, the section requires all responsible employers to develop and implement a CBDPP that is integrated into DOE's existing worker protection program. 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, if applicable, under predecessor orders) and related DOE health and safety initiatives. The existing industrial hygiene and occupational medicine programs provide the basis for protecting 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 may create redundant and potentially inconsistent requirements.

One commenter (Ex. 23) stated that the proposed requirement to specify in the CBDPP existing and planned operational tasks within the scope of the rule would not be feasible for decontamination and decommissioning (D&D) closure sites. This commenter argued that, due to the non-routine and unpredictable nature of D&D projects, identifying D&D tasks in the CBDPP would result in unnecessary costs, project delays, and administrative burdens because the CBDPP would have to be constantly updated. DOE strongly disagrees, and believes that identifying operational tasks within the scope of the CBDPP at D&D closure sites is practical and necessary. The non-routine and unpredictable nature of operations on D&D closure sites often makes such operations more hazardous than routine production operations involving beryllium. DOE believes that the appropriate way to protect workers from this increased hazard potential is through the implementation of the structured assessment, planning, and control provisions of the CBDPP. Based on experience under the interim CBDPP policy, DOE believes the CBDPP is feasible for D&D operations. DOE also notes that OSHA's Hazardous Waste Operations and Emergency Response standard, 29 CFR 1910.120, requires employers at hazardous waste remediation sites, in addition to conducting ongoing task-specific hazard analyses, to develop a site specific safety and health plan that addresses existing and planned activities. Thus, DOE has retained this requirement in the final rule.

Section 850.11(b) requires responsible employers to tailor the scope and content of their CBDPPs to the specific hazards associated with the DOE beryllium activities being performed. In addition, section 850.11(b)(1) requires that these programs include formal plans outlining how responsible employers will ensure that occupational exposures to beryllium are maintained at or below the PEL (8-hour TWA PEL of 2 $\mu g/m^3$).

Section 850.11(b)(2) further specifies that the responsible employer's CBDPP must, at a minimum, address each requirement in Subpart C of the rule. Section 850.11(b)(3) clarifies 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; (iii) minimizing the disability and lost time experienced by workers due to CBD, beryllium sensitization, and associated medical care; and (iv) 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 and in moving toward the

ultimate goal of preventing CBD within the DOE complex.

DOE is sensitive to concerns that exist within its community regarding the need to approach exposure reduction and minimization objectives in a responsible and realistic manner. Accordingly, section 850.11(b)(3)(iv) establishes a performance-based requirement that will allow responsible employers to establish their own exposure reduction and minimization goals tailored to their unique workplace needs and conditions, subject to DOE review and approval pursuant to section 850.10(b). DOE intends for responsible employers to establish reasonable, but challenging, goals based on sound industrial hygiene principles and the specific circumstances for each affected DOE workplace and location. DOE expects responsible employers to consider, in establishing these goals, 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.

Section 850.12–Implementation

Proposed in section 850.12 required responsible employers to manage and control beryllium exposures in all DOE beryllium activities consistent with the approved CBDPP, the rule, or any other program, plan, schedule or other process established by this part, as well as requirements in other applicable Federal statues and regulations. One commenter (Ex. 16) believed that the preceding requirement should be changed to state that DOE and contractor personnel follow the CBDPP only. This commenter's concern was that including all applicable programs, plans, etc., was too broad. DOE agrees and has deleted including all applicable programs, plans, etc., from the final rule.

Section 850.12(c) clarifies DOE's position that tasks involving potential beryllium exposure that are not covered under the CBDPP may not be initiated until the CBDPP has been updated to include them and the updated plan has been approved by the appropriate Head of DOE Field Element. The rule provides an exception to this requirement for urgent and unexpected situations. In such cases, the task could proceed with the written approval from the Head of DOE Field Element prior to the CBDPP being revised and approved. One commenter (Ex. 16) sought clarification as to when a change in the CBDPP was required. This commenter proposed that when new beryllium activities require additional controls and/or procedures, a change in the CBDPP is warranted. Also, when new activities are within the range of potential exposures to beryllium as described in the existing CBDPP, the commenter suggested that no revision should be necessary. DOE's position is consistent with the views of this commenter. In general, only those activities outside the scope of the existing CBDPP would require a revision to the CBDPP.

Section 850.12(d) recognizes that, depending on the circumstances of the work, responsible employers may have to take other actions to protect their workers, and DOE does not intend to preclude such actions by the provisions of the rule. DOE recognizes that individuals responsible for implementing CBDPP activities must use their professional judgment in protecting the health and safety of workers. Nothing in the 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.

Section 850.13–Compliance

Section 850.13(a) requires responsible employers to conduct DOE activities involving beryllium in compliance with their respective CBDPP that has been approved by the Head of DOE Field Element. Through this provision, DOE recognizes that even the best CBDPP will not adequately protect workers if it is not followed at the site. Section 850.13(b) requires that once the rule takes effect, responsible employers have 2 years to fully implement all aspects of the program (written plans, schedules, and other measures). Although DOE seeks to lessen the burden on responsible employers by permitting them to phase in costly controls over the 2-year period, DOE expects employers to implement portions of the program as soon as practical during the 2-year period.

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

Subpart C—Specific Program Requirements

Subpart C of this rule establishes performance-based requirements for the CBDPP. These requirements are designed principally to prevent CBD by reducing the number of workers 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. DOE expects implementation of the rule to increase its understanding of the development and course of CBD, which may lead DOE, at some future date, to propose modifications of this rule.

Section 850.20—Baseline Beryllium Inventory

Section 850.20(a) requires responsible employers to develop a baseline beryllium inventory. By developing the baseline inventory, responsible employers will accomplish the following functions that are critical to the success of the CBDPP: (1) Identification of locations and operations that should be physically isolated from other areas to prevent the spread of contamination, (2) identification of areas in which worker access should be restricted to minimize the number of workers who could be exposed, (3) identification of beryllium contamination that must be controlled in facilities that are scheduled for decontamination and decommissioning, (4) identification of beryllium contamination in facilities that are being used for non-beryllium activities, to determine the need for cleanup, and (5) the determination of which workers should be covered under the CBDPP.

Section 850.20(b) supplements the generic inventory requirement under DOE Order 440.1A by requiring responsible employers to review current and historical records, interview workers, and sample as necessary to document the characteristics and locations of beryllium at DOE sites. These supplemental requirements are necessary because those persons who are responsible for activities at DOE sites may not recognize that activities under their supervision involve beryllium or are conducted in areas where beryllium was used in the past. Workers often know of past beryllium activities for which no records exist. Sampling can identify beryllium contamination where the record reviews and worker interviews are not conclusive. These supplemental requirements are particularly necessary because past beryllium operations at DOE facilities were often conducted in uncontrolled work areas.

Section 850.20(b)(3) requires that responsible employers conduct air, surface, and bulk sampling procedures to characterize the beryllium. Characterizing the beryllium is

necessary to assess and control beryllium workplace hazards. Responsible employers should conduct the sampling that is appropriate for the specific workplace conditions and the suspected types and locations of beryllium contamination. Sampling techniques could include collecting area and wipe samples and collecting personal breathing zone samples. (Sections 850.24(a), (b), and (e)–(g) address the personal monitoring that may be a component of the baseline inventory.)

Section 850.20(c) requires responsible employers to ensure that individuals conducting the baseline beryllium inventory activities have sufficient qualifications in industrial hygiene. DOE believes that this provision is necessary to ensure that the inventory is accurate and complete. DOE requested in the NOPR that interested parties submit comments on the need to provide further specification in the rule regarding the minimum qualifications that an individual must possess to perform certain components of the CBDPP, such as hazard assessments and exposure monitoring. One alternative approach suggested was use of OSHA's ''competent person'' definition to define competency of the individual. Another alternative was to require that hazard assessments and exposure monitoring be performed by a ''certified industrial hygienist'' (CIH) as defined by the American Board of Industrial Hygiene (ABIH).

DOE received 14 comments in response to this request. Two of the 14 commenters (Exs. 4, 16) agreed with DOE's approach in proposed sections 850.20(c), 850.21(b) and 850.24(a). A commenter (Ex. 16) noted that if more prescriptive definitions are used to define personnel qualifications, the definitions should be appropriate to the required task. For instance, CIHs should conduct hazard assessments, while individuals possessing a lower level of knowledge should conduct exposure monitoring. Another commenter (Ex. 4) favored the use of OSHA's ''competent person'' definition over requirements for a CIH if DOE elected to use one of these more prescriptive definitions.

Two commenters (Ex. 20, 29) stated that the industrial hygiene competency requirements in proposed sections 850.20(c), 850.21(b) and 850.24(a) were too subjective and recommended instead, the use of OSHA's ''competent person'' definition. A commenter (Ex. 20) further noted that OSHA's Asbestos Standard, 29 CFR 1926.1101(b), included definitions for ''competent person,'' ''industrial hygienist,'' and ''certified industrial hygienist'' and outlined specific training courses that a competent person must complete. Two other commenters (Exs. 3, 31) favored the use of OSHA's ''competent person'' definition in lieu of the industrial hygiene competencies, but took exception to the last phrase of the definition: ''and who has the authorization to take prompt corrective measures to eliminate [hazards].'' The commenters were concerned that limiting the performance of assessments and monitoring to individuals with the authority to take prompt corrective actions would exclude other qualified individuals, such as third-party industrial hygienists.

Nine of the 14 commenters recommended that a CIH participate at some level in the performance of beryllium inventories, hazard assessments, and exposure monitoring. One commenter (Ex. 30) stated that monitoring and assessments must be performed by a CIH, while the other commenters (Exs. 3, 11, 13, 16, 19, 26, 28, 31) suggested that qualified and trained persons working under the direct supervision of a CIH could conduct these tasks, and that limiting the actual performance of monitoring and assessments to CIHs would be too restrictive and unnecessary. Although these commenters did not believe that a CIH is needed to actually perform monitoring and assessments, many did believe that minimum qualifications for those individuals performing these tasks must be specified in the final rule. For instance, one commenter (Ex. 11) recommended that DOE require that these individuals possess sufficient industrial hygiene experience in addition to knowledge. Another commenter (Ex. 13) suggested that a CIH, Industrial Hygienist in Training (IHIT) as defined by the ABIH, or person with ''demonstrably equivalent qualifications'' perform assessments and monitoring. Another commenter (Ex. 23) suggested that the industrial hygienist definitions in DOE's ''Functional Area Qualification Standard,'' or as defined by AIHA, be used to prescribe the qualifications required to perform monitoring and assessments.

DOE agrees with the overwhelming majority of commenters who favored a more prescriptive definition. DOE believes that a more prescriptive definition will ensure proficiency and consistency in the conduct of assessments and monitoring as well as in the overall implementation of the CBDPP. Accordingly, DOE has provided language in sections 850.20(c), 850.21(b) and 850.24(a)(1) of the final rule for the use of qualified individuals such as a CIH to manage and supervise beryllium inventories, hazard assessments, and exposure monitoring, and the use of individuals with sufficient industrial hygiene knowledge and experience to actually perform these tasks. DOE believes this will provide the level of consistency required to ensure that hazards are properly identified and workers are appropriately protected without being overly prescriptive. In this regard, DOE agrees with the commenters who stated that the level of expertise needed to perform beryllium inventories, hazard assessment, and exposure monitoring does not require a CIH, and that such a requirement would cause an unnecessary resource strain on both DOE and its contractors.

Five persons commented on other provisions of the proposed baseline inventory section. Three of the commenters (Exs. 9, 21, 28) suggested that DOE provide in the final rule greater specificity than DOE proposed for baseline inventory requirements. DOE agrees with these commenters and in the final rule has modified the requirement for reviewing records to cover both current and historical records. The final rule also modifies the requirement for conducting sampling to specify air, surface, and bulk sampling. DOE believes that these changes clarify DOE's intent, express good industrial hygiene practice, and continue to allow the responsible employer appropriate flexibility in conducting the baseline inventory. One commenter (Ex. 9) suggested that DOE also specify in the final rule that baseline inventories include the locations where beryllium activities are planned. DOE considers locations where beryllium activities are planned to be locations of potential beryllium contamination and exposure that must be included in the baseline inventory under paragraph (a), and, therefore, no change is needed.

One commenter (Ex. 18) recommended that the final rule mandate the disclosure of health and safety documents related to past beryllium emissions and exposures. DOE has not included such a provision in the final rule because the Freedom of Information Act (5 U.S.C. 552) already provides for the release of federal government records, except for specified types of records that contain sensitive information, such as classified information relating to national defense or foreign policy, information in personnel and medical files, and trade secrets or other confidential business information. Requests to DOE for release of information related to past beryllium use and exposures may be submitted to the appropriate DOE field office. Such requests should follow DOE's

procedures for Freedom of Information Act requests in 10 CFR Part 1004. Also see the discussion of public access to beryllium records in the preamble discussion of section 850.39 (Recordkeeping and use of information).

The same commenter (Ex. 18) recommended that the final rule provide for independent review of the responsible employer's implementation of the CBDPP. DOE does not think that such a provision is necessary, because existing mechanisms already provide independent oversight of DOE's contractors and include independent oversight of DOE's field organizations. The DOE Office of Environment, Safety and Health's Office of Oversight is charged with providing information and analysis needed to ensure that DOE's top management officials, Congress, and the public have an accurate and comprehensive understanding of the effectiveness, vulnerabilities, and trends of DOE's environment, safety, health, nuclear safeguards, and security policies and programs. In addition, any interested individual or organization may conduct a review of a responsible employer's compliance with this rule based on information obtained from DOE.

One commenter (Ex. 14) recommended that the final rule provide funding for the baseline inventory, and contended that responsible employers will not conduct the baseline inventories unless the funding required for this task is explicitly established by the final rule. DOE does not require its contractors to perform unfunded tasks, but funding of DOE programs is appropriately handled through the federal government's budget process and not through the regulatory process. DOE expects that its program offices will request the funds needed to meet the obligations and objectives of their programs and activities, including compliance with the CBDPP.

Section 850.21—Hazard Assessment

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, section 850.21 of the final rule requires responsible employers to conduct a beryllium hazard assessment to characterize workplace beryllium exposure hazards. This requirement allows each site the flexibility to determine the appropriate risk-based approach for assessing beryllium-related hazards in its worksites where the baseline inventory has established that beryllium is present. As noted by one commenter (Ex. 25), flexibility in conducting hazard assessments is particularly important because operations, conditions, and the potential for exposure may vary greatly from operation to operation and facility to facility.

Section 850.21(a) requires the responsible employer to conduct an analysis of existing worksite conditions, exposure data, medical surveillance trends, and the exposure potential of planned activities. In addition, section 850.21(a) specifies that the responsible employer must prioritize potential exposure activities so that the activities with the greatest risks of exposure are evaluated first. DOE believes that prioritizing activities is a logical first step in initiating a hazard assessment. Targeting high-risk beryllium operations is an effective way to reduce potential beryllium exposures throughout DOE facilities.

Section 850.21(b) requires responsible employers to ensure that hazard assessments are managed by qualified individuals (e.g., a CIH), and that the individuals assigned to conduct hazard assessments have sufficient knowledge and experience to perform such activities properly. DOE requested in the NOPR that interested persons submit comments on the need to further specify in the rule the minimum qualifications that an individual must possess to perform certain key components of the CBDPP, such as hazard assessments. DOE received 14 comments in response to this request. As noted in the preamble discussion of section 850.20(c), 10 of the commenters either suggested or supported establishing an additional specification that hazard assessments be performed under the supervision of a CIH. DOE generally agrees with these commenters about the need for a qualified individual to manage hazard assessments and certain other tasks required by the rule. But DOE will not require that person to be in all cases a CIH. Thus, DOE provides in section 850.21(b)(1) that a qualified individual, such as a CIH, must manage hazard assessments performed for the CBDPP. By use of this language, DOE leaves open the possibility that a responsible employer, in a particular case, may determine that someone who is not a CIH possesses the requisite qualifications to manage the hazard assessments.

In addition to the comments on the CIH issue, DOE received only minor comments on section 850.21. One commenter (Ex. 21) suggested that the exposure potential of planned activities should be rank ordered to better focus each site's resources and efforts. DOE agrees with this commenter, and in the final rule has modified the requirement for hazard assessments to require the prioritization of beryllium activities, beginning with those activities that present the greatest risks of exposure. Another commenter (Ex. 30) was concerned about the use of existing data, such as exposure monitoring results, in the hazard assessment. While this commenter believed that using existing data is appropriate, the commenter warned against the potential for errors when relating existing data to current operations. In particular, this commenter suggested that existing data relating to exposure monitoring is often not well documented or is of poor quality, thus making it difficult to determine whether the sampling is representative of current beryllium operations. DOE agrees that existing data can be a valuable tool if collected and documented properly, and in many cases use of such data will expedite the hazard assessment process. At the same time, DOE also shares this commenter's concerns regarding the accuracy and applicability of existing data and has retained in section 850.21(b) the requirement for the hazard assessment to be managed by a qualified individual, such as a CIH. DOE's intent is that this requirement will help ensure that the data considered in the hazard assessment accurately reflects current site conditions and hazards.

Another commenter (Ex. 24) favored the triggering of a hazard assessment at detectable airborne beryllium levels from personal air samples. DOE agrees that if such data is available, it must be considered in the hazard assessment. As another commenter (Ex. 28) pointed out, however, a hazard assessment should not be limited to the inhalation risks posed by beryllium but must also include the presence and characteristics of beryllium contamination in a facility. Accordingly, the final rule requires the responsible employer to perform a hazard assessment whenever the baseline inventory establishes the presence of beryllium in an area.

Still another commenter (Ex. 11) requested that DOE include a non-mandatory appendix to the rule to provide guidance on how to perform a hazard assessment. This commenter was concerned that inexperienced industrial hygienists may be called upon to perform a hazard assessment, and suggested that additional guidance would be needed to assure accuracy and consistency. DOE believes this concern is addressed in section 850.21(b), which requires that hazard assessments be managed by qualified individuals, such as CIHs, and performed by individuals

with sufficient knowledge and experience to perform such tasks. Accordingly, DOE has not included the requested appendix to provide guidance on how to perform a hazard assessment as a part of this rulemaking.

Section 850.22—Permissible Exposure Limit

In the NOPR preamble, DOE reviewed the scientific evidence suggesting that the current OSHA 8-hour TWA PEL does not sufficiently protect worker health. However, DOE also stated that, in its view, it is difficult to determine from this scientific evidence the exposure level necessary to eliminate the risk of contracting CBD. For this reason, DOE retained the existing OSHA 8-hr TWA PEL in proposed section 850.22, and proposed other provisions to minimize worker exposure to airborne beryllium in DOE facilities. In addition, DOE included in proposed section 850.22 language providing that DOE would adopt a more stringent 8-hour TWA PEL if OSHA promulgated one through the rulemaking process. Finally, DOE requested in the NOPR that interested persons submit any compelling scientific evidence that would assist DOE in establishing a new, more protective exposure limit for DOE facilities.

Fifteen persons commented on the 8-hour TWA permissible exposure limit requirements in the proposed rule. Of these 15 commenters, four supported DOE's proposal to retain the OSHA 8-hour TWA PEL (Exs. 4, 19, 26, 29). One of these four (Ex. 29) took issue with DOE's conclusion that the existing OSHA PEL was not protective. This commenter pointed to the inaccuracies associated with the use of area monitoring data in referenced studies and the fact that most of the referenced studies acknowledged that infrequent exposures above the PEL had occurred within the study group. As a result, this commenter felt that the OSHA PEL should be retained as the exposure limit in DOE work places.

Two commenters cited DOE's policy established in DOE Order 440.1 to adopt the more protective of either OSHA's PEL or ACGIH's threshold limit value (TLV) and recommended that DOE adopt the ACGIH's proposed 8-hour TWA TLV of 0.2 $\mu g/m^3$ as the new DOE exposure limit (Exs. 28, 30). One commenter (Ex. 28) also supported adopting the proposed ACGIH TLV as an 8-hour TWA action level, which DOE has done in the final rule. (See section 850.23 in this Section-by-Section Discussion for further discussion of the action level.) Another commenter opposed adopting the proposed ACGIH limit and took issue with the policy in DOE Order 440.1A, stating that any new DOE limit should be subject to the rulemaking process (Ex. 16).

Five other persons suggested that DOE adopt one of a variety of lower exposure limits ranging from the limit of detection to the NIOSH Recommended Exposure Limit (REL), which is a ceiling limit of 0.5 $\mu g/m^3$. These commenters cited the occurrence of CBD among workers exposed to beryllium at levels below the 8-hour TWA PEL, and some of these commenters argued that studies presented in the Health Effects discussion of the NOPR provided a sufficient basis for the establishment of a new exposure limit. For example, one commenter (Ex. 35) cited two studies that evaluated the occurrence of CBD among the general population around a beryllium plant in Lorain, Ohio (refs. 5 and 6). Relying on these studies, this commenter suggested that the U.S. Environmental Protection Agency's ambient air criterion for beryllium of 0.01 $\mu g/m^3$ could be used as a basis for a new 8-hour TWA exposure limit. Two other commenters (Exs. 14, 24) cited the two Lorain, Ohio community studies, the occurrence of CBD among workers with beryllium exposures ''well below the PEL,'' a study published in 1997 (ref. 31) which suggests that beryllium sensitization occurs at airborne beryllium exposure levels as low as 0.01 $\mu g/m^3$, and the DOE policy to provide a workplace free of recognized hazards (DOE Order 440.1A) to support their position that workers should not be exposed to any detectable level of beryllium. The remaining two commenters that offered suggestions for an alternative exposure limit agreed with DOE's conclusion that the OSHA 8-hour TWA PEL was not sufficiently protective and recommended adopting limits established by other occupational health groups. One commenter (Ex. 18) suggested that DOE adopt NIOSH's REL as a DOE exposure limit while the other (Ex. 22) suggested that DOE apply a safety factor of 4 to the ACGIH 8-hour TLV and use 0.05 $\mu g/m^3$ as the new DOE limit.

Two other commenters (Ex. 20, 32) agreed with DOE's conclusion that the OSHA 8-hour TWA PEL is not sufficiently protective and recommended that DOE establish a new exposure limit. These commenters, however, did not offer suggestions for alternative new exposure limits. Another commenter did not directly address DOE's proposal to retain the OSHA PEL, but instead recommended that DOE should consider the possible effects of particle size on the occurrence of CBD.

DOE has carefully considered each of these comments and available scientific data, and continues to believe that its original conclusion, as outlined in the proposed rule, remains valid. Specifically, DOE believes that existing scientific data indicates that there are reasonable grounds to conclude that the OSHA 8-hour TWA PEL for beryllium may not be sufficiently protective of worker health, a conclusion supported by 12 of the 15 commenters that addressed this section of the proposed rule. DOE is particularly influenced by the published studies (refs. 16–17, 21) indicating that workers exposed below the current PEL are contracting beryllium disease and exhibiting Be-LPT sensitivity. A recent article by Eisenbud (ref. 29) also concludes that it ''appears'' the current PEL is not protective enough.

However, DOE also believes, based on available scientific data, that it is difficult to determine the exposure level necessary to eliminate the risk of contracting CBD and, therefore, that the best approach to providing improved worker protection is through the establishment of a conservative 8-hour TWA action level, coupled with aggressive exposure reduction and minimization efforts, and the collection of medical surveillance data to better understand the cause of CBD. Accordingly, DOE has retained the OSHA 8-hour TWA PEL in section 850.22 of the final rule and has retained the action level concept of the proposed rule, although at a lower level (see section 850.23 discussion). Section 850.22 has been revised to simply reference 29 CFR 1910.1000, instead of specifying the current numerical limit. DOE intends this provision to result in the automatic incorporation of a more stringent PEL that OSHA may subsequently promulgate. This does not represent a substantive change to the provision as proposed.

In this rule, however, DOE has decided not to follow the policy under the more general worker protection program established by DOE Order 440.1A of adopting the more protective of either the OSHA PEL or the ACGIH TLV. The incorporation of any new ACGIH TLV in this rule would require that DOE conduct a rulemaking on the specific exposure level and present the scientific basis for public comment. As stated previously in this **SUPPLEMENTARY INFORMATION** section, DOE believes, based on the existing scientific evidence, that such a rulemaking is premature. By contrast, DOE may incorporate an OSHA PEL in this rule because the OSHA PEL is promulgated following notice and comment

rulemaking, and the rules of the Office of the Federal Register permit a reference to another part of the Code of Federal Regulations.

DOE proposed, in section 850.22(a) of the NOPR, to adopt the STEL established by the ACGIH of 10 μg/m³, averaged over a 15-minute sampling period. In the final rule the STEL has been deleted, because the proposed STEL would not provide any added protection for the worker given that the new action level of 0.2 μg/m³ would be exceeded in less than 15 minutes where exposure levels are at 10μg/m³. DOE did not seek to establish a lower STEL because, as in the case of a lower PEL, available scientific data do not provide a sufficient basis for the establishment of a new STEL.

Section 850.23—Action Level

DOE proposed in the NOPR to establish an 8-hour TWA action level of 0.5 μg/m³. In selecting the proposed action level, DOE considered a number of factors. DOE considered OSHA's substance-specific health standards, which typically establish action levels for hazardous and toxic substances at one-half the 8-hour TWA PEL. Applying this approach to beryllium would have resulted in a proposed 8-hour TWA action level of 1.0 μg/m³. OSHA's action levels are premised on the safety of its PELs, and are set to provide an additional margin of safety. As explained in the preceding discussion, however, there is a body of evidence suggesting that the OSHA PEL for beryllium does not adequately protect worker health. Therefore, DOE decided that a lower action level is appropriate for DOE facilities. According to the results of the 1996 DOE survey of DOE facilities which reported potential beryllium exposures, two DOE facilities (Pantex and Rocky Flats) had already employed an action level of 0.5 μg/m³. Another facility (Lawrence Livermore National Laboratory) reported the use of an ''administrative warning range'' of 0.2 to 2.0 μg/m³, which triggered a requirement for an investigation, and six DOE facilities employed an action level of 1.0 μg/m³. In light of this experience, DOE proposed adopting an action level at the lower end of existing DOE complex action levels (0.5 μg/m³), rather than follow the typical OSHA practice, in order to implement aggressive yet achievable exposure minimization.

The majority of comments received on the proposed rule agreed with the DOE's approach of using an action level that is lower than the typical OSHA action level, but called for an even lower level than DOE had proposed. The most commonly recommended level was 0.2 μg/m³, which is the same level as the ACGIH proposed TLV. Most commenters believed that this level would prevent additional cases of beryllium sensitization and disease. DOE believes that there is reasonable technical basis for selecting 0.2 μg/m³ as an action level, based on the following scientific analyses.

The U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System includes a Reference Concentration of 0.02 μg/m³ for beryllium, which is ''an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of noncancer effects during a lifetime'' (ref. 33). This concentration is based on epidemiology studies. This continuous 24-hour per day, level translates into an 8-hour TWA level of 0.84 μg/m³.

Merrill Eisenbud conducted a study of CBD based on air sampling, atmospheric dispersion modeling, and analysis of a beryllium production plant's past operations. Eisenbud concluded that the lowest beryllium concentration at the 3/4-mile boundary, beyond which no community cases of chronic beryllium disease were found, was 0.025 μg/m³ during the 7-year period the plant operated at full capacity (ref. 29). This 24-hour per day level translates into an 8-hour TWA level of 0.84 μg/m³, which essentially is the same level that the EPA found to be without appreciable risk of causing noncancer effects (i.e., CBD).

The ACGIH, a professional organization that publishes occupational health consensus standards, has proposed to change its 8-hour TWA TLV from 2 μg/m³ to 0.2 μg/m³, based on its review of recent beryllium epidemiology studies (ref. 32).

The DOE recognizes that the EPA (0.84 μg/m³), Eisenbud (0.84 μg/m³), and ACGIH (0.2 μg/m³) levels are normally used as exposure limits rather than action levels. However, based on limitations of the studies done to date, the difficulties in determining a safe threshold level for occupational exposure to beryllium, and DOE's decision to implement aggressive exposure reduction and minimization efforts, DOE has decided that the most prudent course is to lower the action level to 0.2 μg/m³ rather than set a new exposure limit. The available science suggests that this level would be protective; is one-quarter of the EPA and Eisenbud levels and the same as the ACGIH proposed level. This is the lowest action or trigger level reported by any DOE facility under the interim CBDPP, and a lower level has not been demonstrated as being practicable. Lowering the action level to 0.2 μg/m³ will result in greater protection for the affected DOE work force by triggering additional monitoring, surveillance, respiratory protection, and other protective measures.

Benefits of lowering the action level. As specified in this rule, the action level triggers the use of a number of controls and protective measures designed to protect employees from exposures to beryllium, including:

- Periodic exposure monitoring (10 CFR 850.24 (c));
- Exposure reduction and minimization measure (10 CFR 850.25); [4]
- Regulated areas (10 CFR 850.26);
- Hygiene facilities and practices (10 CFR 850.27);
- Respiratory protection (10 CFR 850.28); and
- Protective clothing and equipment (10 CFR 850.29).

Thus, DOE sites where exposure levels exceed the action level would be required to implement these controls to provide further protection to workers exposed above the action level. This additional protection will reduce the exposure levels experienced by these workers, consequently reducing their risk of developing beryllium-related disease and other health effects. Setting the action level at 0.2 μg/m³, as opposed to 0.5 μg/m³, does not alter the set of controls that are triggered,[5] but does alter the timing of these additional controls. The additional protective measures triggered by the action level will be put into effect earlier. For example, consider an activity where airborne concentrations of beryllium start very low (below 0.2 μg/m³), but rise over time (e.g., over a course of days or weeks) in the workplace. Assume also that airborne concentrations will eventually exceed 0.5 μg/m³. If the responsible employer recognizes the potential for exposures to exceed the action level in this activity, this rule (as well as prudent industrial hygiene practice) would require the responsible employer to conduct exposure

[4] The rule does not require that exposure reduction and minimization efforts (e.g., engineering controls and work practices) be triggered by the action level. DOE expects, however, that affected sites will specify that some engineering controls and work practices be triggered by the action level in their CBDPP plans.

[5] DOE did alter the set of controls that are triggered by the action level between the proposed and the final rule. This, however, was not done as a result of setting a lower action level, but was in response to comments on the proposed rule.

monitoring to determine if and when the action level is exceeded. In this situation, once the 0.2 μg/m³ threshold is crossed, the responsible employer would be required to implement the controls specified above, and workers would benefit from the additional protection provided by those controls. Under an action level of 0.5 μg/m³, protective measures would not be implemented until the airborne concentrations exceeded 0.5 μg/m³. Thus, during the time that exposures are between 0.2 μg/m³ and 0.5 μg/m³, workers would not be afforded the additional protection of the triggered controls. Thus, the first incremental benefit of setting the action level lower is the reduction in risk afforded by the controls triggered during the time that exposures are between 0.2 μg/m³ and 0.5 μg/m³ (See Table 9).

The second benefit from setting the action level lower is to expand the number of workers afforded the additional controls (See Table 10). DOE believes there are a number of workers exposed to airborne concentrations of beryllium between 0.2 μg/m³ and 0.5 μg/m³, but who are never exposed above 0.5 μg/m³. DOE estimates that between 342 and 460 workers may be exposed at these levels.[6] Under an action level of 0.5 μg/m³, these workers would not be afforded the protection of controls triggered by the action level. Under an action level of 0.2 μg/m³, however, these workers are afforded the additional controls. These additional controls will reduce the exposures faced by these workers, leading to a reduction in their risk of developing beryllium-related disease and other health effects. Thus, the second benefit of using the lower action level is a reduction in risk among workers exposed to airborne concentrations between 0.2 μg/m³ and 0.5 μg/m³.

Quantitative estimates of the reduction in risk and the consequent reduction in the incidence of beryllium-related disease and other health effects are not possible due to a lack of necessary information. As discussed in this preamble and the Economic Analysis (Chapter 1, Section 1.1), no quantitative dose-response relationship has been defined for beryllium. Without this information, DOE is unable to provide a quantitative estimate of the benefit of using a lower action level. Nevertheless, DOE believes that the use of 0.2 μg/m³ action level as opposed to the 0.5 μg/m³ is justified based on the benefits discussed above and the number of comments that suggested that an action level lower than 0.5 μg/m³ is necessary.

Other issues. This revision to the final rule does not accommodate the comments (Exs. 12, 18, 32) that urged DOE to lower its action level to any detectable level of beryllium. DOE believes it would not be practicable to use any detectable level of beryllium as its action level because beryllium is ubiquitous; it can be detected virtually anywhere if a sufficiently large air sample is taken. Furthermore, according to the EPA's Integrated Risk Information System, discussed above, the United States population is being exposed to detectable background levels of beryllium without an appreciable risk of contracting CBD in their lifetime. Therefore, that level is not supported by the available science.

TABLE 9.—COMPARATIVE COST ANALYSIS FOR DIFFERENT ACTION LEVELS

Category/requirement	Annualized cost for 0.2 μg/m³ action level (final rule)	0.5 μg/m³ action level		0.1 μg/m³ Action level	
		Annualized cost	Difference from 0.2 μg/m³ action level	Annualized cost	Difference from 0.2 μg/m³ action level
Requirements Triggered By The Action Level in the Final Rule:					
Periodic exposure monitoring	$1,962,620	$1,104,421	($858,199)	$3,574,937	$1,612,317
Notify workers monitoring results	66,932	40,411	(26,521)	82,104	15,171
Exposure reduction and minimization	2,707,636	[2] 2,707,636	0	3,579,513	871,877
Regulated areas	0	0	0	8,496	8,496
Change rooms and showers	249,730	249,730	0	272,337	22,607
Respiratory protection	9,085	9,085	0	342,495	333,410
Protective clothing	0	0	0	382,528	382,528
Disposal of protective clothing	0	0	0	42,738	42,738
Subtotal	4,996,004	4,111,284	(884,720)	8,285,149	3,289,144
Other Requirements	26,555,397	26,555,397	0	26,555,397	0
Total for all requirements [1]	31,551,401	30,666,680	(884,720)	34,840,545	3,289,144

Note: Column totals may contain some rounding error.

[1] For this row, the annualized cost represents the annualized cost of the proposed rule for the specified action level.

[2] The costs for exposure reduction and minimization may be lower with a 0.5 μg/m³ action level since fewer requirements would be triggered under the higher action level. The information provided to DOE by the sites, however, did not contain enough information to make an estimate of the reduction in the costs for this category.

[6] The lower bound estimate (342) is the difference between the number of workers exposed above the 0.5 μg/m³ action level estimated in the Economic Analysis (EA) for the proposed rule (894 workers) and the number of workers exposed above the 0.2 μg/m³ action level estimated in the EA for the final rule (1,236 workers). The estimates contained in the two versions of the EA are not, however, completely comparable. In developing the EA for the final rule, DOE obtained new data from the sites on the number of workers exposed above 0.2 μg/m³. For some sites, the reported number of workers exposed above 0.2 μg/m³ was less than DOE's previous estimate of the number exposed above 0.5 μg/m³. To correct for this inconsistency, DOE used the minimum of the two estimates for each site as an estimate of the number exposed above 0.5 μg/m³. This resulted in an estimated 776 workers exposed above 0.5 μg/m³. The difference between this new estimate and the estimated number exposed above 0.2 μg/m³ (1,236 workers) provides the upper bound estimate (460 workers).

TABLE 10.—ESTIMATED NUMBER OF WORKERS BY EXPOSURE LEVEL

Beryllium exposure levels (μg/m³)	Estimated number of workers [1]	Percent of all affected workers
0.0 to 0.1	0	0
0.1 to 0.2	398	24.4
0.2 to 0.5	342 to 460	20.9 to 28.2
Above 0.5	776 to 894	47.5 to 54.7
Total	1,634	100
Total Above 0.1	1,634	100
Total Above 0.2	1,236	75.6

[1] The Economic Analysis (EA) for the final rule estimates that 1,236 workers are exposed above the action limit of 0.2 μg/m³ and that a total of 1,634 workers are currently exposed to beryllium. Thus, 398 workers must be exposed below 0.2 μg/m³ (398 = 1,634 − 1,236). Given that measurements of exposure levels below 0.1 μg/m³ begin to near the detection limits, DOE assumes that all workers exposed below 0.2 μg/m³ would be in the 0.1 to 0.2 group. Next, DOE estimated the upper bound of the above 0.5 group by taking the estimated number of workers exposed above 0.5 μg/m³ from the EA for the proposed rule (i.e., 894 workers). The difference between this number and 1,236 (the number exposed above 0.2 μg/m³) provided the lower bound of the 0.2 to 0.5 group (342 = 1,236+894). To provide the lower bound of the above 0.5 group (776 workers), DOE corrected for an inconsistency between the EA for the proposed rule and the EA for the final rule. In developing the EA for the final rule, DOE obtained new data from the sites on the number of workers exposed above 0.2 μg/m³. For some sites, the reported number of workers exposed above 0.2 μg/m³ was less than DOE's previous estimate of the number exposed above 0.5 μg/m³ (in the EA for the proposed rule). To correct for this inconsistency, DOE used the minimum of the two estimates (i.e., the estimated number of workers exposed above 0.2 μg/m³ in the EA for the final rule and the estimated number of workers exposed above 0.5 μg/m³ in the EA for the proposed rule) for each site as an estimate of the number exposed above 0.5 μg/m³. This resulted in an estimated 776 workers exposed above 0.5 μg/m³ which DOE uses as the lower bound for that group. The difference between this number and the estimated number exposed above 0.2 μg/m³ (1,236 workers) provides the upper bound estimate for the 0.2 to 0.5 group (460 = 1,236 − 776).

NOTE: Column total may contain some rounding error.

Section 850.24—Exposure Monitoring

Section 850.24 establishes CBDPP worker exposure monitoring requirements. The exposure monitoring provisions in this section are necessary to determine the extent of exposure at the worksite; prevent worker overexposure; identify the sources of exposure to beryllium; collect exposure data so that the responsible employer can select the proper control methods to be used; evaluate the effectiveness of selected controls; and provide continual feedback on the effectiveness of the program in controlling exposures. These requirements are more specific than the provisions of exposure monitoring in DOE Order 440.1A.

Exposure monitoring is important not only to determine the level of beryllium to which workers are exposed and the frequency at which workers should be monitored, but also to determine whether other protective provisions of the rule need to be implemented. The employer's obligation to provide respiratory protection under section 850.28, for example, is triggered by monitoring results showing that a worker is exposed at or above the action level. Exposure monitoring results also may help DOE 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.

Because of the importance of adequately characterizing and monitoring worker exposures to beryllium, DOE included a specific request in the NOPR asking interested persons for views or information on the need for daily exposure monitoring of all beryllium workers. DOE was considering whether daily exposure monitoring was needed 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. Of the ten commenters who responded to this request for information, three favored a daily monitoring requirement while seven were opposed.

The commenters who favored daily monitoring for all workers (Exs. 18, 25, 30) argued that daily monitoring of each worker would more accurately document and characterize beryllium exposures. One commenter (Ex. 16) suggested that initial daily monitoring could be replaced with periodic monitoring after sufficient data was obtained. Another (Ex. 30) noted that daily exposure monitoring might be the only accurate way to determine exposures during changing workplace conditions. This commenter suggested that daily monitoring is important in identifying specific work activities that contribute to the worker exposures.

The majority of commenters responding to this request (Exs. 3, 4, 16, 17, 26, 28, 29) objected to daily monitoring of all workers to determine beryllium exposures. These commenters stated that daily monitoring would generate large amounts of data, at great cost, while producing little or no added benefit. Some of these commenters (Exs. 3, 26, 28, 29) favored representative sampling of the workplace, using statistical analysis to determine the number of samples required. These commenters asserted that the principal benefits of a statistically-based monitoring strategy would be the reduction in the number of samples needed and resources used.

After considering all of the comments, DOE agrees that daily monitoring would be unnecessarily burdensome for responsible employers, and that a statistically-based approach will ensure the adequate characterization of worker exposures. This position is reflected in section 850.24(b), as discussed below.

Section 850.24(a) requires that exposure monitoring be managed by a qualified individual such as a CIH, and conducted by individuals with sufficient industrial hygiene knowledge and experience. DOE requested in the NOPR that interested persons submit comments on the need to further specify the minimum qualifications that an individual must possess to perform certain key functions under the CBDPP, including exposure monitoring. Most of the commenters suggested or supported adding a requirement that exposure monitoring be performed under the supervision of a CIH. DOE agrees that a CIH is often best qualified to manage exposure monitoring activities, and provides in section 850.24(a)(1) that exposure monitoring performed for the CBDPP be managed by a qualified individual, such as a CIH. However, in keeping with the performance-based philosophy underlying this rule, DOE

does not preclude a responsible employer from determining, in a particular situation, that a person other than a CIH possesses the requisite knowledge to perform this function. Most of the commenters were of the view that individuals conducting the monitoring, under the management of a qualified individual, need sufficient knowledge and experience but not necessarily the same level of qualification as a CIH.

Section 850.24(b) requires the responsible employer to perform initial exposure monitoring for all persons who work in areas that may have airborne concentrations of beryllium, as determined through the baseline beryllium inventory and hazard assessment. The responsible employer must employ a statistically-based monitoring strategy to obtain the number of samples needed to characterize worker exposures. The initial exposure information is necessary to determine the need for engineering and work practice controls, to select appropriate personal protective clothing and respiratory protective equipment where needed, and to identify the need to establish regulated areas. One commenter (Ex. 28) recommended that sampling should be conducted to determine particle size and chemical characterization of the potential exposure, and another commenter (Ex. 30) recommended use of particle size-selective personal monitoring. DOE has decided to leave details of this nature to the qualified individual who manages exposure monitoring under the CBDPP, rather than attempt to prescribe them in regulations. This type of issue also may be addressed in future DOE guidance on implementing the CBDPP.

Section 850.24(b)(1) requires the responsible employer to determine the beryllium exposure of workers by collecting personal breathing zone samples that reflect worker's exposure to airborne concentrations of beryllium over an eight-hour period. As specified in the definition of ''worker exposure'' in section 850.3, this is a measurement of the exposure that would occur if the worker were not using respiratory protective equipment. Section 850.3 also includes a definition of ''breathing zone,'' which means ''a hemisphere forward of the shoulders, centered on the mouth and nose, with a radius of 6 to 9 inches.'' Thus, a breathing zone sample is taken as close as practical to the nose and mouth of the worker. For a full description of breathing zone samples, see OSHA's Instruction CPL 2–2.20B, CH–1, Nov. 13, 1990.

DOE recognizes that many of its responsible employers may have performed initial monitoring as part of their efforts to implement DOE Notice 440.1. DOE does not intend to require employers to repeat these efforts if they are adequate under the rule. Accordingly, section 850.24(b)(2) allows employers to use initial monitoring data collected within 12 months before the effective date of this rule to satisfy the rule's initial monitoring requirements. One commenter (Ex. 31) cautioned DOE that any sampling performed prior to the issuance of the final beryllium rule should only be accepted by DOE if the work conditions during the sampling period are the same as current conditions. DOE agrees with this commenter, and notes that several provisions of the final rule require responsible employers to ensure that sampling results reflect current workplace conditions. Specifically, section 850.24(b) requires that the responsible employer obtain a sufficient number of sample results to adequately characterize exposures, and section 850.24(d) requires that the responsible employer perform additional monitoring if operations, maintenance, or procedures change, or if the responsible employer has any reason to suspect a change has occurred which may result in new or additional exposures. Further, DOE believes that the requirement that exposure monitoring be managed by a qualified individual will help assure that exposure monitoring results accurately characterize worker exposures.

Section 850.24(c) requires the responsible employer to conduct periodic exposure monitoring of workers who work in areas where airborne concentrations of beryllium are at or above the action level. Periodic monitoring provides the responsible employer with assurance that workers are not experiencing higher exposures that may require the use of additional controls. In addition, periodic monitoring reminds workers and responsible employers of the continued need to protect against the hazards associated with exposure to beryllium. The collection of exposure monitoring data also enables the SOMD to be informed of the existence and extent of potential sources of beryllium exposure.

Some commenters argued that the periodic monitoring requirements in the rule should be more conservative than proposed in the NOPR. For instance, one commenter (Ex. 13) recommended that the requirement for periodic monitoring be implemented if employee exposures exceed 10% of the PEL while another commenter (Ex. 18) suggested that periodic monitoring be required for all workers regardless of previously measured exposures. DOE has addressed the first commenter's concerns by establishing the action level in the final rule at no greater than 0.2 $\mu g/m^3$ (ten percent of the PEL). DOE does not believe that periodic monitoring should be mandated for all workers regardless of exposure level, as suggested by the other commenter, but rather that the responsible employer should determine the frequency of periodic monitoring where levels are below the action level. However, DOE does encourage sites to establish lower action levels to trigger components of their CBDPP, as part of their exposure reduction and minimization efforts required under section 850.25.

A third commenter (Ex. 14), addressing the periodic monitoring requirements of proposed section 850.24(c), stated that periodic monitoring on a continuous basis is the only way to determine worker exposures. While DOE acknowledges that certain operations may warrant continuous monitoring due to the dynamic nature of day-to-day operations, DOE believes that an inflexible, one-size-fits all monitoring policy is inappropriate due to the wide range of beryllium-related operations within the DOE complex. Accordingly, DOE provides responsible employers the flexibility to determine the monitoring frequency that is needed to sufficiently characterize worker exposures. DOE believes that responsible employers are best positioned to evaluate the potential variability of worker exposures in their operations and to tailor their periodic monitoring approaches as appropriate. Nevertheless, because slight process or procedural changes may go unnoticed over time and because equipment maintenance, aging, or deterioration can affect performance, DOE, in section 850.24(c), is requiring a minimum exposure monitoring frequency of every 3 months (quarterly) for workers who are exposed to airborne concentrations of beryllium at or above the action level.

DOE recognizes that the minimum quarterly monitoring of workers exposed at or above the action level is more frequent than is required in most OSHA expanded health standards. However, DOE considers this minimum monitoring frequency to be necessary due to the uncertainties regarding the adequacy of the current PEL. To supplement this periodic monitoring requirement, section 850.24(d) requires that responsible employers perform additional exposure monitoring when beryllium-related operations or

procedures change, or they have any reason to suspect a change, which may cause new or additional exposures to workers. This additional monitoring is needed to protect workers from elevated exposures resulting from changed circumstances, 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, section 850.24(e) requires that responsible employers use monitoring and analytical methods that have accuracy, at a confidence level of 95 percent, of not less than plus or minus 25 percent for airborne concentrations of beryllium at the action level. The main reason DOE is requiring this degree of accuracy for exposure monitoring results is to ensure that exposure monitoring results are sufficiently accurate at the exposure level that is relevant for the CBDPP. Accuracy of measurements is critical, since certain central requirements of the rule (e.g., engineering controls, exposure reduction and minimization, respirator use, and regulated areas) are triggered by measured worker exposures that meet or exceed the action level. In addition, the medical removal provision requires that a removed worker not be placed in a job where exposure levels are at or above the action level.

Section 850.24(f) further ensures 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 AIHA, or a laboratory that demonstrates quality assurance for metals that is equivalent to AIHA accreditation. Equivalency to AIHA's accreditation means that a laboratory can demonstrate that their testing protocols meet the accreditation standards of AIHA. These accuracy and quality requirements are consistent with similar requirements that appear in many of OSHA's expanded health standards for toxic substances. The only commenter (Ex. 13) to address this issue agreed with DOE that the use of an AIHA accredited laboratory will ensure the quality control, consistency, and accuracy of beryllium sample analyses. DOE has added to the final rule the language ''or a laboratory that demonstrates quality assurance for metals analysis that is equivalent to AIHA accreditation,'' to provide responsible employers more flexibility in selecting a laboratory and to allow the use of an appropriate laboratory currently being used by the employer.

Section 850.24(g)(1) requires responsible employers to notify affected workers of monitoring results, in writing, within 10 working days of receipt of the monitoring results. This section also provides responsible employers with two alternative methods of worker notification: (1) written notification to each affected worker, or (2) posting of monitoring results in a location or locations readily accessible to affected workers. Two commenters (Exs. 16, 23) expressed concern about the use of personal identifiers in posted monitoring results, citing worker privacy concerns.

One commenter (Ex. 26) objected strongly to DOE's proposal to provide notice to workers in a manner that does not identify the worker. This commenter argued that not only is there no right to privacy implicated by posting of sampling results, but that anonymous notification would not further personal accountability for work practices. This commenter cited the Atomic Weapons Establishment's (AWE) experience at its Cardiff (United Kingdom) facility to show the beneficial effects of peer pressure on individual workers' adherence to good work practice. DOE recognizes AWE's experience and the benefits of peer pressure on workers' adherence to good work practices. However, DOE is following the approach used in OSHA's substance-specific standards that have posting requirements, which does not incorporate the principle of applying peer pressure to establish good work practice procedures. DOE, therefore, provides in the final rule that when the posting option is selected, responsible employers must post the results without disclosing the identity of the affected workers. This protection of workers' privacy is consistent with OSHA's substance-specific standards that have posting requirements.

Sections 850.24(g)(2) and (3) deal with cases in which monitoring results indicate that the worker exposure level meets or exceeds the action level. In such cases, the responsible employer is required by paragraph (g)(2) to include in the notice to workers a description of the corrective actions being taken to reduce worker exposure to below the action level. Paragraph (g)(3) requires the responsible employer to notify the SOMD of the results within 10 working days of receipt of the monitoring 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.

Section 850.25—Exposure Reduction and Minimization

Section 850.25 establishes the exposure reduction and minimization provisions of the CBDPP that reflect DOE's goal of achieving aggressive reduction and minimization of worker exposures to airborne beryllium.

Section 850.25(a) establishes the baseline requirement that responsible employers ensure that no worker is exposed to airborne beryllium at levels above the exposure limit established in section 850.22.

Section 850.25(b)(1) requires the responsible employer to include in the CBDPP a formal exposure reduction and minimization program to reduce exposure levels that are at or above the action level to below the action level, if practicable. Sections 850.25 (b)(1)(i)-(iv) provide that the formal exposure reduction and minimization program must include: (1) exposure reduction and minimization goals, (2) the rationale to support the goals and a strategy for achieving them, (3) the specific actions that the responsible employer plans to take to achieve the goals, and (4) a means of tracking progress towards meeting the goals or demonstrating that the goals have been met. Where levels are below the action level, section 850.25(b)(2) requires responsible employers to include in their CBDPP a description and rationale for the steps they plan to take to reduce and minimize exposures, if such steps are practicable. Such steps are applicable when exposures are measured below the action level to provide additional worker protection. This requirement assures responsible employer's commitment to address and further reduce exposures, as practicable, below the action level and implementing the steps included in their CBDPP.

Section 850.25(c) provides that responsible employers must apply the hierarchy of industrial hygiene controls, as already required under DOE Order 440.1A, to achieve exposure control. This hierarchy dictates that responsible employers first must implement feasible engineering controls, followed by administrative controls, in their efforts to reduce and minimize exposures. Responsible employers can supplement these controls with personal protective clothing and equipment to reduce exposures where engineering and administrative controls are not feasible.

In summary, section 850.25 establishes a graded approach to reducing and minimizing beryllium exposures to levels as low as

practicable. This approach is familiar to the DOE community because it is similar to DOE's ''as low as reasonably achievable'' approach to radiation protection. DOE's requirement that the responsible employer establish a formal program of setting and tracking reduction goals for exposures above the action level will result in greater management attention to potential high exposures. The requirement that the responsible employer take steps to reduce and minimize exposures that are below the action level commits DOE to continue reducing and minimizing exposures, but without the same level of management attention since these exposures are believed to represent a lower risk to workers.

Six persons commented on the exposure reduction and minimization requirements of the proposed rule. Two of the commenters (Exs. 18, 23) recommended that the rule require responsible employers to initiate reduction and minimization actions to maintain exposures below the action level, rather than below the exposure limit. DOE would essentially be setting a new DOE exposure limit if it followed this recommendation. As previously explained, DOE believes that setting a new exposure limit would be inappropriate because the scientific data is not fully developed and does not yet provide an adequate basis for determining an appropriate new limit. The discussion of section 850.22, Permissible Exposure Limit, provides greater detail on the issue of lowering the exposure limit.

Three of the commenters (Exs. 4, 18, 33) made recommendations that relate to the appropriate trigger for requiring responsible employers to initiate reduction and minimization actions where exposure levels are below the action level. Two commenters (Exs. 18, 33) recommended that the rule require responsible employers to initiate reduction and minimization actions wherever beryllium is detected. One commenter (Ex. 4) interpreted Table 5 in the NOPR preamble to mean that DOE would expect the responsible employer to undertake actions anywhere exposure levels are greater than zero. DOE believes that using either the limit of detection or greater than zero as the trigger is not practicable because trace levels of beryllium are ubiquitous, and beryllium levels in air can be measured everywhere if a large enough air sample is taken to accumulate sufficient beryllium to exceed the lower detection limit of the analytic method being used. DOE believes that final section 850.25(b)(2) best meets DOE's intention of establishing an effective performance-based rule by requiring responsible employer actions, if practicable, where exposure levels are below the action level.

Another commenter (Ex. 3) questioned the efficacy of enforcing a rule that allows each site to establish individual exposure reduction and minimization goals. DOE believes that this approach is adequately enforceable based on its positive experience using contractual mechanisms to enforce similar requirements in radiation protection regulations.

Section 850.26—Regulated Areas

Section 850.26 establishes the regulated area provisions of the CBDPP. Regulated areas are an effective means of minimizing the number of workers exposed to airborne concentrations of beryllium because they prevent or minimize the spread of beryllium to clean areas. This is consistent with good industrial hygiene practice whenever exposure to a toxic substance can cause serious health effects.

The final rule's requirements for regulated areas are essentially the same as those proposed, with certain good hygiene practices being added in response to a commenter's (Ex. 1) concern discussed below under section 850.26(d).

Section 850.26(a) requires the responsible employer to establish regulated areas where, based on breathing zone samples, the employer determines that workers are exposed to airborne concentrations of beryllium at or above the action level.

Three commenters addressed this provision, as proposed, and suggested either alternate or supplemental criteria to trigger the establishment of regulated areas. One commenter (Ex. 18) suggested that the trigger level be lowered to require that regulated areas be established wherever beryllium is detected. DOE believes that the final rule's significantly lower action level provides a suitable mandatory trigger for the establishment of regulated areas. In addition, DOE believes that the CBDPP exposure reduction and minimization provisions will result in the use of an even lower site-specific action level as improved controls become feasible throughout the DOE complex.

The two other commenters (Ex. 3, 34) suggested that the proposed provision for regulated areas be supplemented with a surface contamination level limit that would trigger the establishment of regulated areas. No reliable correlation has been established between surface contamination level and airborne concentrations of beryllium. DOE, therefore, believes that using a surface contamination level limit as a trigger for the establishment of regulated areas would produce minimal benefits to worker health and has not adopted this recommendation.

One of the commenters (Ex. 3) suggested that if engineering or process controls bring exposure levels to below the action level in a regulated area, the area should remain a regulated area to ensure that controls remain in place. DOE does not agree with this comment. While the rule would not prevent responsible employers from implementing such a practice, requiring that regulated area provisions remain in effect after exposures have been reduced to acceptable levels would impose additional financial burdens on employers with no corresponding improvement in worker protection. In addition, DOE believes that such a mandatory provision could undermine the incentives this rule creates for employers to implement effective engineering or process controls. If employers were required to maintain regulated areas regardless of whether they had implemented effective engineering controls, employers might have less motivation to implement the controls. This commenter's concern is at least partly addressed by section 850.24(d), which requires the performance of additional exposure monitoring if operations or procedures change or if the employer suspects a change that could affect exposure levels.

Section 850.26(b) of the rule requires responsible employers to demarcate areas where worker exposures are at or above the action level in a manner that alerts workers to the boundaries of such areas. Under section 850.38 of this part, warning signs must be posted, stating that only authorized personnel are allowed in the area. Due to the serious nature of the adverse health effects associated with exposure to beryllium, no one should be in a regulated area without proper personal protection.

Section 850.26(c) requires responsible employers to limit access to regulated areas to authorized persons only. DOE intends that only individuals who are essential to the performance of work in the regulated area will be authorized to enter regulated areas. Responsible employers will 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 are authorized to enter. Methods for preventing unauthorized persons from entering a regulated area may include posting a sign indicating that only authorized persons may enter, the use of locked access doors, and other

security measures as required by worksite conditions. DOE believes that employers are best equipped to determine whether any access control methods are needed in addition to warning signs specified in section 850.38.

Two commenters (Exs. 1, 31) suggested the incorporation of additional personal hygiene controls, specifically recommending that the rule prohibit smoking, eating, and drinking in regulated areas. DOE agrees with these commenters and has included in section 850.27 a prohibition on smoking, eating, and drinking in areas where beryllium is above the action level (i.e., in regulated areas).

Section 850.26(d) requires responsible employers to 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 type of work performed. One commenter (Ex. 26) stated that a log of worker activities is not needed unless DOE is conducting a ''prospective risk assessment.'' This commenter believed that a simple log, only documenting who entered regulated areas, would be sufficient. The intended function of these records is clarified in section 850.39, Recordkeeping and Use of Information. DOE believes that recordkeeping must be adequate to permit DOE to monitor the effectiveness of each responsible employer's compliance activities and to provide information regarding each worker's history of potential exposures. This information will assist the responsible employer's occupational medicine staff in establishing appropriate medical surveillance protocols and will aid in DOE's efforts to establish links between working conditions and potential health outcomes. DOE has retained the proposed regulated area recordkeeping requirements in section 850.26(d) of the final rule.

Section 850.27—Hygiene Facilities and Practices

Section 850.27 of the final rule retains the NOPR requirements for responsible employers to provide change rooms or areas and hand washing and shower facilities for beryllium workers. In addition to these provisions, the final rule also requires responsible employers to provide lunchroom facilities that are readily accessible to beryllium workers, ensure that tables for eating are free of beryllium, that no worker is exposed at any time at or above the action level, and specifies that all of these facilities must comply with the requirements of 29 CFR 1910.141. These hygiene provisions are common in OSHA's expanded health standards designed to protect workers from exposures to hazardous particulates.

Sections 850.27(a)(1) and (2) requires responsible employers to assure that workers observe prohibitions on the availability and use of cosmetics, tobacco and chewing products, and food and beverages in areas where beryllium is above the action level. Section 850.27(a)(3) requires responsible employers to prevent beryllium workers from exiting areas that contain beryllium with contamination on their bodies or their personal clothing. DOE believes that these provisions promote sound work place hygiene practices that may protect workers from exposure to other substances present in the workplace, as well as beryllium. These provisions are commonly included in OSHA's substance-specific health standards.

Section 850.27(b) requires responsible employers to provide clean change rooms or areas for workers who work in regulated areas. In addition, section 850.27(b)(1) requires 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 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.

Section 850.27(b)(2) requires that the change-rooms used to remove beryllium-contaminated clothing and protective equipment be maintained under negative pressure, or be located in a manner or area that prevents dispersion of beryllium contamination into clean areas.

DOE received two comments on the hygiene facilities and practices provisions of the NOPR. A commenter (Ex. 25) suggested that the requirement to provide change rooms, hand washing facilities, and showers be based on a hazard assessment. DOE believes that requiring responsible employers to perform a separate hazard assessment to determine the need for change rooms and showers is unnecessary and overly burdensome to responsible employers. The requirement for change rooms and showers is triggered by the requirement to establish regulated areas. Regulated areas, in turn, are required wherever a hazard assessment identifies the potential for worker exposures at or above the action level. Thus, the requirement for change rooms and showers is already indirectly triggered by the results of a hazard assessment.

A commenter (Ex. 23) expressed concern that the impact and burden of constructing new change rooms for D&D closure sites has not been considered in the development of the change room provisions, and argued that alternative methods of compliance should be considered for D&D operations. In fact, DOE has addressed the economic impact of requiring responsible employers to provide change rooms for workers in the economic analysis prepared for the NOPR and made available for public review. Based on that economic analysis, DOE is aware that the cost of change rooms may be substantial for some DOE facilities. However, DOE believes that providing change rooms and showers for workers who work in regulated areas is the most effective method for preventing workers from carrying beryllium contamination on their work clothes and bodies from regulated areas to other areas of DOE facilities and to workers' private automobiles and homes. DOE is unaware of any equally effective alternative method for achieving this objective and, thus, has retained the change room and shower provisions in the final rule. The economic burden may be lessened by steps employers already have taken to comply with existing hygiene facility requirements. For example, 29 CFR 1910.120(n)(7) of OSHA's Hazardous Waste Operations and Emergency Response standard already requires employers to provide showers and change rooms for workers on D&D operations of six months duration or longer. DOE contractors at DOE sites are subject to this requirement through their contracts, which require compliance with DOE Order 440.1A or other analogous Orders or standards.

Consistent with the goal of preventing the spread of contamination into adjacent work areas and into affected workers' homes, section 850.27(c)(1) requires responsible employers to provide shower and hand-washing facilities for workers assigned to regulated areas. In addition to controlling the spread of contamination, showering also reduces the worker's period of exposure to beryllium by removing any beryllium that may have accumulated on the skin and hair. Requiring workers to change out of work clothes, which are segregated from their street clothes, and to shower before leaving the plant, leaving work clothing

at the workplace, significantly reduces the movement of beryllium from the workplace. These steps ensure that the duration of beryllium exposure does not extend beyond the work shift and, thus, protect workers and their families from off-site exposures. DOE recognizes that the installation of such facilities may take time in some cases. Accordingly, section 850.13(b) of the final rule allows responsible employers two years to achieve full compliance with the requirements of the rule.

Section 850.27(d) requires responsible employers to provide beryllium workers working in regulated areas with readily accessible lunchroom facilities in which tables for eating are free of beryllium and no worker is exposed at any time to a concentration of beryllium at or above the action level. DOE believes that it is imperative that workers have a clean place to eat to reduce the likelihood of additional exposure to loose beryllium dust through inhalation or ingestion.

Responsible employers must also assure that workers in regulated areas do not enter the lunchroom wearing protective clothing unless the clothing is properly cleaned beforehand. Responsible employers are given discretion to choose any method for removing surface beryllium from the clothing that does not disperse the dust into the air. These requirements are similar to the hygiene facilities and practices provisions in a number of OSHA's health standards.

Section 850.28–Respiratory Protection

Section 850.28 establishes the respiratory protection requirements for the CBDPP. Section 850.28(a) requires that responsible employers comply with OSHA's Respiratory Protection standard (29 CFR 1910.134). Section 850.28(b) requires that responsible employers provide appropriate respiratory protective equipment for all workers exposed, or potentially exposed based upon task analyses, to airborne concentrations of beryllium at or above the action level. This section also requires the responsible employer to ensure that workers use respirators. Section 850.28(c) requires the responsible employer to include in the respiratory protection program any beryllium-associated worker who requests to use a respirator, regardless of exposure level. Section 850.28(d) requires that responsible employers select and use only National Institute for Occupational Safety and Health (NIOSH)-approved respiratory protective equipment or, if none exist for a DOE beryllium activity, DOE-accepted respiratory protective equipment.

Some of the requirements of section 850.28 are not new. For instance, DOE contractors have historically been required to comply with OSHA standards, including 29 CFR 1910.134, through contract provisions requiring compliance with DOE Order 440.1A and its predecessor orders. DOE also has followed OSHA standards in implementing the Federal Employee Occupational Safety and Health Program. DOE Order 440.1A requires employers to provide, and DOE workers to use, appropriate respiratory protective equipment necessary to protect workers from exposures to hazardous substances. In addition, the provisions of 29 CFR 1910.134 include a requirement that employers select only NIOSH-approved respirators. DOE Order 440.1A expands this requirement to allow for the use of DOE-accepted respiratory protection if NIOSH-approved respiratory protection does not exist for a specific DOE task. The provisions of section 850.28 that are new in this final rule are the requirements for the use of respiratory protection: (1) at the action level (rather than at OSHA's PEL); (2) based on the analyses of job activities (rather than only on measured levels); and (3) when requested by beryllium-associated workers regardless of exposure level. DOE does not expect that these new provisions will greatly increase the number of workers who wear respirators at DOE sites. Under current practice, DOE sites require use of respirators at their established action level (ranging from 0.2 to 1.0 $\mu g/m^3$) rather than at the PEL (see CBDPP Economic Analysis, Chapter 3, Section 3.2.8).

The NOPR (Section V, Request for Information) requested comments on changing the trigger for requiring respiratory protection from the PEL to the action level. Seven of the thirteen commenters on respiratory protection (Exs. 16, 18, 23, 25, 26, 28, 30) recommended that the rule be more protective of workers' health by requiring the use of respiratory protection at the proposed action level. None of the remaining four commenters on this issue (Exs. 3, 4, 20, 31) recommended retaining the PEL as a trigger. The seven supporters of using the action level as a trigger represent a wide variety of stakeholders. These commenters' predominant reason for recommending the more protective level as the trigger is the uncertainty about the protection afforded by the current PEL. These commenters provided the following additional reasons for lowering the respiratory protection trigger from the PEL to the action level: (1) To provide a greater margin of safety because of the imperfections in measuring exposure levels; (2) to provide a greater margin of safety because of the imperfections in understanding how to set exposure limits for materials, such as beryllium, for which the cause of illness is the body's immune system reaction; and (3) to establish an internally consistent CBDPP which includes consistent triggers for its protective provisions and, therefore, is rational and easy to communicate. DOE generally agrees with these comments and has revised section 850.28 to require the use of respirators when exposures are at or above the action level.

One commenter (Ex. 3) was concerned that using the action level as a trigger for respiratory protection would render the action level a de facto PEL, because OSHA uses the PEL as the trigger for respiratory protection in OSHA substance-specific standards. Similarly, two commenters (Exs. 4, 20) believed that using the action level as a trigger for respiratory protection signifies that DOE believes that the PEL is not adequately protective. Section I.C., Health Effects, of the Supplementary Information section provides a detailed explanation of the difficulties of determining a safe threshold level for occupational exposure to beryllium, given the current state of knowledge of occupational exposures and the etiology of beryllium disease. DOE's strategy is to require a rigorous program to prevent chronic beryllium disease by reducing and minimizing exposures, while studies continue that may provide the data needed to establish a safe level of exposure to airborne beryllium. The preamble discussions of sections 850.22 and 850.23 explain in greater detail DOE's rationale for continuing to defer to OSHA's PEL, while establishing a more protective action level for DOE.

One commenter (Ex. 26) recommended that the responsible employer provide respiratory protection when warranted based upon an analysis of the worker's job activities. DOE recognizes that many tasks involving beryllium may result in high concentrations of airborne beryllium due to a procedure error, a work error, or an equipment failure. An analysis of the worker's job activities will determine whether respiratory protection is necessary for such tasks. Therefore, DOE added section 850.28(b)(2) requiring responsible employers to provide respiratory protection for task involving such circumstances.

Two commenters (Exs. 26, 30) recommended that the responsible employer provide respiratory protection when it is not otherwise required if requested by a worker due to the uncertainty about what is a safe level and uncertainties in monitoring and controlling a substance like airborne beryllium. DOE agrees with these commenters and has added section 850.28(c), which requires the responsible employer to provide respiratory protection upon the request of the beryllium-associated worker regardless of measured exposure levels.

One commenter (Ex. 3) recommended requiring respiratory protection for exposures at or above the STEL. DOE agrees with the commenter that the STEL would have been an appropriate trigger for respiratory protection if the action level had remained at 0.5 $\mu g/m^3$. However, a STEL of 10 $\mu g/m^3$ for 15 minutes, as proposed in the NOPR, would provide no added protection for workers as a trigger for respiratory protection in the final rule because its action level of 0.2 $\mu g/m^3$ will be exceeded in less than 15 minutes where exposure levels are at 10 $\mu g/m^3$. As explained in the discussion of section 850.22, DOE has decided that it would not be appropriate, given the current science, to establish a lower STEL in this rule.

DOE has clarified its expectations on the use of DOE-accepted respirators in response to one commenter (Ex. 31) who questioned the use of DOE-accepted respirators rather than NIOSH-approved respirators. This requirement as proposed in section 850.28(c) could have been interpreted, as it was by this commenter, to mean that responsible employers could choose between NIOSH-approved respirators and DOE-accepted respirators. This was not DOE's intent. DOE's revision in section 850.28(d)(2) clarifies that responsible employers may use the DOE-accepted respirators only if NIOSH-approved respirators do not exist for particular DOE tasks. This section also references DOE's Respirator Acceptance Program to clarify that DOE only accepts for use respirators that DOE deems acceptable based upon the results of a formal testing and evaluation program.

One commenter (Ex. 31) recommended that the rule specify that all respiratory protective equipment be furnished at no cost to the worker. Section 850.28(a) requires that responsible employers comply with 29 CFR 1910.134, Respiratory Protection, which currently requires in section 1910.134(c)(4), that employers provide respirators at no cost to the employee. Accordingly, DOE will continue to rely upon OSHA's requirements in lieu of making specific changes to the rule.

Section 850.29–Protective Clothing and Equipment

Section 850.29 establishes the protective clothing and equipment provisions (other than respirator use) of the CBDPP. The objectives of this section are to provide clothing and equipment that protects workers against the hazards of skin and eye contact with dispersible forms of beryllium and to prevent the spread of contamination outside work areas that could occur from the improper handling of beryllium-contaminated clothing and equipment.

DOE has clarified the proposed requirement for the responsible employer to provide protective clothing and equipment where skin or eye contact with beryllium is possible. Section 850.29(a) requires that responsible employers provide protective clothing and equipment to beryllium workers where dispersible forms of beryllium may contact workers' skin, enter openings in workers' skin, or contact workers' eyes.

The openings in workers' skin could include fissures, cuts, and abrasions. DOE recognizes that the potential for the development of contact dermatitis, chronic ulcerations, and conjunctivitis is mainly associated with contact with soluble forms of beryllium compounds that are not included in the definition of ''beryllium'' in this rule. Insoluble beryllium, however, has also been shown to cause chronic ulcerations if introduced into or below the skin via cuts or abrasions (ref. 34). DOE believes that it is prudent industrial hygiene practice to avoid skin or eye contact with a material that causes chronic ulcerations and, therefore, has included protecting workers' skin and eyes from contact with insoluble beryllium in section 850.29(a). The protective equipment required by this section could include coveralls, overalls, jackets, footwear, headwear, face shields, goggles, gloves, and gauntlets, depending on the nature of the operation and the related skin and eye exposure hazards involved.

In the NOPR, DOE requested 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 requested comments regarding the need for the protective clothing and equipment provisions of proposed section 850.29(a)(2), given a DOE survey that had found that soluble beryllium compounds apparently were not present within the DOE complex. One commenter (Ex. 4) recommended excluding soluble beryllium from section 850.29 based on that survey result. However, as a result of other public comments, DOE learned that that survey result was incorrect because one DOE commenter (Ex. 16) indicated that its facilities contain soluble beryllium. Moreover, other commenters (Exs. 26, 30) pointed out that DOE facilities may contain soluble beryllium in the future.

Nevertheless, DOE has not changed the definition of ''beryllium'' in the final rule to include soluble forms of beryllium, because the principal focus of this rule is on preventing CBD, which is caused by exposure to insoluble forms of beryllium. One commenter (Ex. 26) correctly pointed out that the skin and eye effects that this section is intended to prevent are different health effects than CBD. Although another commenter (Ex. 25) questioned DOE's view that soluble beryllium exposure to the lungs does not cause CBD, DOE finds no evidence in the information on health effects presented in section I.C. that exposure of the lungs to soluble forms of beryllium causes CBD. DOE expects responsible employers to address soluble beryllium hazards in existing worker protection programs under DOE Order 440.1 or analogous Orders or standards cited in responsible employers' contracts with DOE.

Section 850.29(a)(1) requires responsible employers to provide protective clothing and equipment to beryllium workers, at no cost, where airborne beryllium levels are measured or presumed to be at or above the action level, because elevated airborne levels are likely to generate elevated surface levels which represent a skin and eye hazard. DOE has included ''presumed to be'' in section 850.29(a)(1) in response to a recommendation that one commenter (Ex. 26) made with respect to respiratory protection that applies equally to protective clothing and equipment. The commenter recommended that the responsible employer provide respiratory protection when warranted based upon task analyses. DOE recognizes that many tasks involve beryllium that could readily become airborne in high concentrations due to a procedure error, a worker error, or an equipment failure, but which will have no measurable exposure level unless one or more of these problems occur. DOE believes that an analysis of the worker's job activities would show the need for protective clothing and equipment, and respiratory protection to perform such activities.

Another commenter (Ex. 3) recommended that DOE add a surface contamination level that would also trigger the requirement to provide protective clothing and equipment. DOE agrees with this commenter because elevated surface levels represent a skin and eye hazard, and, accordingly, DOE has added paragraphs (a)(2) and (a)(3) to this section. Section 850.29(a)(2) requires responsible employers to provide protective clothing and equipment to beryllium workers where surface contamination levels are measured to be, or prior to initiating work are presumed to be, above the housekeeping level prescribed in section 850.30. Section 850.29(a)(3) requires responsible employers to provide protective clothing and equipment to beryllium workers where surface contamination level results obtained to confirm housekeeping efforts are above the prescribed housekeeping level.

Section 850.29(a)(2) addresses the situation in which the responsible employer is planning to conduct a task involving beryllium and has time to measure or estimate surface levels before the task begins. Section 850.29(a)(3) addresses the situation in which the responsible employer learns from routine surface monitoring conducted at the end of a shift that housekeeping efforts did not reduce surface levels to below the surface contamination level specified in section 850.30. DOE recognizes that sampling to confirm the adequacy of housekeeping efforts at the end of shifts, and the turnaround time of as much as 24 hours for sample analysis, could result in workers not using protective clothing and equipment for more than a day where surface contamination levels exceed the prescribed surface contamination level. However, DOE believes that these situations will be rare, because routine post-shift cleaning should keep these surface contamination levels from becoming excessive. Also, DOE believes that responsible employers will be motivated to reduce turnaround times for analyses in their efforts to reduce and minimize exposures. DOE selected the term ''results'' in section 850.29(a)(3) to avoid creating a situation in which the responsible employer would violate the rule simply because the employer did not know that the housekeeping criterion had been exceeded until surface monitoring results were available.

Section 850.29(a)(4) requires the responsible employer to provide protective clothing and equipment upon the request of the beryllium-associated worker, regardless of measured exposure levels.

Section 850.29(b) incorporates into this rule 29 CFR 1910.132, Personal Protective Equipment General Requirements. This OSHA standard is responsive to a commenter's (Ex. 31) recommendation that the rule should require the responsible employer to furnish the clothing and equipment at no cost to the employee, and covers other well-established practices, such as the topics to be included in protective clothing and equipment training, and ensuring that protective clothing and equipment fits properly. This requirement to comply with 29 CFR 1910.132 is consistent with the general worker protection provisions of DOE Order 440.1A, and analogous Orders or standards cited in the responsible employer's contract with DOE.

Section 850.29(c)(1) requires the responsible employer to establish procedures for donning, doffing, handling, and storing protective clothing and equipment that prevent beryllium workers from exiting areas that contain beryllium with contamination on their bodies or their personal clothing. DOE added this provision because one commenter (Ex. 3) correctly pointed out that it was omitted in the proposed rule and is needed to ensure that workers do not track contamination out of areas that contain beryllium. The same commenter recommended that DOE explicitly require HEPA vacuuming of contaminated protective clothing and equipment as part of the required doffing procedure. This final rule does not include a requirement to include HEPA vacuuming in doffing procedure, because DOE believes that this would not allow the employer sufficient flexibility in selecting cleaning procedures.

Section 850.29(c)(2) requires that the procedures for donning, doffing, handling, and storing protective clothing and equipment include a requirement that beryllium workers exchange their personal clothing for full-body protective clothing and footwear (work shoes or booties) before beginning work in regulated areas. 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 onto affected workers' private property. A recent study (ref. 35) has documented the transport from work areas of beryllium on workers' hands and inside their personal vehicles.

One of DOE's objectives is to prevent the spread of beryllium contamination, thereby reducing the number of persons exposed and the opportunities for potential exposures. Thus, sections 850.29(d) through (f) establish provisions to control the handling, maintenance, cleaning, and disposal of beryllium-contaminated protective clothing and equipment.

Section 850.29(d) requires the responsible employer to ensure that workers do not remove beryllium-contaminated protective clothing and equipment from areas that contain beryllium, except for authorized activities such as cleaning and repairing the clothing and equipment. DOE replaced ''site'' in the proposed rule with ''area that contains beryllium'' in the final rule to clarify its intent to minimize contamination of other areas at the site as well as outside the site.

Section 850.29(e) requires the responsible employer to prohibit the removal of beryllium from protective clothing and equipment by blowing, shaking, or other means that may disperse beryllium into the air. Although DOE generally believes that responsible employers should have the flexibility to determine the most appropriate means to clean contaminated clothes based on their own specific worksite conditions, DOE has included this well recognized and accepted industrial hygiene control to prevent the dispersion of beryllium particles into the workplace atmosphere.

Section 850.29(f), which was proposed as section 850.29(c), requires responsible employers to clean, launder, repair, and replace protective clothing and equipment as needed to ensure its continued effectiveness in protecting workers. This section allows contractors flexibility in determining the required frequency for laundering protective clothing based on specific work conditions and the potential for contamination.

Section 850.29(f)(1), which was proposed as section 850.29(b), paragraphs (1)–(2), requires the responsible employer to ensure that protective clothing and equipment removed for laundering, cleaning, maintenance, or disposal, is placed in containers that prevent the dispersion of beryllium dust, and that these containers are labeled in accordance with section 850.38. These warning labels will help ensure appropriate subsequent handling of beryllium-

contaminated materials and may prevent inadvertent exposures that could result if laundry, maintenance, or disposal personnel are not aware of the beryllium contamination and the precautions prescribed by the responsible employer to prevent the release of airborne beryllium. In section 850.29(f)(1) of the final rule, DOE has deleted the words ''impermeable'' and ''are designed'' which were in proposed section 850.29(b)(1) in response to a commenter's (Ex. 8) recommendation to clarify DOE's intent. This change eliminates the possible implication that DOE expects responsible employers to provide special containers even if existing containers are capable of preventing the spread of contamination.

Section 850.29(f)(2), which was proposed as section 850.29(d), requires the responsible employer to ensure that organizations that launder or clean DOE beryllium-contaminated protective clothing or equipment are informed that exposure to beryllium is potentially harmful, and that clothing and equipment should be laundered or cleaned in the manner prescribed by the responsible employer to prevent the release of airborne beryllium. DOE replaced ''any individual'' with ''organizations'' to clarify that DOE's objective for this section is to ensure that any organization that launders beryllium contaminated clothing is informed of the hazards of handling beryllium contaminated items so that the organization can take steps to protect its workers. The proposed wording ''any individual'' could have been interpreted as establishing a direct relationship between the responsible employer that generated the contaminated clothing and the employee of the laundry or cleaning organization, which is not DOE's intent. Also, DOE clarifies in section 850.29(f)(2) that this section requires informing both on-site cleaning and laundry services, as well as off-site cleaning and laundry vendors. On-site cleaning and laundry services are covered by this rule, but may not know about the presence and hazards of beryllium on the clothing and equipment unless the responsible employer informs them.

DOE has deleted the words ''at or above the action level or above the STEL,'' which in proposed section 850.29(a) qualified the requirement to inform downstream launderers or cleaners of beryllium-contaminated protective clothing and equipment. This change is consistent with final section 850.25, which requires reduction and minimization, if practicable, where exposure levels are below the action level.

One commenter (Ex. 31) recommended including in the rule provisions for preventing heat stress. DOE recognizes that requiring protective clothing and equipment for dispersible forms of beryllium compounds at the final rule's lower action level is likely to result in greater use of protective clothing and equipment, including respirators, and consequently greater potential for heat stress. DOE believes that the health benefit from lowering the risk of CBD outweighs any increased health risk caused by heat stress that results from the requirements of this section. DOE has not included heat stress provisions in this rule because it is a potential problem for many DOE activities that require the use of protective clothing and equipment; and DOE expects heat stress issues to be addressed in the responsible employer's existing worker protection program.

Section 850.30—Housekeeping

Section 850.30 establishes the housekeeping provisions of the CBDPP. Good housekeeping practices are necessary in operational areas where beryllium is used or handled, to prevent the accumulation of beryllium contamination on surfaces throughout the workplace. Such accumulations, if not controlled, may lead to the spread of beryllium contamination on surfaces and the re-suspension of beryllium particles into the air, both in the area where beryllium dusts were originally generated and in other work areas. In addition, the uncontrolled accumulation of beryllium-contamination on equipment in the workplace increases the potential for worker exposure to beryllium during the performance of equipment maintenance, handling, and disposal tasks.

DOE in section 850.30(a) has established that the removable contamination housekeeping level on surfaces must not exceed 3 μ/100 cm^2 during non-operational periods. Establishing a surface removable contamination limit reduces the potential for spread of beryllium contamination. Responsible employers must perform measurements to determine if the operational work area is in compliance with the rule. In addition, monitoring surface contamination levels is an indispensable tool for ensuring that beryllium emissions from operations are under control. The only practical method of monitoring surface levels is to maintain the surface contamination at an established housekeeping level so that elevations above that level can readily be detected.

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

Two commenters (Exs. 26, 28) questioned the scientific basis for establishing a 3 μg/100 cm^2 surface removable contamination level. In addition, these two commenters stated that the variability associated with wipe sampling makes surface sampling method an unreliable method for sampling. DOE views wipe sampling as a useful and accepted method for providing qualitative information on chemical contamination of work surfaces, and agrees with the following statement in the OSHA Technical Manual (Section II: Chapter 2, Sampling for Surface Contamination): ''Wipe sampling is an important tool of work site analysis for both identifying hazardous conditions, and in evaluating the effectiveness of * * * housekeeping, and decontamination programs.'' Accordingly, this requirement is intended only as a housekeeping performance measure, and should not be viewed as a mechanism for measuring, or predicting airborne concentrations of beryllium. In addition, this requirement only applies to removable or loose surface contamination, which could become re-suspended in the workplace air or spread to non-controlled areas.

DOE does not intend the requirement for surface wipe sampling in this rule to preclude the use of other surface sampling methods for measuring beryllium contamination. DOE agrees with comments calling for more research (Exs. 16, 28) and encourages the use, research, and development of new technologies such as direct reading instruments, which may provide better results than wipe sampling.

Section 850.30(a) requires that responsible employers conduct routine surface sampling in operational areas, to ensure the effectiveness of their housekeeping efforts. This sampling would not include the interior of installed closed systems such as enclosures, glove boxes, chambers, or ventilation systems. Sampling should not be carried out during a normal work shift, but rather it should be undertaken after normal clean-up and during non-operational periods.

Affected sites throughout DOE have already established, under the interim CBDPP, allowable beryllium surface contamination levels to ensure the

effectiveness of their housekeeping procedures. These levels range from 1 to greater than 5 μg/100 cm^2, with the majority of the sites using approximately 3 μg/100 cm^2 or less as the criterion for determining the cleanliness of their working environment outside of regulated areas. Comments on the NOPR called for setting levels ranging from less than 1 μg/100 cm^2 (Exs. 14, 18) to 5 μg/100 cm^2 (Ex. 24). Information collected from the sites during the development of the interim beryllium CBDPP indicated that the Pantex and Y–12 facilities currently have an allowable surface concentration level of 25 μg/100 cm^2 for regulated areas. Los Alamos National Laboratory (LANL) procedures call for re-evaluation of the operations with additional cleaning of beryllium operations areas at levels greater than 26 μg/ft^2 (2.8 μg /100 cm^2). Lawrence Livermore National Laboratory (LLNL) indicated those areas with surface concentrations greater than 3 μg/100 cm^2 are designated as regulated areas. Rocky Mountain Remediation Services (a sub-contractor at Rocky Flats) indicated that a surface contamination level greater than 25 μg/ft (2.7 μg/100 cm^2) outside of regulated areas triggers clean up actions at its site. The AWE facility at Cardiff (United Kingdom) has utilized a surface action level of 10 μg/ft^2 (1 μg/100 cm^2) outside of regulated areas since 1990. Based on this range of data, DOE adopted the 3 μg/100 cm^2 housekeeping level in the proposed rule and continues to believe it is a reasonable surface removable contamination level that should not be exceeded.

One commenter (Ex. 3) recommended that the surface removable contamination level be the same level as the criterion for releasing contaminated equipment for other uses. Another commenter (Ex. 23) objected to establishing a single surface limit for removable beryllium contamination that would be both a housekeeping and release level, recommending instead a tiered approach, with different levels for normal or safe work conditions (and free release of equipment), for beryllium work, and for special work conditions. For the reasons discussed under section 850.31, Release Criteria, DOE has adopted different levels for the release of equipment that depend on the intended future use of the equipment.

One commenter (Ex. 24) expressed concern that certain beryllium oxide weapons components could not meet the 3 μg/100 cm^2 level, and recommended that weapons components be exempt from surface contamination limits. DOE has revised section 850.30 to clarify that the surface removable contamination level is to be measured post-shift, and that the purpose of the surface level is not to have an absolute value of 3 μg/100 cm^2 at all times during the machining or working with beryllium or beryllium parts. DOE is aware that it may not be possible to maintain surface levels of beryllium in an operational work area below the 3 μg/100 cm^2 limit at all times. Again, the surface removable contamination level is intended as a post-shift measure of the effectiveness of routine housekeeping efforts.

DOE emphasizes that the housekeeping concerns addressed by section 850.30 apply to areas where workers may be exposed to beryllium, not to closed-off rooms or buildings. To make this clear, DOE has added the term ''operational areas'' in section 850.30(a). If routine surface sampling during non-operational or post-shift periods shows that the removable contamination level has been exceeded, clean-up measures must be instituted.

DOE agrees with the comment (Ex. 28) that the meaning of the term ''removable'' contamination may not be clear. Therefore, DOE has added a new definition of ''removable contamination'' and deleted the definition of ''surface contamination'' in section 850.3. The definition of ''removable contamination'' is taken from the U.S. Department of Energy Radiological Control Manual (DOE/EH–0256T Revision 1, April 1994). Use of this language in this rule maintains a consistent approach with DOE's radiological surface sampling program.

Two commenters suggested the use of wet wipes for surface sampling, while another commenter (Ex. 24) indicated that there is no basis for the application of a wet method. NIOSH, in its recent publication on beryllium contamination inside worker vehicles, supports the use of a wet wipe sampling method to collect beryllium samples in potentially contaminated employee vehicles (ref. 35).

The use of diverse sampling methods (e.g., differences in type of sample media, type of solvent (if any) on the sample media, area sampled, etc.) may easily lead to the reporting of inconsistent results. To reduce the variability in reported surface contamination across the DOE complex, DOE recommends, but does not require, the use of a single sampling method: NIOSH method 9100 (NIOSH Manual of Analytical Methods, 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. Sites using other methods, e.g., dry wipe sampling, should transition to the NIOSH method in a cost-effective manner. Current data is not clear on the relative efficiency of dry verses wet sampling on the variety of surfaces found in the DOE. Therefore, immediate adoption of the NIOSH method at sites across DOE may be impractical and add no immediate value to worker health and safety. In the long term, by recommending a single method (a wet method) for conducting the surface sampling, DOE believes that the variability associated with surface sampling will be reduced without specifying a particular method in the rule.

One commenter (Ex. 3) suggested that the term ''routine'' in section 850.30(a) should be more clearly defined, i.e., weekly or monthly. Because DOE believes that this rule should be as performance-based as possible, the frequency of ''routine'' monitoring procedures under this section should be developed by the local health and safety specialist (industrial hygienist) based on the specific circumstances at the site.

Section 850.30(b) prohibits the use of compressed air or dry methods and requires the use of vacuuming, wet or similar methods for the cleaning of beryllium-contaminated floors and other surfaces. The purpose of using these methods is to reduce or eliminate the potential for re-suspension of beryllium dust into the air and breathing zone of the worker.

One commenter (Ex. 23) requested flexibility in cleaning methods, such as permitting the use of sticky tack cloths. DOE agrees with the comment and in the final rule has allowed the use of other cleaning methods, such as sticky tack cloths, that have the same end result as wet vacuuming (i.e., a reduction of dust-producing cleaning methods). These are appropriate methods for complying with the housekeeping requirement of the rule.

Section 850.30(c) requires the use of HEPA filters in all vacuuming operations used to clean contaminated or potentially contaminated surfaces, and further requires filter replacement as needed, to maintain the capture efficiency of the vacuum system. 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. HEPA filters must be used to prevent the spread of dust by effectively collecting the dust that is collected by vacuum systems. Responsible employers should have procedures for the cleaning or replacement of filters that ensure

minimum employee exposure to beryllium dust on the filter.

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

Section 850.31—Release Criteria

Section 850.31 establishes beryllium contamination levels and other requirements that must be met before equipment and other items used in beryllium work areas may be released or transferred to the general public and non-beryllium areas of DOE facilities, or to facilities engaged in work involving beryllium. DOE requested comments on the setting of ''beryllium free-release'' public contamination levels in the NOPR. After considering the comments received in response to this broad request for views and information, DOE reopened the comment period on June 3, 1999, to invite public comment on specific options for release criteria that were being considered by DOE (64 FR 29811). Section 850.31 reflects DOE's consideration of the substantial number of comments received from organizations and individuals on this topic.

In the notice of reopening of the comment period, DOE suggested that a reasonable contamination level for release of equipment and other items to the public for non-beryllium uses would be 0.1 μg/100cm^2. This level was based on the housekeeping and release levels believed to be in effect at various DOE facilities and the AWE facility in the United Kingdom. DOE also stated that it was inclined to adopt a contamination level of 3 μg/100 cm^2 for release of items for beryllium work in other facilities. This level was based principally on the practice at the Rocky Flats.

Ten organizations and individuals submitted comments that recommended release level values. These values ranged from non-detectable to 3 μg/100 cm^2 for public release and non-detectable to 10 μg/100 cm^2 for release to beryllium facilities.

One commenter (Ex. 47) stated that there should be a single contamination level for both the housekeeping standard for beryllium areas and for release of items for beryllium and non-beryllium uses. Another commenter (Ex. 43) urged DOE to adopt a single criterion for release to the public and DOE non-beryllium facilities and to beryllium-handling facilities because it would be simpler to administer. DOE does not agree with these comments, because the workers in operational areas where beryllium is used have been trained in the hazards of beryllium and the proper use of protective equipment that is required to be worn in those areas. DOE does not believe that the general population or DOE non-beryllium workers should be exposed to the same level of a hazardous material as workers who have been trained in the safe handling of that material. DOE, therefore, has included in the rule separate requirements for the release of beryllium-contaminated equipment and other items to facilities engaged in beryllium work and for releases to the general public or DOE non-beryllium facilities.

Section 850.31(a) requires the responsible employer to clean beryllium-contaminated equipment and other items to a contamination level that is as low as practicable, but not to exceed the removable contamination levels specified in section 850.31(b), for release to the general public or to non-beryllium areas of DOE facilities, and section 850.31(c), for release to facilities performing work with beryllium. In addition, DOE has included in these sections other requirements that are designed to protect workers and others from the hazards associated with exposure to beryllium. DOE uses the words ''and other items'' after ''equipment'' in section 850.31(a) to cover tools, supplies, documents, etc., and any personal property in beryllium-handling areas that may not be encompassed by the term ''equipment.'' The phrase ''equipment and other items'' does not include real property or buildings.

Release to the public and for use in DOE non-beryllium areas. Section 850.31(b)(1) sets the removable contamination level for equipment and other items to be released to the general public or for use in DOE non-beryllium work areas at 0.2 μg/100cm^2 or the concentration level of beryllium in soil at the point of release, whichever is higher. The equipment also must be labeled, in accordance with section 850.38(b), to warn recipients of potential beryllium hazards. The responsible employer must condition the release of equipment and other items to the public based on the recipient's commitment to implement controls to ensure that exposure does not occur. Such a commitment should be based on the nature and possible future uses of the equipment and other items, the nature of the beryllium contamination, and whether exposure to beryllium is foreseeable.

In the notice of reopening, DOE referenced a comment by the AWE (Ex. 1) which reported that the housekeeping surface action level in its Cardiff, Wales facility had been reduced to 1 μg/ft^2 (about 0.1 μg/100 cm^2) in 1990. DOE reasoned that, based on the AWE experience and release limits included in DOE facilities' interim CBDPPs, a public release limit as low as 0.1 μg/100 cm^2 would be achievable. Several commenters (Exs. 41, 43, 46, 47, 51) argued that this level would be difficult and costly to achieve, and that there is no technical basis for concluding that it would be more beneficial than a higher level. AWE (Ex. 38) commented that it is not using 0.1 μg/100 cm^2 as a release level; its current policy is to dispose of contaminated items in a landfill site. The Pantex Plant (Ex. 46) stated that its reported use of 0.1 μg/100 cm^2 as a release criterion was incorrect, possibly due to a typographical error, and it recommended using 3 μg/100 cm^2 for the public release limit. Rocky Flats (Ex. 47) pointed out significant differences between the AWE Cardiff facility, which is a stable work environment, and the Rocky Flats facility, which is engaged in decontamination and decommissioning work. Two commenters (Exs. 43, 46) argued that a surface removable contamination level of 0.1 μg/100 cm^2 could easily be exceeded by background levels of beryllium.

Other commenters (Exs. 44, 45, 48, 49) took the position that any detectable level of beryllium on the surface of an item should be presumed to present a health risk and, therefore, that no item having a detectable level of beryllium should be released to anyone for any purpose. One commenter (Ex. 48) stated that the correlation between surface beryllium levels and associated health hazards is unknown, and the possibility exists for fixed or inaccessible beryllium to be liberated when equipment is worked on or repaired. Another commenter (Ex. 49) stated that DOE should take a cautious stance because of the current lack of information regarding the nature of the exposure-response relationship and the factors that underlie individual sensitization towards beryllium. Two commenters (Exs. 49, 52) recommended life-cycle

administrative controls for beryllium-contaminated equipment.

Section 850.31(b)(3) responds to the recommendation of comments (Exs. 26, 38) calling for a risk assessment that considers the downstream user's exposure potential, the history and type of equipment, and the nature of the contamination, in order to decide whether and how to release equipment and other items for non-beryllium uses. As recognized by DOE in the reopening notice, surface or wipe sampling is not an adequate means of characterizing potential exposure risk. For example, a lathe or other piece of equipment released because it is determined to be beryllium-free on the surface may contain internal beryllium dust that could become airborne and present a health hazard during future maintenance. On the other hand, other types of equipment may contain internal beryllium that is combined with other substances (e.g., grease) which would make it unlikely that the beryllium would ever become airborne. The presence of this type of suspended contamination, even at levels above the surface release criterion, would not necessarily present a health hazard. Accordingly, an assessment of potential risk of exposure should be undertaken before the release of any equipment or other item to either the general public or to DOE for non-beryllium uses. Based upon the assessment, the decision should be made as to ultimate disposition of the equipment and any conditions that should be placed on its future use.

After considering the comments, DOE is persuaded that it would be costly, if not infeasible, to implement a contamination level of 0.1 μg/100 cm^2 or lower as the public release criterion. Section 850.31(a)(1) requires responsible employers to clean equipment and other items to the lowest contamination level practicable and to ensure that removable contamination on surfaces does not exceed 0.2 μg/100 cm^2 or the concentration level of beryllium in local soil. This removable contamination criterion is based, in large measure, on information provided in comments submitted by the contractor that manages the Rocky Flats facility (Ex. 47). To comply with the interim CBDPP established by DOE Notice 440.1, Rocky Flats conducted an extensive site characterization (over 6000 samples) using 0.2 μg/100 cm^2 as the target contamination level. Rocky Flats reported that they found the 0.2 μg/100 cm^2 to be an achievable level and determined (using recently published re-suspension factors) that any airborne beryllium generated from re-suspending beryllium from surfaces, even with some beryllium surface levels above 0.2 μg/100 cm^2, would be expected to be well below the EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) limit of 0.01 $\mu g/m^3$ and therefore, at safe levels. EPA's NESHAP is the national standard for community air that the population continuously breathes.

DOE has addressed the concerns of commenters (Exs. 46, 50) that it may not be possible to clean equipment and other items to below the natural background of beryllium in local soil. It is highly unlikely that this rule would apply to soil because soils generally contains less than 0.1 percent beryllium and, therefore, is not considered beryllium for the purposes of this rule. Nonetheless, DOE included in section 850.31(b)(3) the words ''or the concentration level of beryllium in local soil at the point of release'' to eliminate the possibility that the rule would compel a responsible employer to clean local soil off of equipment and other items before release.

DOE does not agree with the view of some commenters that, in the absence of scientific evidence of a threshold or ''safe'' level of exposure to beryllium, the surface contamination release level should be at the limit of detection or zero. Although one commenter (Ex. 45, 45B) submitted information indicating that re-suspension of beryllium in the air is possible on surfaces with less than 1.0 μg/100 cm^2 of beryllium, there currently is no scientific evidence that surfaces cleaned to that level would result in airborne concentrations of beryllium at levels that would be harmful to workers.

DOE has addressed the concern about the potential for exposure to re-suspended beryllium by requiring a case-by-case assessment of risk before equipment and other items are released for non-beryllium uses. There is likely to be wide variation in these situations, and DOE is not prepared at this time to prescribe uniform management controls. However, this is an area for which DOE may develop guidance to assist field elements, as experience is gained under this rule.

One commenter (Ex. 43) recommended establishing a general surface release level of 1 μg/100 cm^2, plus labeling of items. The commenter suggested the use of labels to shift responsibility for controlling future exposures to the recipients of the equipment or items. DOE does not believe that simply cleaning the outside of the equipment and other items and providing warning to the new user is adequate because some recipients, particularly recipients who have not performed work using beryllium, may not fully understand the risks associated with beryllium exposure.

Release for beryllium work. Section 850.31(c)(1) sets the contamination level for equipment or other items released for use in other facilities engaged in beryllium work at 3 μg/100 cm^2. The equipment or item also must be labeled in accordance with section 850.38(b). Section 850.31(c)(3) requires the responsible employer to ensure that a released item is enclosed or placed in sealed, impermeable bags or containers to prevent exposure to beryllium during handling and transportation to its destination. Enclosure of equipment and other items to be released to other beryllium operations can be accomplished by any practical means, such as wrapping in plastic.

Several commenters recommended that DOE establish a higher surface contamination release level for equipment and other items to be transferred to another facility for beryllium work than is allowed for items released to the public or for use in DOE non-beryllium work (Exs. 38, 41, 42, 46, 51). Surface contamination levels recommended by the commenters (see Table 9) for release of equipment and other items to be used in beryllium areas range from 0 and non-detectable to 10 μg/100 cm^2. Rocky Flats (Ex. 47) previously established a release level for equipment and other items to be transferred to other DOE facilities for beryllium work at 2.5 μg/100 cm^2. Several commenters (Exs. 41, 42, 51) and a number of the DOE sites reporting release levels support the use of 3 μg/100 cm^2 or less as a release level for equipment and other items that will be used for beryllium work.

Based upon current surface sampling technology, DOE sees no appreciable difference between 2.5 μg/100 cm^2 and 3 μg/100 cm^2 and, therefore, has adopted the 3 μg 100 cm^2 value for release of equipment and other items to other facilities for beryllium work. Adoption of this value also maintains a consistency with the housekeeping requirements for operational beryllium areas, which will simplify implementation by DOE facilities.

Other issues. One commenter (Ex. 51) recommended that the rule specify that an industrial hygienist should determine the number and location of swipe samples. DOE views the determination of the number and location of swipe samples to be part of the hazard assessment, which must be managed by a qualified individual such as a CIH (see discussion for section 850.21).

Two commenters (Exs. 49, 50) were concerned with dermal exposures to beryllium. DOE agrees that there is a potential health hazard associated with dermal exposure to beryllium, and has imposed requirements under sections 850.29 and 850.37 to protect workers handling beryllium. The hazards associated with dermal exposures also are dealt with in the DOE facilities' health and safety programs under DOE Order 440.1A or, analogous Orders or standards cited in responsible employers' contract with DOE.

Section 850.32—Waste Disposal

Section 850.32 (proposed as section 850.31) establishes the waste disposal provisions of the CBDPP. Like many of the provisions of the rule (e.g., regulated areas, protective clothing and equipment, and housekeeping), the waste disposal provisions are designed to minimize the spread of beryllium contamination throughout the facility or beyond the sites boundaries.

DOE believes that the most effective way to control the spread of contamination resulting from waste disposal activities is to prevent or minimize the generation of beryllium waste. Accordingly, section 850.32(a) of the final rule requires responsible employers to employ waste minimization principles in conducting beryllium activities. Good housekeeping practices, required by section 850.30, aid in this effort by continually removing beryllium dust accumulations from work surfaces, thereby reducing the level of contamination of workplace equipment. The performance of hazard analyses on operations with the potential to generate wastes, as required by section 850.21, can help responsible employers 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.

Section 850.32(b) of the final rule requires responsible employers to dispose of beryllium-containing waste, and beryllium-contaminated equipment and other items that are disposed of as waste, in sealed impermeable bags, containers, or enclosures that are labeled in accordance with section 850.38. Enclosure can be any practical mechanism for sealing, such as wrapping in plastic. DOE believes these waste disposal provisions are necessary to prevent the re-suspension of beryllium contamination into the workplace atmosphere. Warning labels are necessary to ensure that workers are aware that bags, containers, or enclosures contain beryllium so that they can take appropriate precautions. Furthermore, responsible employers must comply with applicable Federal, state, and local regulations governing the management, transportation, and disposal of waste that contain beryllium.

DOE received two comments regarding the waste disposal provisions of the NOPR. One commenter (Ex. 31) applauded DOE for including waste minimization principles as a control measure for reducing beryllium exposures. This commenter suggested that DOE consider developing a non-mandatory appendix to the rule or stand-alone guidance to illustrate waste minimization principles and provide ideas for workers and employers. DOE recognizes the utility of non-mandatory guidance in assisting responsible employers in implementing certain mandatory requirements of the CBDPP. DOE notes, however, that the U.S. Environmental Protection Agency and other Federal agencies have already developed a wide variety of guidance materials addressing waste management, waste minimization, and pollution prevention principles and practices. Not only are these guides readily available to the DOE community, but many DOE sites have used these guides to develop their own hazardous waste management plans. For this reason, DOE believes that the development of an additional guidance document to address waste minimization principles for the final CBDPP rule is not necessary. DOE is developing an implementation guide for the CBDPP rule that will provide general guidance for disposal of beryllium waste.

The other commenter (Ex. 18) suggested that the waste disposal provisions should address the declassification of beryllium parts that are classified for national security purposes at certain DOE sites. This section of the final rule requires responsible employers to control the generation of beryllium-containing waste, and beryllium-contaminated equipment and other items that are disposed of as waste and to dispose of this equipment and other items in a safe manner. DOE does not intend for these provisions to alter or affect the classification of beryllium-contaminated equipment and other items, nor to supersede the applicable requirements for protection of such equipment and items. Accordingly, beryllium-contaminated materials that are classified must be handled in accordance with the governing national security regulations, standards, and policies. Responsible employers also must dispose of such materials in accordance with the provisions of this rule.

Section 850.33—Beryllium Emergencies

Section 850.33 (proposed as section 850.32) establishes the beryllium-related emergency provisions of the CBDPP. Such provisions are particularly important in light of the possibility, suggested by several commenters, that a single, high-level beryllium exposure may have been the cause of CBD occurring among several workers thought to have had no exposure or only incidental, low-level exposures to beryllium.

Proposed section 850.32 would have established broad performance-based provisions requiring responsible employers to develop procedures for responding to and alerting workers to beryllium emergencies, to ensure the availability and use of appropriate protective equipment during related cleanup operations, and to provide emergency response workers with appropriate training on proper response procedures.

Two commenters (Exs. 11, 31) responded to the proposed beryllium emergencies section, and both requested that DOE provide additional guidance regarding beryllium emergency procedures, training, and personal protective equipment requirements. One commenter (Ex. 31) suggested that this guidance was needed to ensure a consistent and coordinated response to beryllium emergencies in cases in which workers from different employers respond to the same event. Both commenters suggested that DOE consider incorporating elements of the emergency response provisions of OSHA's Hazardous Waste Operations and Emergency Response standard (29 CFR 1910.120) in the CBDPP rule.

DOE agrees with the commenters, and notes that the beryllium emergencies provisions of the NOPR were not intended to supersede the applicable provisions of 29 CFR 1910.120. Accordingly, to avoid confusion and duplicative efforts and to ensure consistent and coordinated responses to beryllium emergencies at DOE facilities, DOE has revised the beryllium emergencies section (renumbered section 850.33 in the final rule) to require responsible employers to comply with 29 CFR 1910.120(l) for

emergency response activities related to hazardous waste cleanup operations, and 29 CFR 1910.120(q) for emergency response activities related to all other operations. Also, DOE will provide general guidance on preparing for, and responding to, emergencies involving beryllium in the DOE implementation guide for this rule.

Section 850.34—Medical Surveillance

Section 850.34 (proposed as section 850.33) establishes the medical surveillance provisions of the CBDPP. These provisions are aimed at: (1) Identifying workers at higher risk of adverse health effects from exposure to beryllium; (2) preventing beryllium-induced disease by linking health outcomes to beryllium tasks; and (3) making possible the early treatment of beryllium-induced disease.

Several changes have been made to the medical surveillance provisions as proposed. These changes include enlarging the scope of the covered population to include former beryllium workers who are still employed at DOE facilities in non-beryllium work; adding the term ''beryllium-associated worker,'' which includes all current workers who have or had the potential for exposure to beryllium; adding a multiple and alternate physician review process; deleting the requirement that exposure be at or above the action level before initiating medical surveillance; and deleting the requirement for Office of Environment, Safety and Health review of the written medical surveillance program. In addition, DOE has made editorial changes to clarify various provisions.

The medical surveillance program is designed to ensure the prompt identification, and makes possible the proper treatment, of workers who become sensitized to beryllium or develop CBD. In addition to determining the incidence of CBD in the workforce, the medical surveillance program fulfills a critical information development function, including identifying the risk factors associated with the development of CBD and beryllium sensitization. This rule requires that medical surveillance be given to workers who are at the greatest risk from continued exposure. This determination should be made on the basis of the air monitoring results, the SOMD's recommendation, and any other relevant information the responsible employer may possess, such as past medical or air monitoring records, workers' job tenure, etc.

DOE realizes that some workers may elect not to participate in the medical surveillance program because they believe that a diagnosis of CBD or beryllium sensitization could have a negative impact on future employment opportunities or on their health insurance. In light of this concern and DOE's desire to maximize worker participation in the medical surveillance program, DOE in the NOPR requested interested parties to comment on the feasibility and utility of including anonymous testing as a provision in the final rule. In requesting public comment, DOE noted two concerns it had regarding the use of anonymous testing; specifically, concern about DOE's inability to correlate collected exposure data to health outcomes for workers choosing anonymous testing, and concern about the effect of anonymous testing on DOE's ability to conduct follow-up tests to confirm positive Be-LPT results.

Eight commenters (Exs. 4, 16, 17, 23, 26, 28, 30, 31) responded to DOE's request for information regarding anonymous testing. Most commenters stated that anonymous testing would not provide significant additional benefits or protection for workers. In addition, all of the commenters shared DOE's concerns regarding the resulting inability to correlate collected exposure data to health outcomes, and the difficulty of tracking employees for follow-up testing to confirm positive results. The commenters believed that these two drawbacks overshadow any potential increase in worker participation.

One commenter (Ex. 17) expressed concern that the use of anonymous testing would limit the employer's ability to provide support to workers receiving medical surveillance. This commenter noted that ongoing support and reassurance is essential for those workers with positive or inconclusive test results. Three commenters (Exs. 16, 23, 26) stated that medical surveillance should be used to determine workplace exposures and evaluate the effectiveness of workplace controls. These commenters believe that anonymous testing would hamper this effort by preventing responsible employers from identifying specific jobs or tasks that lead to beryllium-related health effects.

For reasons stated in the NOPR and expressed by all eight commenters, DOE has decided against the use of anonymous testing. However, DOE has taken steps in the final rule to protect the privacy of beryllium-associated workers, e.g., by requiring the use of unique identifiers (see discussion of section 850.39). DOE cannot responsibly accomplish the tasks of ameliorating the effects of exposure to beryllium and developing needed data on the cause and development of CDB through anonymous testing. DOE also believes that offering anonymous testing as a supplement to identified testing would discourage workers from participating in identified testing. Accordingly, provisions for anonymous testing are not included in the final beryllium rule.

Section 850.34(a)(1) requires responsible employers to establish and implement a medical surveillance program for beryllium-associated workers. DOE adheres to its view that participation in the medical surveillance program should not be mandatory for workers. The responsible employer's obligation is to offer to provide the medical tests and procedures as required. DOE expects that where worker confidence in the medical program exists, refusal to participate will be minimal.

The term ''beryllium-associated worker'' is used in the final rule where DOE has determined that coverage of provisions should not be limited to current workers regularly employed in DOE beryllium activities. Use of the term ''beryllium-associated worker'' will increase the population eligible to receive medical surveillance by including current workers with past beryllium exposures or potential for exposures.

Numerous commenters (Exs. 2, 3, 4, 14, 16, 17, 28, 30, 29, 31) made recommendations regarding the level of employee exposure that should trigger worker participation in the medical surveillance program. Two of these commenters (Exs. 3, 4) objected to offering medical surveillance to all workers potentially exposed to beryllium. However, their reasons for not wanting to include all potentially exposed workers differed. One commenter (Ex. 3) stated that placing all potentially exposed employees in the medical surveillance program would be inconsistent with the permissible exposure limit. The other commenter (Ex. 4) was concerned with the costs associated with such a strategy, and the potential for causing worker anxiety from false-positive Be-LPT test results for workers with limited exposure potential. While these commenters agreed that some level of worker beryllium exposure should trigger the medical surveillance program, neither provided recommendations for an appropriate trigger level.

One commenter (Ex. 16) suggested that DOE use a graded approach to the medical surveillance program which would include current beryllium workers and other workers with exposures or potential exposures at or above the action level. DOE has

determined that a graded approach linked to exposure at or above the action level would not ensure the necessary surveillance of all DOE and contractor workers who may have had exposure to beryllium, whether current or past.

Several commenters (Exs. 2, 14, 16, 17, 28, 29, 30, 31) favored the inclusion of all potentially exposed workers in the medical surveillance program regardless of the measured exposure level. These commenters argued that medical surveillance should not be limited to workers exposed to levels of beryllium at or above the action level, but rather should include all workers with the potential for any beryllium exposure. Three of these commenters stated that current scientific evidence does not indicate a ''safe'' level of beryllium exposure, and that CBD has been identified in individuals thought to have only low or incidental exposure to beryllium. Their concern was that restricting medical surveillance to ''beryllium workers,'' as defined in proposed section 850.3, would exclude such workers, who in their view are also at risk of contracting CBD. In addition, two of the commenters (Exs. 28, 30) noted that allowing workers exposed at any level to participate in the medical surveillance program would act as an incentive for employers to minimize the number of individuals who work in beryllium areas.

Similarly, three commenters (Exs. 28, 29, 31) argued that current workers with past beryllium exposures should be offered the opportunity to participate in the medical surveillance program. One commenter (Ex. 31) noted that, based on the proposed definition of ''beryllium worker,'' medical surveillance would not be made available to current workers with past beryllium exposure unless they were covered under the medical removal provisions of proposed section 850.34. Another commenter (Ex.15) suggested that all employees at DOE facilities, even those with no exposure to beryllium, should be given the option of participating in the medical surveillance program.

Several commenters (Exs. 2, 16, 28, 31, 19) raised the issue of medical surveillance for former workers with past beryllium exposures who no longer work at a DOE facility. The commenters stated that former DOE workers should also be provided the opportunity to participate in medical monitoring. They acknowledged DOE's proposed establishment of a separate, directly funded program that offers medical examinations to former workers at risk of developing CBD. However, two of the commenters (Exs. 16, 31) argued that this program should be made available to former workers at the same time as the program for current workers. Another commenter argued that maintaining two separate databases and programs was not practical.

DOE has revised the final rule to require responsible employers to provide medical surveillance for all beryllium-associated workers. DOE based this revision on the beryllium cases suggesting that low and even incidental exposure to beryllium can lead to sensitization or beryllium disease. This approach will ensure the early identification of workers at risk of health effects from exposure to beryllium, provide the greatest protection of worker health, and provide a more complete documentation of beryllium exposures. Beryllium-associated workers eligible for medical surveillance include any current worker who is exposed or was exposed or potentially exposed to airborne concentrations of beryllium at a DOE facility. Thus medical surveillance will be available to a beryllium worker (as defined in section 850.3), a current worker whose work history shows that the worker may have been exposed to airborne concentrations of beryllium at DOE facilities, a current worker who exhibits signs and symptoms of beryllium exposure, and a worker who is receiving medical removal protection benefits.

Section 850.34(a)(2) requires responsible employers to designate a Site Occupational Medical Director (SOMD) who will be responsible for administering the medical surveillance program. One commenter (Ex. 18) stated that a panel comprised of individuals representing management, labor, the public, and the local medical community should select the SOMD. DOE has not adopted this recommendation because DOE believes that the responsible employer must have ultimate responsibility for ensuring compliance with this requirement.

A number of commenters (Exs. 12, 14, 20, 23) were concerned about the quality of health care for workers with CBD and, more specifically, whether or not workers would have a choice of physicians. One commenter (Ex. 20) pointed out that OSHA no longer restricts the performance of medical evaluations to licensed physicians because this requirement is too prescriptive and fails to recognize the realities of today's health care system. This commenter suggested adding a provision to include other licensed health care professionals among those who may perform medical evaluations.

DOE agrees with this commenter and has revised section 850.34(a)(3) of the final rule to require responsible employers to ensure that all medical evaluations and procedures are performed by or under the supervision of a licensed physician who is familiar with the health effects of beryllium. Although a licensed physician is the appropriate person to supervise and evaluate a medical evaluation, certain required elements of the evaluation may be performed by another, appropriately qualified person under the supervision of the physician. The licensed physician is required to be familiar with the health effects of beryllium. DOE expects that the medical evaluations and procedures required to diagnose CBD will be performed or validated by a specialist in pulmonary medicine, occupational medicine, or other physician with specialized equipment and examination protocols required to definitively differentiate between CBD and other lung diseases. DOE believes that this is necessary due to the unusual nature of CBD and the fact that not all physicians are familiar with the evaluation of beryllium-associated patients.

Three commenters (Exs. 15, 18, 22) expressed concern about certain language in the NOPR preamble that they interpreted to mean that workers would be limited to an evaluation performed by an employer's physician. One commenter (Ex. 22) suggested that DOE adopt OSHA's Lead Standard as a model for selecting physicians. DOE never intended to limit an employee's choice of physicians. To clarify this point, DOE has included in section 850.34, paragraphs (c) and (d), provisions for a multiple physician and alternate physician review. These provisions are explained in the discussion that follows.

DOE views medical surveillance as a primary tool for determining the extent of CBD risk within the worker population. Therefore, section 850.34(a)(4) requires responsible employers to maintain and give to the SOMD a list of beryllium-associated workers who may be eligible for medical surveillance. The list must be based on hazard assessments, exposure records, and any other information that will identify beryllium-associated workers (section 850.34(a)(4)(i)). In addition, section 850.34(a)(4)(ii) requires responsible employers to regularly update the list based on the information from the periodic evaluations performed pursuant to paragraph (b)(2) of this section.

One commenter (Ex. 16) questioned why DOE proposed to give the SOMD the task of identifying working conditions that contribute to the risk of CBD and determining the need for

additional exposure controls. This commenter believed that this task should be performed by an industrial hygienist. Similarly, another commenter (Ex. 23) stated that the SOMD should not be responsible for performing data analysis to determine which workers should be included in the medical surveillance program, or for maintaining the list of beryllium workers at a site. The commenter argued that both of these tasks are management functions that should be carried out by the responsible employer based on technical guidance provided by the industrial hygiene department and the SOMD. DOE agrees with both of these commenters. The responsible employer, not the SOMD, should have the function of identifying working conditions and evaluating the need for workplace controls. Consequently, DOE has revised the final rule to require that responsible employers identify beryllium-associated workers. However, medical judgments that are requisite to management decisions are the SOMD's responsibility.

Section 850.34(a)(5) requires the responsible employer to provide the SOMD with the information needed to operate and administer the medical surveillance program. This information includes, but is not limited to, the baseline beryllium inventory, hazard assessment results, 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.

Section 850.34(a)(6) requires the responsible employer to provide the SOMD and the examining physician with (1) A copy of this rule and its preamble; (2) a description of the workers' duties as they pertain to beryllium exposure; (3) records of the workers' beryllium exposure; and (4) a description of personal protective and respiratory protective equipment in current or anticipated use. DOE 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-associated worker.

Several commenters (Ex. 8, 17, 18, 19) suggested including provisions for providing beryllium education and training programs to physicians and other health care providers in the rule. DOE has not adopted this suggestion, because it would expand the scope of the rule.

Section 850.34(b) requires responsible employers to provide, without cost to beryllium-associated workers, all medical evaluations and procedures performed to comply with these regulations. This section also requires that all evaluations and procedures be performed at a time and place that are convenient for the worker. This provision is consistent with similar provisions in OSHA's expanded health standards. This section also requires responsible employers to provide the SOMD with a list of beryllium-associated workers who may be eligible for protective measures under the rule.

Section 850.34(b)(1) requires responsible employers to provide a baseline medical evaluation to beryllium-associated workers. The purpose of the baseline medical evaluation is to: (1) Establish the current health status of the worker and determine whether it is appropriate to assign the worker to jobs with beryllium exposure; (2) initially determine what level of medical surveillance the responsible employer must provide to the worker; and (3) establish essential baseline data for the worker which is used to assess subsequent health changes attributable to beryllium exposure.

DOE received a number of comments regarding baseline medical evaluations and medical testing. One commenter (Ex. 25) requested clarification as to the differences between pre-placement exams, as specified in DOE Notice 440.1, ''Interim Chronic Beryllium Disease Prevention Program,'' and the baseline exams specified in the NOPR. The final rule will supersede DOE Notice 440.1, and the interim medical surveillance program requirements will be replaced with those of the final rule. The final rule does not refer to pre-placement exams. Another commenter (Ex. 23) recommended that the meaning of spirometry be clarified to ensure consistency. DOE agrees and has specified the measurement of forced vital capacity (FVC) and forced expiratory volume at 1 second (FEV_1) in section 850.34(b)(1)(v) of the final rule.

A commenter (Ex. 19) questioned the value of baseline pulmonary function tests and x-rays. This commenter suggested that baseline studies cannot be used to determine which health changes are related to work hazards and which are related to other activities or disease processes. This commenter favored the approach of following patients clinically and using Be-LPT and other studies, to augment clinical impressions. Early identification of CBD, this commenter states, might have no positive effect on the course of the disease.

DOE disagrees with this comment. Early identification and intervention are important for identifying workers at higher risk of exposure to beryllium, and for preventing and minimizing the effects of beryllium-induced disease. DOE's position is supported by a commenter (Ex. 29) who stated that while spirometry and X-rays may not be predictive, X-rays have in some instances identified CBD cases in individuals who had a normal Be-LPT. This commenter stated that these cases are likely to be missed if spirometry and X-rays are not required, and also recommended X-ray screening for Be-LPT negative individuals with persistent chest problems. Another commenter (Ex. 19) emphasized the benefits of good data collection to determine if early removal of beryllium sensitized workers prevents the progression to CBD.

One commenter (Ex. 33) suggested that, if available, recent chest X-rays be utilized for the baseline medical evaluation to reduce X-ray exposure. DOE agrees that if previous chest X-rays have been conducted, for a baseline beryllium evaluation, additional X-rays should not be used unless specified by a physician. However, to ensure that the chest X-ray correlates with other diagnostic and historical information, only those X-rays taken for the purpose of a baseline beryllium evaluation or equivalent evaluation should be used to establish a baseline.

Section 850.34(b)(1)(vi) requires responsible employers to provide a Be-LPT as part of the baseline evaluation. The Be-LPT is the only available laboratory test for determining individual immune response to beryllium in vitro. Its use in a surveillance program will permit detection of beryllium-related health effects at a pre-clinical 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 provides an early opportunity for diagnosis and treatment of CBD.

Finally, section 850.34(b)(1)(vii) authorizes the examining physician to make available to the worker any additional tests deemed medically necessary. DOE believes that it is important that the examining physician have such discretion because individuals may exhibit different responses to beryllium. In this regard, one commenter (Ex. 16) expressed concern regarding proposed section 850.33(i), which provided that workers

would be referred for further diagnostic evaluation if there were two or more positive Be-LPTs. The commenter interpreted this provision as a mandatory requirement. DOE's intent is that workers have the opportunity for additional testing if recommended by the examining physician. A worker is not required by the rule to undergo additional medical evaluation and treatment.

One commenter (Ex. 29) recommended clinical referral for additional diagnostic tests after one positive Be-LPT, instead of two or more as proposed by DOE. DOE believes that the examining physician is in the best position to determine which additional tests, if any, would be useful in evaluating the health of an individual worker. Therefore, DOE has removed the requirement for follow-up testing based on two or more positive Be-LPT tests, relying instead on the examining physician's discretion under section 850.34(b)(1)(vii) to order follow-up tests when appropriate.

Section 850.34(b)(2) requires responsible employers to provide medical evaluations to beryllium workers annually, and to other beryllium-associated workers every 3 years. Responsible employers must provide the periodic medical evaluation elements described in section 850.34(b)(2)(i) to detect, at an early stage, any pathological changes that could lead to CBD or be aggravated by beryllium exposure. By detecting abnormalities early, workers may be medically removed to prevent further beryllium exposure.

Section 850.34(b)(2)(ii) requires responsible employers to provide to beryllium-associated workers a chest radiograph (X-ray) every 5 years. DOE includes this requirement for periodic X-rays because X-rays have been shown to be effective in the early detection of beryllium-related health effects (Ex. 29).

Following an emergency in which a worker, who is not already participating in the beryllium medical surveillance program, is exposed to an elevated amount of beryllium, the responsible employer is required by section 850.34(b)(3) to provide a medical evaluation as soon as possible.

A commenter (Ex. 23) suggested that a standard respiratory symptom questionnaire, medical work history form, and physical examination form be used at all DOE sites for consistency. DOE agrees that such standardized forms may help ensure consistency across the DOE complex, but is concerned that mandating the use of standardized forms may limit the discretion of the SOMD in determining the appropriate medical surveillance for each individual. Accordingly, DOE has decided to include appropriate standardized forms as non-mandatory guidance in an implementation guide to accompany the final rule. Another commenter (Ex. 29) was concerned that the NOPR required a respiratory symptom questionnaire for periodic medical evaluations, but not for the baseline evaluation. DOE acknowledges this oversight and has included the respiratory symptom questionnaire as part of both the periodic and baseline medical evaluations in sections 850.34(b)(1)(ii) and (b)(2)(I)(B) of the final rule.

Section 850.34(c) requires responsible employers to establish a multiple physician review process for affected beryllium-associated workers. DOE has identified three benefits of providing a multiple physician review process: (1) to strengthen and broaden the bases for medical decisions made pursuant to this rule when a beryllium-associated worker questions the findings, recommendations, or determinations of an initial physician retained by the responsible employer; (2) to increase beryllium-associated workers' confidence in the soundness of medical findings, recommendations and determinations made under this rule; and (3) to increase beryllium-associated worker's acceptance of, and participation, in the medical surveillance program.

Given the shortage of trained and experienced occupational physicians, it is possible that some physicians performing examinations or consultations under the beryllium rule will misdiagnose CBD. However, rather than requiring multiple medical opinions in all cases, which would be expensive and potentially wasteful, DOE is providing to beryllium-associated workers an opportunity to obtain an independent review of the findings, determinations or recommendations of the physician selected by the responsible employer. Over time, this independent review is likely to show either that a perceived low level of confidence in the physician retained by the responsible employer is unwarranted, or that the responsible employer should improve the quality of the medical surveillance being provided. In either case, the multiple physician review process will have served a beneficial purpose.

In section 850.34(c)(1), a beryllium-associated worker may designate a second physician to review any findings, determinations, or recommendations of the physician chosen by the responsible employer, and to conduct such examinations, consultations, and laboratory tests as the second physician may deem necessary to facilitate this review. The responsible employer's obligation to provide information to the examining physician extends to other physicians involved in the multiple physician review or alternate physician review process so that all of the physicians involved will have an equal opportunity to assess the beryllium-associated worker's health status.

Section 850.34(c)(2) requires that after an initial physician conducts an examination or consultation, the responsible employer must promptly notify the worker of his or her right to seek a second medical opinion. This notification must be in writing.

Section 850.34(c)(3) requires that after the worker is notified of this right, the responsible employer may condition its participation in, and payment for, multiple physician review upon the worker, within 15 days after receipt of the notification or the initial physician's written opinion, whichever is later, both (1) informing the responsible employer that the worker intends to seek a second medical opinion, and (2) initiating steps to make an appointment with a second physician.

The rule contains no limitation on a beryllium-associated worker's choice of a second physician, except the requirement in section 850.34(a)(3) that the second physician must be a licensed physician who is familiar with the health effects of beryllium.

If the second physician's findings, determinations, and recommendations are the same as those of the initial physician, then the multiple physician review process comes to an end. However, as provided in section 850.34(c)(4), if the opinions of the two physicians are in conflict, then the responsible employer and the beryllium-associated worker must undertake to encourage the two physicians to resolve any disagreement. DOE expects that the two physicians will communicate with each other to resolve their differences, but the rule requires the responsible employer and worker to encourage such a resolution. In most cases, this professional interaction should resolve any differences of opinion.

In cases where differences remain, these differences of opinion are likely to be genuine and substantial. If the first two physicians are unable to resolve expeditiously any differences of opinion with respect to a beryllium-associated worker, then it is necessary for a third qualified physician to resolve the dispute. It is critical that this third

physician has the confidence of those concerned and is competent to resolve the dispute. Consequently, section 850.34(c)(5) requires that the responsible employer and the beryllium-associated worker together, through their respective physicians, must designate the third physician.

Under section 850.34(c)(5) the third physician will have a full opportunity to review the findings, determinations, and recommendations of the two prior physicians, and to conduct such examinations, consultations and laboratory tests as the third physician deems necessary. DOE's expects that the third physician will consult with the other two physicians. The third physician should provide a written medical opinion to the SOMD which will be used to resolve the disagreement between the other two physicians. Section 850.34(c)(6) requires the SOMD to act in a manner consistent with the findings, determinations, and recommendations of the third physician, unless the SOMD and the beryllium-associated worker reach an agreement that is otherwise consistent with the recommendations of at least one of the other two physicians.

Since the multiple physician review process will be a means by which medical surveillance is provided to a beryllium-associated worker, responsible employers must bear the expense of this process when it is used. Based on OSHA's practice and experience with multiple physician review in its health standards, DOE does not expect the costs of this process to be burdensome to the responsible employers. If responsible employers establish and administer medical surveillance programs that engender worker confidence, workers should have little or no need to seek second medical opinions.

The requirement for multiple physician review is not intended to preclude responsible employers from establishing and implementing alternate medical protocols. DOE has included language in section 850.34(d) to provide for alternate physician determination. Under that section, the responsible employer and beryllium-associated worker, or the worker's designated representative, may agree upon the use of any expeditious alternate physician determination process, instead of the multiple physician review process. The only condition is that the alternate process be no less protective of the worker's health than the multiple review process. For example, a jointly agreed upon physician might be used in the first instance without recourse to other physicians. DOE encourages responsible employers and workers to adopt medical determination procedures in which all parties have trust and confidence.

Section 850.34(e)(1) requires the SOMD to provide to responsible employers, within two weeks after receipt of results, a written and signed medical opinion after each medical evaluation of a beryllium-associated worker. The purpose of requiring the SOMD to give the responsible employer a written opinion is to inform the responsible employer of the medical basis for determining the job placement of the examined worker. This written medical opinion, as described in section 850.34(e)(i–iii), must contain any diagnosis of the worker's condition related to occupational exposure to beryllium; any other detected medical conditions relevant to further beryllium exposure; any recommended restrictions on the worker's exposure to beryllium or on the use of protective clothing or equipment; and a statement indicating that the SOMD or the examining physician has provided to the worker the results of the test, the medical evaluation, including all tests results and any medical condition related to beryllium exposure that requires further evaluation or treatment.

Section 850.34(e)(2) requires the SOMD to withhold from the responsible employer, orally or in the written medical opinion, specific findings or diagnoses not related to occupational exposure to beryllium.

Two commenters (Ex. 23, 28) expressed concern regarding proposed section 850.33(j)(2), which stipulated that the physician's written medical reports be delivered within 15 calendar days after the completion of a medical evaluation. The commenters noted that Be-LPT tests are time-consuming and may exceed the 15-day time frame, and suggested that the 15-day period should begin after receipt of the test results. DOE agrees, and has revised section 850.34(f) to require the SOMD to give beryllium-associated workers a written medical opinion containing the results of all medical tests or procedures, an explanation of any abnormal findings, and any recommendation that the worker be referred for additional testing within 10 working days after the SOMD's receipt of test results.

In section 850.34(f)(2), upon request by the beryllium-associated worker, the responsible employer is required to provide the worker with a copy of the information the responsible employer is required to provide to the examining physician.

Section 850.34(g) requires the responsible employer to report on the applicable OSHA reporting form (currently OSHA Form No. 200) beryllium sensitization, CBD, or any other abnormal condition or disorder of workers caused or aggravated by occupational exposure to beryllium. Although not included in the proposed rule, this provision reflects current practices and does not impose a new burden on employers. Reporting abnormal conditions and disorders that are occupationally caused and beryllium-related will contribute to the development of occupational health statistics that eventually may lead to improved disease prevention and medical intervention for beryllium-associated workers. It will also provide DOE with information and data helpful in assessing the effectiveness of the CBDPP rule and in considering what, if any, modification should be made to the rule in the future.

Section 850.34(h)(1) requires responsible employers to establish a routine and systematic analysis of medical, job, and exposure data. The purpose of this requirement is to collect and analyze information so that the prevalence of disease can be accurately described and conclusions reached on causes or risk factors for the disease. This data analysis is an effective means of measuring performance under the CBDPP, and for correcting and improving the CBDPP. Section 850.34(h)(2) requires the responsible employer to use the results of these analyses to determine which workers should be offered medical surveillance and the need for additional exposure controls.

Section 850.35—Medical Removal

Section 850.35 (proposed as section 850.34) requires responsible employers to establish medical removal protection (MRP) and medical removal protection benefits (MRPB) as part of the CBDPP.

Medical surveillance can only be effective in detecting and preventing disease if beryllium-associated workers: (1) voluntarily seek medical attention when they feel ill; (2) refrain from efforts to conceal their true health status; and (3) fully cooperate with examining physicians to facilitate accurate medical diagnoses and effective treatment. This sort of worker participation and cooperation cannot be evoked by coercion; it will occur only where no major disincentives to meaningful worker participation exist. Without such participation, it would be much more difficult, if not impossible, to adequately monitor workers' health and to identify workers who need temporary or permanent medical removal.

MRP is a logical result of medical surveillance. Without MRP, responsible employers would be free to maintain high-risk workers in their current jobs, which would not be sufficiently protective of their health. Alternatively, responsible employers could choose to terminate workers or transfer them from higher-paying, beryllium-exposed jobs to lower-paying, non-beryllium jobs. This might be protective, but it would impair the workers' standards of living. In either case, the effectiveness and integrity of the medical surveillance program would be compromised.

With MRP, beryllium-associated workers are assured of being removed to jobs where exposure to beryllium is low if such removal is determined to be necessary to protect their health. With MRPB, workers are assured that, if they fully participate in medical surveillance and if the results of medical surveillance require removal from their beryllium exposed jobs, their normal earnings and job status will be protected for a pre-determined period.

Thirty-two commenters (Ex. 12 is a form letter submitted by 16 beryllium workers) commented on the proposed MRP and MRPB provisions in the NOPR. They addressed a wide variety of issues and frequently expressed opposing viewpoints. For instance, two commenters (Exs. 16, 26) stated that the proposed MRP provisions went too far (e.g., two years of protection is too long; accepted applicants should not be included under the provisions), while others (Exs. 3, 8, 12, 14, 17, 18, 22, 24, 28, 29, 31) stated that the provisions did not go far enough (e.g., two years of protection is not long enough; one follow-up examination is not enough; the training costs limits are too restrictive; the rule should provide provisions for multiple physician reviews). Several commenters (Exs. 20, 22, 31) argued against the voluntary nature of the proposed provisions, stating that it would be unethical to allow a worker with CBD to continue to be exposed to beryllium, and suggesting that workers could be wrongfully pressured into staying in beryllium-related jobs. Other commenters (Exs. 29, 30) agreed with DOE's proposal to require employee consent, and requested that DOE provide additional guidance to help workers make more informed decisions regarding their medical removal. DOE has decided, consistent with some of the comments, to use the provisions of OSHA's expanded health standards as the basis for the MRP and MRPB provisions of the final rule. DOE has modeled the MRP and MRPB provisions of this final rule upon similar provisions in OSHA's Cadmium, Lead and Benzene standards, 29 CFR 1910.27, 1910.1025 and 1910.1028, respectively. DOE's rationale for each provision of section 850.35 in the final rule is discussed below.

Section 850.35(a) requires responsible employers to offer a beryllium-associated worker medical removal from exposure to beryllium on each occasion that the SOMD determines in a written medical opinion that medical removal is required. The SOMD's determination must be based upon one or more positive Be-LPT results, CBD diagnosis, an examining physician's recommendation, or any other signs or symptoms the SOMD deems medically sufficient to show that the worker has a medical condition that places the worker at increased risk of material impairment to health from further exposure to beryllium.

Section 850.35(a)(1) deals with temporary removal. It requires the responsible employer to offer temporary medical removal to a beryllium-associated worker whenever the SOMD determines in a written medical opinion that the worker should be removed pending a final medical determination on the worker's health. The responsible employer must offer to temporarily remove a worker regardless of whether a job is available into which the removed worker may be transferred. If no such job is available, the responsible employer must pay medical removal protection benefits to the worker for up to one year. Section 850.35(a)(1) (iii) and (iv) require that for each time a beryllium-associated worker is temporarily removed, the responsible employer must maintain the worker's total normal earnings, seniority and other employment rights as if the worker were not removed, either by providing an appropriate alternative job or by paying MRPB, for one year.

If a final medical determination is made that the worker does not have a medical condition which places the worker at increased risk of material impairment to health from exposure to beryllium, the temporary MRP must be lifted so that the affected worker may return to his or her normal duties.

Section 850.35(a)(2) requires the responsible employer to offer beryllium-associated workers permanent medical removal whenever the SOMD determines in a written medical opinion that the beryllium-associated worker should be permanently removed from exposure to beryllium. Once a worker is permanently removed, the worker will receive the medical removal protection benefits specified in section 850.35(b) of this rule.

Section 850.35(a)(3) is intended to ensure that beryllium-associated workers are given the information needed to make an informed decision on whether to accept temporary or permanent removal from a job with a potential for beryllium exposure.

Section 850.35(a)(4)(i) prohibits the responsible employer from returning a beryllium-associated worker who has been permanently removed to the worker's former job status, unless the SOMD has determined in a written medical opinion that removal is no longer necessary to protect the worker's health, or the exception in section 850.35(a)(4)(ii) applies. Under section 850.35(a)(4)(ii), if there are special circumstances that make medical removal an inappropriate remedy, or if the SOMD's professional opinion is that continued exposure will not pose an increased risk to the worker's health (e.g., the potential decrements to the worker's lung function are not projected to be any greater if the worker were permitted to continue on the job than they would be if the worker were removed), the SOMD must fully discuss the matter with the worker and, in a written medical determination, may recommend returning the worker to his or her former job status. The purpose of this exception is to provide some flexibility where it is reasonably clear that returning the worker to his or her normal job is unlikely to adversely affect the worker's health. For example, a return to work may be justified if a worker who is not experiencing a decrease in lung function, has been on medical removal for 2 years and is about to retire, and the time that the worker will continue to be occupationally exposed at or above the action level is very limited. If the SOMD recommends return of the worker in such cases, the SOMD may require the responsible employer to provide the worker with additional protection, such as a supplied air respirator operated in a positive pressure mode. In any event, a decision to return the worker should be made only after the SOMD has fully explained the relevant facts and prognoses to the worker.

Section 850.35(b) establishes the MRPB that must be provided to removed workers. DOE believes that the establishment of MRPB is critical to minimize the disability associated with CBD. Removal from exposure and effective job-placement efforts, coupled with early diagnosis and treatment, will increase the likelihood that affected beryllium-associated workers will continue as productive members of the DOE workforce. In addition, MRPB will encourage worker participation in the

medical surveillance program by providing beryllium-associated workers with a reasonable level of assurance that a finding of sensitization or diagnosis of CBD will not lead to the loss of their employment.

Under section 850.35(b)(1), the responsible employer is required to provide up to two years of MRPB to a beryllium-associated worker on each occasion that he or she is medically removed from exposure to beryllium in accordance with this part.

Section 850.35(b)(2) requires the responsible employer to provide the ''total normal earnings, seniority, and all other workers rights and benefits'' of a removed beryllium-associated worker as if the worker had not been removed. The purpose of this requirement is to ensure that a removed worker does not suffer economic loss due to the removal. Thus, if a removed worker routinely earned overtime pay on the job from which he or she was removed and would have continued to do so during the removal period, then MRPB must include the amount of expected overtime as part of the worker's ''total normal earnings.'' DOE selected 2 years as the maximum period during which the responsible employer is required to pay MRBP to a worker who accepts removal instead of the 18 month protection period established in OSHA's Lead and Cadmium standards. DOE has established a different protection period for beryllium because of the toxicological differences between beryllium and the two metals covered in the OSHA standards. Specifically, the early stages of the health impairments associated with exposure to lead or cadmium will reverse in time with no additional exposure, but beryllium sensitization and CBD will not. The objective of OSHA's 18 month period is to provide workers with sufficient recovery time so that they can return to their job. The objective of DOE's 24 month period, however, is to allow beryllium-associated workers who accept permanent medical removal sufficient time to be retrained and placed in different job. DOE believes that this period should be long enough to enable the majority of removed beryllium-associated workers to be retrained and placed in another job or, for those workers who can be returned to their former job status, to be returned before their MRPB expire.

Under section 850.35(b)(3), if a removed worker files a claim for workers' compensation payments for a beryllium-related disability, the responsible employer must provide MRPB pending disposition of the claim. The responsible employer receives no credit for the workers' compensation payments received by the worker for treatment related expenses.

In section 850.35(b)(4), the responsible employer's obligation to provide MRPB is reduced by the amount of any compensation the beryllium-associated worker receives from any other source for earnings lost during the period of removal. This provision is necessary to ensure that MRPB does not result in a ''windfall'' to the worker who collects other compensation, including salary from another job, while the worker is on medical removal from exposure to beryllium.

Section 850.35(b)(5) provides that the requirement that a responsible employer provide MRPB is not intended to expand upon or restrict any rights a worker has or would have had, absent medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

Section 850.35(b)(6) provides that a responsible employer may condition the provision of MRPB upon the beryllium-associated worker's participation in medical surveillance. Thus, although the rule does not require worker participation in medical surveillance, it permits the responsible employer to deny economic protection to workers who are unwilling to participate in medical surveillance. Since the responsible employer must bear the financial burden of medical removal, the employer has a legitimate interest in minimizing the need for medical removal. Unless workers participate in medical surveillance, the responsible employer may not be able to identify workers whose exposure to beryllium should be reduced to avoid the need for medical removal.

In providing the responsible employer the authority to condition provision of MPRB upon a beryllium-associated worker's participation in medical surveillance, DOE does not intend to permit an employer to deny MRPB for insignificant lapses in such participation. The worker's actions should be assessed reasonably, in light of the goal of prevention of disease and the employer's interest in minimizing the need for medical removal.

Section 850.36—Medical Consent

Section 850.36 (proposed as section 850.35) establishes the medical consent provisions of the CBDPP. Because worker participation in the medical surveillance program established by this rule is voluntary, this section is necessary to ensure that beryllium-associated workers receive adequate information to make an informed decision regarding their participation in the program.

Section 850.36(a) requires responsible employers to provide beryllium-associated workers with a summary of the medical surveillance program, the type and purpose of data to be collected, how the data will be maintained, and protections for ensuring the confidentiality of medical records. Responsible employers must provide this information at least one week before any medical evaluation or tests, or when requested by the worker.

Section 850.36(b) requires responsible employers to provide beryllium-associated 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 examination or test. DOE expects responsible employers to make reasonable efforts to help workers understand the material. Accordingly, section 850.36(b) requires responsible employers to give beryllium-associated workers an opportunity to ask questions and receive answers before a medical evaluation is performed.

Section 850.36(c) requires responsible employers to have the SOMD obtain the beryllium-associated worker's signature on the informed consent form found in Appendix A to this part, before medical evaluations or tests are performed.

Section 850.37—Training and Counseling

Section 850.37 (proposed as section 850.36) establishes requirements for training and counseling workers regarding exposure to beryllium, and the potential health effects associated with such exposure. This worker training is necessary because the appropriate implementation of the required workplace procedures of the CBDPP ultimately rests upon the front-line workers who will be performing work on, with, or near beryllium or beryllium-contaminated materials. These workers cannot be expected to implement the required CBDPP procedures if they are not aware or fully appreciative of the significance of these procedures.

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

Section 850.37(a)(1) requires responsible employers to develop and implement a worker training program for beryllium-associated workers and all other individuals who work at a site where beryllium activities are conducted, and ensure their participation in the program. DOE recognizes that OSHA's Hazard Communication standard (29 CFR 1910.1200) already requires that employers provide their workers with training regarding the risks associated with all hazardous materials in the workplace. DOE does not intend that employers would implement separate and redundant training and information programs to comply with both this rule and the Hazard Communication standard. Accordingly, sections 850.37(b)(1) and (2) require responsible employers' CBDPP training and information programs to comply with the Hazard Communication standard as well as address the contents of the CBDPP. Through this provision, DOE intends for responsible employers to integrate their CBDPP training and information efforts into their existing Hazard Communication training program. This will minimize the burden on responsible employers and provide for a consistent approach to worker training and the communication of workplace hazards.

DOE added ''contents of the CBDPP'' to the training requirements in section 850.37(b) because this information is essential for a worker to understand how to effectively participate in the CBDPP. OSHA's Hazard Communication standard (29 CFR 1910.1200) does not explicitly refer to anything like a CBDPP. In the final rule, DOE has removed specific mention of several subjects (beryllium health risk, exposure reduction, and safe handling of beryllium and medical surveillance) that were specifically identified in the proposed rule. These subjects are adequately covered in the Hazard Communication standard.

One commenter (Ex. 3) recommended detailed training for workers who have had, or are likely to have, exposures to beryllium because their assigned tasks may have involved beryllium. DOE generally agrees with the commenter and in the final rule has used a performance-based approach to identifying the workers to be trained. Section 850.37(b), paragraphs (1) and (2), require detailed training for beryllium-associated workers.

In the NOPR (Section V, Request for Information), DOE stated that it was considering including a requirement that responsible employers develop and implement an outreach education program for family members of beryllium workers. Commenters generally agreed on the need to inform workers' families about beryllium hazards, but had different views about how it should be accomplished. Two commenters (Exs. 16, 26) recommended that an outreach requirement not be included in the rule and, instead, that workers be relied upon to relay beryllium information to their families. Several other commenters (Exs. 17, 28, 30, 31) recommended that DOE include an outreach requirement in the rule, and require employers to provide beryllium information without relying on the workers. After considering all of the comments, DOE has added section 850.37(b)(3), which requires the responsible employer to provide to its workers information about risks to family members. This section relies upon the workers to relay the relevant beryllium hazard information to their families. DOE encourages responsible employers to provide beryllium-associated workers with information about beryllium risks that is readily understandable to family members and others, as well as to the workers.

One commenter (Ex. 4) recommended that the requirement for outreach not be included as part of the rule, but that DOE provide outreach information from a central point in DOE. The commenter felt that this approach would be more efficient than having each responsible employer develop and provide its own outreach information. DOE disagrees with this comment, and is of the view that more effective outreach will be provided if responsible employers include information about beryllium risks to families and others as part of the detailed training provided to beryllium-associated workers and those who use protective clothing and equipment.

One commenter (Ex. 3) recommended general awareness training for workers who are not beryllium-associated workers but who, at some time, may be at risk because they work at a site where beryllium activities are conducted. DOE agrees with this recommendation, and section 850.37(c) requires the responsible employer to provide general awareness training about beryllium hazards and controls to these workers.

Section 850.37(d) requires that the responsible employer provide training to workers prior to initial assignment and at least every two years thereafter to ensure that workers are appropriately prepared to deal with the hazards and risks of working with beryllium. The initial training requirement of this paragraph is important to ensure that workers have the information they need to protect themselves before they are actually subject to exposure or potential exposure hazards. Periodic training is necessary to reinforce and update initial training, especially with regard to the protective actions workers must take at their current jobs to reduce their potential for exposure to beryllium. DOE has established the frequency of two years as a minimum requirement, rather than the proposed one year.

Section 850.37(e) requires the responsible employer to provide additional training when the employer has reason to believe that a beryllium worker lacks the proficiency, knowledge, or understanding needed to work safely with beryllium. This situation could occur because of changes in workplace operations, controls, or procedures or the availability of new or updated information regarding the health risk associated with exposures to beryllium. Also, a worker's performance may show that the worker has not retained the requisite proficiency. DOE used the retraining requirements of the OSHA scaffold standard (29 CFR 1926.454(c)) as a model for section 850.37(e).

Section 850.37(f) requires the responsible employer to develop and implement a worker counseling program to assist beryllium-sensitized workers and workers diagnosed with CBD. The purpose of the counseling program is to communicate to workers information that may help them make important health-and work-related decisions and perform administrative activities, such as filing workers' compensation claims. This section also requires the responsible employer to communicate information concerning the following topics: the medical surveillance program; medical treatment options; medical, psychological, and career counseling; medical benefits; administrative procedures and worker rights under applicable workers' compensation laws and regulations; work practices aimed at limiting worker exposure to beryllium; and the risk of continued exposure after sensitization.

One commenter (Ex. 23) cautioned that the proposed language dealing with workers' compensation counseling could have been interpreted as imposing obligations that exceed employer obligations under states' workers' compensation statutes. DOE has included in section 850.37(f) the qualifying language ''administrative procedures and worker rights'' and ''under applicable workers' compensation laws and regulations'' to make clear that DOE does not intend to establish any new workers' compensation obligations. DOE understands that responsible employers

may develop such counseling programs in consultation with labor organizations representing covered workers, and that employers may wish to advise the workers to consult their own attorneys on these matters.

Another commenter (Ex. 22) recommended that beryllium training be provided by organizations or persons who receive grants from DOE. This commenter asserted that it is inappropriate for DOE contractors, who are responsible employers, to conduct beryllium training because these employers are not sufficiently independent. DOE does not agree with this comment and has not adopted this recommendation. The vast majority of DOE's safety and health training is currently being conducted adequately by responsible employers, and it is common outside of DOE for employers to provide safety and health training to their employees.

One commenter (Ex. 21) recommended that this section be revised to include the adult education principles outlined in Appendix E of OSHA's Hazard Communication standard (29 CFR 1910.1200) because these principles have been effective when applied to training workers. While DOE has not explicitly referenced this advisory Appendix in the final rule, nothing in the rule prohibits its use. Although the Appendix appears to be a good example of the use of adult educational principles that an employer could use to train workers on their hazard communication program, it does not expressly identify or describe these principles. Responsible employers would have to infer the principles from Appendix E and then apply those principles to their beryllium training program. In addition, DOE believes that an explicit reference to this Appendix in the rule would be confusing because this Appendix is not specifically applicable to beryllium training.

Section 850.38—Warning Signs and Labels

Section 850.38 (proposed as section 850.37) requires responsible employers to post warning signs and labels to ensure that the presence and dangers associated with beryllium and beryllium-contaminated materials or areas are communicated to workers. Section 850.38(a) requires the posting of warning signs at all entranceways to established regulated areas and that these signs bear the following warning:

DANGER
BERYLLIUM CAN CAUSE LUNG DAMAGE
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY

The purpose of these signs is to minimize the number of persons in a regulated area by warning workers prior to entry. The signs 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 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.

Sections 850.38(b)(1) requires responsible employers to label with appropriate hazard warnings all containers of beryllium, beryllium compounds, or beryllium-contaminated clothing, equipment, waste, scrap, or debris to ensure that individuals who come in contact with the containers are aware of their contents and 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, section 850.38(b)(2) further specifies that labels bear the following information:

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

Section 850.38(c) clarifies that the warning signs and labels developed to comply with the CBDPP must also comply with the OSHA Hazard Communication standard, 29 CFR 1910.1200. DOE believes this clarification is needed to avoid duplication of effort. In addition, DOE believes that ensuring that the content and format of warning signs and labels comply with the Hazard Communication standard will result in a consistent, recognizable, and comprehensive approach to alerting workers to beryllium's potential to cause disease.

One commenter (Ex. 20) asked if DOE had given consideration to requiring that warning signs and labels be provided in languages other than English or the use of universal symbols to communicate information. DOE notes that 29 CFR 1910.1200(f)(9) (OSHA's Hazard Communication standard) states that employers with employees who speak other languages may present the information in those other languages, as long as the information is presented in English as well. DOE agrees with this approach. Thus, section 850.38(c) requires that all warning signs and labels comply with 29 CFR 1910.1200.

Another commenter (Ex. 23) noted that the warning signs provisions specified in the NOPR differed slightly from those in DOE Notice 440.1, and suggested that DOE retain the NOPR language in the final rule in lieu of the language in the Interim CBDPP. DOE notes that the warning signs and labels provisions of the NOPR were based on the provisions of the Interim CBDPP, with minor modifications added to clarify the intent of the requirements. DOE has retained these clarifications in section 850.38 of the final rule.

A third commenter (Ex. 9) was concerned that references to cancer and cancer hazards in warning signs and labels may be misleading and deceptive, and, noting that the reference did not represent the opinion of a qualified medical professional, recommended that DOE obtain a ''qualified medical opinion'' to resolve this issue. DOE believes that the action of the International Agency for Research on Cancer (IARC) and ACGIH in classifying beryllium as a human carcinogen provides sufficient basis for retaining the cancer warning on warning signs and labels for beryllium-contaminated materials. DOE further notes that NIOSH has classified beryllium as a potential occupational carcinogen since 1977.

Section 850.39—Recordkeeping and Use of Information

Section 850.39 (proposed as section 850.38) requires responsible employers to establish and effectively manage records that relate to the CBDPP and to periodically submit to the Office of Environment, Safety and Health a registry of beryllium-associated workers.

Section 850.39(a) requires the responsible employer to establish and maintain up-to-date and accurate records of all beryllium inventory information, hazard assessments, exposure measurements, exposure controls, and medical surveillance data. DOE believes that up-to-date and accurate records are essential for effectively implementing the CBDPP, assessing its adequacy, and studying the relationship between workplace conditions and CBD. Some of these records will be needed to implement the

performance feedback provisions in section 850.40.

One commenter (Ex. 31) recommended that the final rule explicitly reference OSHA's regulations at 29 CFR 1910.1200 and CFR 1910.1020. OSHA regulations at 29 CFR 1910.1200 (Hazard Communication) already require employers to keep records of beryllium inventory information, and regulations at 29 CFR 1910.20 (Access to Employee Exposure and Medical Records) already require employers to keep records of beryllium hazard assessments, exposure measurements, and medical surveillance data. DOE has not, however, included in section 850.39 references to these OSHA standards. DOE believes that this rule's requirements for maintaining and transferring CBDPP-related records, while ensuring confidentiality of personal information, are stated in clear and concise wording specifically related to the CBDPP that is preferable to cross-referenced OSHA standards. Furthermore, one commenter's (Ex. 31) primary concern was ensuring that workers have access to the information that relates to their personal exposure and medical status. DOE has addressed this concern in section 850.24(g), by requiring responsible employers to notify affected workers of beryllium monitoring results, and in section 850.34(d)(2), by requiring the SOMD to provide to workers the results of medical tests and procedures.

DOE encourages responsible employers to take advantage of existing recordkeeping systems to minimize the burden of implementing section 850.39. Responsible employers also may find that records that are generated outside the CBDPP may be useful in implementing the CBDPP. Examples are records of beryllium training, personnel demographics, beryllium mission descriptions, and payroll records of projects that can be used to link workers with potential beryllium exposure.

Section 850.39(b) requires Heads of DOE Departmental Elements to designate all record series required to be generated under this rule as federal records and, therefore, subject to all applicable federal records management and access laws.

One commenter (Ex. 18), in commenting on the baseline inventory provisions of the proposed rule, recommended that DOE require full public disclosure of health and safety documents related to past beryllium emissions and exposures. In the final rule, DOE is requiring Heads of DOE Departmental Elements to designate the CBDPP-required records as federal records. Federal records, except for records containing specific types of sensitive information, are available to the public under the Freedom of Information Act (FOIA) and related federal policy. The FOIA requires the federal government to release government records upon request, except for information that is exempted from disclosure to protect an overriding interest, such as privacy, national security, and trade secrets and other confidential business information. The FOIA exemption for information in personnel and medical files (5 U.S.C. 552(b)(6)) is especially important for DOE CBDPP-required records, because many of these records contain medical information that is protected from release by this FOIA provision and other federal laws.

One commenter (Ex. 21) recommended that DOE address the retention of records in this rule. DOE has added to section 850.39(b) the requirement that Heads of DOE Departmental Elements ensure that the record series generated as required under this rule are retained for at least 75 years, which is consistent with DOE's policy on retaining medical records. This requirement will ensure that required CBDPP records that relate to workplace conditions will be available in the future to correlate with the beryllium-associated workers' medical records. Heads of DOE Departmental elements will be able to ensure that they can comply with section 850.39(b) if the CBDPP-required records generated by DOE responsible employer contractors are identified in the relevant contracts as DOE-owned documents. Therefore, DOE expects that Heads of DOE Departmental elements will direct their DOE contract officers to stipulate DOE ownership of these documents in those contracts.

The same commenter recommended that DOE address the transfer of records to successive responsible employers. DOE agrees that this information should be covered in the rule, and has added section 850.39(c) to require responsible employers to convey to DOE, or its designee, all record series generated under this rule if the responsible employer ceases to be involved in the CBDPP (e.g., ceases to be a DOE contractor).

Section 850.39(d) requires that responsible employers create links between data sets on workplace conditions and health outcomes to serve as a basis for understanding the beryllium health risk. This linkage of data will assist DOE and responsible employers in identifying unsafe work practices and understanding the relationship between workplace conditions and CBD.

Section 850.39(e) requires the responsible employer to ensure the confidentiality of all records containing personal, private information that are generated as required by this rule. Protecting the confidentiality of these records is required by the Americans with Disabilities Act (42 U.S.C. 12112(d)(4)), the Privacy Act (5 U.S.C. 552a) and other applicable laws. In addition, DOE recognizes that many beryllium-associated workers will participate in some of the voluntary components of the CBDPP only if they believe that their personal information will be kept confidential.

Section 850.39(e)(1) explicitly requires responsible employers to ensure that all records that are transmitted to other parties do not contain names, social security numbers or any other variables, or combination of variables, that could be used to identify individuals. DOE recognizes that responsible employers must take these precautions to prevent the violation of confidentiality laws because personal information could be obtained from transmitted records, or inferred from information other than personal identifiers in the records, unless these precautions are taken.

One commenter (Ex. 4) stated that the rule's confidentiality requirements could prevent industrial hygienists from obtaining the health outcome information that is necessary to perform the linkage of site workplace conditions and health outcomes required by section 850.39(d). DOE does not intend health outcome information that would compromise confidentiality to be provided to industrial hygienists. DOE believes that the linkage required by section 850.39(d) could be performed after personal identifiers are removed from the health outcome information, making it consistent with section 850.39(e)(1).

Another commenter (Ex. 16) recommended that the final rule require the responsible employer to place beryllium medical records in the custody of a medical director, as opposed to the proposed requirement that medical records be held by the responsible employer. DOE recognizes that beryllium medical records may be in the custody of physicians involved in CBD studies other than the SOMD. DOE responds to this commenter's (Ex. 16) concern in section 850.39(e)(2)(i) by requiring responsible employers to ensure that individual medical information generated by the CBDPP is either included as part of the worker's site medical records and maintained by

the SOMD, or is maintained by another physician designated by the responsible employer.

Section 850.39(e)(2)(ii) (proposed section 850.38(d)) retains the proposed requirement that responsible employers ensure that individual medical information generated by the CBDPP is maintained separately from other records. A commenter (Ex. 19) recommended that the rule require responsible employers to use only one data system, maintained by the SOMD, to facilitate the analysis of the data and to increase workers' confidence in the confidentiality of SOMD-maintained records. DOE retained this requirement, however, because the separation of medical and other records is good file management. Further, the Americans with Disabilities Act (42 U.S.C. 12112(d)(4)(C)) requires such separation for privately-owned medical information. DOE recognizes that analysis of the data may be somewhat more difficult with separately maintained medical records, but separation of these records is required by law. There also are practical reasons to require the separation of these records. Personnel officials would require authorization from medical directors before accessing personnel records that were stored with medical records. At the same time, the medical directors would need a system to ensure that no confidential medical information was mixed in with the personnel records that personnel officials accessed. Employers eliminate these administrative burdens by maintaining separate medical and personnel records.

Section 850.39(f) requires the responsible employer to maintain all records required by this part in current and accessible electronic form to permit ready retrieval of data in a format that maintains confidentiality. This requirement is necessary to facilitate timely, efficient, and cost-effective transfer and analysis of CBDPP-related data. DOE has added the phrase ''in current and accessible'' to this section because DOE's experience indicates that the ability to use information held in electronic records is severely hampered if the electronic systems are out-of-date or the records are difficult to obtain. Similarly, DOE has added the phrase ''that maintains confidentiality'' to this section because DOE's experience indicates that transferring information while maintaining confidentiality cannot practically be accomplished using systems that must be modified, converted, or replaced before the transfer can occur.

A commenter (Ex. 21) recommended that the final rule require responsible employer contractors to use the same record retrieval identifiers that any predecessor contractor used. This would allow current contractors easily to link their data to the predecessor contractors' data on the same subject. DOE agrees that successive contractor's use of the same record retrieval identifiers would make exposure-health outcome and epidemiology studies easier to conduct. Therefore, DOE encourages successor contractors to use the same record retrieval identifiers as the predecessor contractor. DOE has not, however, made this a requirement in the final rule because it would be inconsistent with DOE's commitment to a performance-based rule to mandate this practice. DOE's goal in developing this rule is to allow the responsible employer maximum flexibility by specifying in the final rule only those record system characteristics and practices that DOE believes are essential for achieving successful CBDPPs.

Section 850.39(g) requires the responsible employer to transmit all records required by this rule, in a format that protects the confidentiality of individuals, to the DOE Assistant Secretary for Environment, Safety and Health on request. DOE replaced ''Headquarters'' in the proposed rule with ''Assistant Secretary for Environment, Safety and Health'' in the final rule to clarify that DOE's Office of Environment, Safety and Health is the DOE organization that is responsible for conducting occupational health studies that involve DOE workers.

Section 850.39(h) requires the responsible employer semi-annually to transmit to the DOE Office of Epidemiologic Studies, Office of Environment, Safety and Health, an electronic registry of beryllium-associated workers. The transmitted registry must protect confidentiality and include (but is not limited to) the following information for each worker in the registry: a unique identifier, date of birth, gender, site, job history, medical screening test results, exposure measurements, and results of referrals for specialized medical evaluations. DOE's collection of this information conforms to DOE Record System 88, ''Epidemiologic and Other Studies, Surveys, and Surveillance,'' established as required by the Privacy Act. The Office of Epidemiologic Surveillance is responsible for administrative and policy decisions related to the beryllium registry and provides technical support to the SOMD.

The medical records generated by the CBDPP will be kept in appropriate agency Privacy Act systems of records, such as DOE–33, ''Personnel Medical Records,'' and/or DOE–88, and will be afforded the protection provided by the Privacy Act. Should the agency receive a request for these records, it will use every argument legally and reasonably available to it, including the authority granted under the FOIA and the Privacy Act and the agency's regulations implementing those statutes, to protect the privacy of individuals in the records generated by the CBDPP. DOE's policy expressed in 10 CFR 1004.3(e)(ii), to maximize public disclosure of records that pertain to concerns about the environment, public health or safety, or employee grievances, has never been applied to jeopardize the privacy interests of individuals in their medical records and will not be applied to jeopardize privacy interests in records generated by the CBDPP.

Section 850.39(h) includes ''exposure measurements'' in the registry as recommended by a commenter (Ex. 14). DOE had inadvertently omitted exposure measurements in the proposed registry provision. Also, section 850.39(h) includes beryllium-associated workers as recommended by a commenter (Ex. 28), rather than the narrower category of beryllium workers as proposed. DOE accepts this recommended change because it recognizes that some DOE workers who currently do not perform tasks involving beryllium are nonetheless at risk of contracting CBD (based on past potential exposure to beryllium) and must be included to complete the registry.

DOE proposed including beryllium-associated workers' names and social security numbers in the data that would be included in the beryllium registry. Several commenters (Exs. 16, 23, 28) argued that including the names and social security numbers of the beryllium-associated workers in the registry would compromise their privacy. DOE has responded to these commenters' concerns by replacing the proposed ''names'' and ''social security numbers'' with ''unique identifier.'' The term ''unique identifier'' is defined in section 850.3(a) to mean the part of a paired set of labels, used in records that contain confidential information, that does not identify individuals except by using the matching label. Only the SOMD will have the key to match the unique identifier to the individual. This approach allows health and safety professionals and researchers to access the registry data and allows the SOMD to inform individuals of relevant study results, while maintaining confidentiality at all times.

The beryllium registry will serve as a repository for information on beryllium-associated workers. DOE will use the registry to determine the exposure profile and disease status of beryllium-associated workers, and provide feedback to the responsible employer on the effectiveness of the CBDPP. The registry will give DOE the ability to combine data from different facilities and perform analyses that are impossible to perform with the small amount of data that is available from each individual facility. The combined data may help DOE identify risk factors for CBD and evaluate the predictive value of medical tests such as the Be-LPT. Also, researchers may use the registry to conduct further epidemiological studies to better understand the cause and development of CBD and better identify those at risk.

One commenter (Ex. 26) recommended that DOE delete the beryllium registry from the final rule because the commenter believes that: (1) DOE has not adequately described the research for which it will be used, and (2) implementing the registry will be costly. This commenter suggested, as an alternative, that DOE retain the beryllium registry, but include in the rule the specific research protocol that would be used. DOE does not agree with the commenter. DOE is confident that the registry as provided in the final rule will support the studies needed to better understand the relationship between workplace conditions and CBD. This knowledge should provide the basis for improved worker protections. DOE also thinks that the expense of the registry is well justified by these benefits. DOE also disagrees with the recommended alternative of including the research protocols in this rule. Stipulating research protocols in regulations that could only be changed through notice-and-comment rulemaking could stifle research activities.

One commenter (Ex. 19) expressed the concern that DOE's Office of Environment, Safety, and Health use of the beryllium registry could overshadow important site-specific studies. DOE believes that studies at both the site and national level are important for understanding the relationship between workplace conditions and CBD. DOE has included section 850.39(d), which requires responsible employers to link data on workplace conditions and health outcomes, in part to facilitate the site level studies. The beryllium registry established by section 850.39(h) will be used by the Office of Epidemiologic Surveillance to support national level studies.

Two commenters (Exs. 19, 23) recommended that the rule require that a university or a university with input from an oversight board, or other suitably qualified organizations design the epidemiological analysis of the CBDPP-generated data. Although responsible employers and DOE's Office of Environment, Safety and Health may use universities or other suitably qualified organizations to design these analyses, DOE thinks it would be inappropriate to specify the use of such organizations in the rule. This recommendation is not adopted.

Section 850.40—Performance Feedback

The final rule requirements for performance feedback in section 850.40 are essentially the same as those proposed. Section 850.40(a) requires that responsible employers conduct periodic analysis and assessment of monitoring results, hazards identified, medical surveillance results, attainment of exposure reduction and minimization goals, and occurrence reporting data. DOE believes that the analysis of these data is important for the continuous improvement of the program.

To ensure that all workers have the information needed to safely perform their assigned tasks, section 850.40(b) requires that results of performance assessments conducted in accordance with this rule be provided to line managers, planners, worker protection staff, workers, medical staff, and others.

LIST OF COMMENTERS

Exhibit No.	Company/Organization
1	Atomic Weapons Establishment (AWE)
2	Oak Ridge Institute for Science and Education (ORISE)
3	U.S. Department of Navy, Navy Environmental Health Center
4	Fluor Daniel Hanford, Incorporated
5	Burlin McKinney
6	Idaho National Engineering and Environmental Laboratory (INEEL), Operated by Lockheed Martin
7	Freddy D. Marler Jr.
8	Alfred Glenn Bell
9	Lockheed Martin Idaho Technologies Company, INEEL
10	A Concerned American Citizen
11	Robert A. Gadon, CIH
12	Daniel R. Roberts, Danny Bush, Willie James Brooks, C.E. Tilley, Robert Lang Freels, Edna & Ernest Hugart, Victoria L. O'Sheel, Kenneth L. Moore, Cheryll A. Dyer, James M. Harvey, J. R. Miller, Luis Revilla, Connie Willis, Bruce Lawson, Lynn & Linda Cox, Roy & Debra Jones
13	American Industrial Hygiene Association (AIHA)
14	Gary Foster
15	Darrell Lawson
16	University of California, Laboratory Administration
17	Hanford Environmental Health Foundation
18	Serious Texans Against Nuclear Dumping (STAND), Incorporated
19	American College of Occupational and Environmental Medicine
20	Occupational Safety and Health Administration (OSHA)
21	University of Cincinnati Medical Center
22	Paper, Allied Industrial Chemical & Energy Workers Union (PACE)
23	Kaiser-Hill Company, Rocky Flats Environmental Technology Site
24	Lockheed Martin Energy Systems, Incorporated, (Y–12 Facility)
25	Lockheed Martin Energy Research Corporation (Oak Ridge Laboratory)
26	Brush Wellman, Incorporated
27	James Turner
28	National Jewish Medical and Research Center
29	National Institute for Occupational Safety and Health (NIOSH)
30	Consortium for Risk Evaluation with Stakeholder Participation (CRESP)
31	International Chemical Workers Union Council of the United Food and Commercial Workers International Union (ICWUC/UFCW)
32	Concerned Citizens for Nuclear Safety (CCNS)
33	Stanford Linear Accelerator Center (SLAC)
34	Fermi National Accelerator Laboratory (Fermi Lab)
35	United Steelworkers, Local 8031
36	U.S. House of Representatives, Van Hilleary
37	National Institute for Occupational Safety and Health (NIOSH)
38	Atomic Weapons Establishment (AWE)
38	Commodore Advance Science, Incorporated
40	Hanford Environmental Health Foundation
41	Oak Ridge National Laboratory
42	Argonne National Laboratory
43	Fluor Daniel Hanford, Incorporated
44	University of Cincinnati Medical Center
45	Gary Foster
46	Pantex Plant
47	Kaiser-Hill, Rocky Flats Environmental Technology Site
48	Paper, Allied Industrial Chemical & Energy Workers Union (PACE)
49	Consortium for Risk Evaluation with Stakeholder Participation (CRESP)
50	Brush Wellman, Incorporated
51	University of Cincinnati

LIST OF COMMENTERS—Continued

Exhibit No.	Company/Organization
52	Building & Construction Trades Department, AFL–CIO

V. Procedural Requirements

A. Review Under Executive Order 12866

This rulemaking 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 proposed rule, which was made available to the public when the NOPR was published in the **Federal Register**, was updated to reflect changes made in the final rule.

Before conducting the assessment, DOE profiled the sites and activities that will be affected by the CBDPP rule and estimated the number of workers that will be affected by the rule. DOE estimates that 1,634 workers may be exposed or potentially exposed to airborne concentrations of beryllium in the DOE complex. Furthermore, DOE estimates that 1,236 of these workers (75.6 percent) are potentially exposed above the action level or the PEL prescribed in the CBDPP rule.

DOE began the cost estimation by reviewing the rule to determine which requirements of the rule will impose costs on affected entities. DOE then determined the controls (e.g., implementation of procedures, purchase of equipment) necessary for affected entities to be in compliance with each requirement. DOE's assessment refers to these determinations as compliance profiles. Since the goal of the compliance cost estimation is to determine the incremental costs of compliance (OMB Guidance, 1996), the compliance profiles were compared to the procedures and controls that are currently in place at DOE facilities affected by the rule (i.e., the baseline). Procedures and controls required by the CBDPP rule that are not currently in place at DOE facilities were considered new to the facilities, and thus would impose incremental costs on the affected entities. The compliance profiles were then adjusted to reflect only the required incremental controls.

The next step in DOE's assessment was to estimate the costs for each compliance profile. DOE collected data on the cost of each element contained in the compliance profiles. The profiles are designed to reflect the full opportunity cost of compliance. For example, the compliance profile for performing a Be-LPT test includes not only the test itself, but also the labor time for the worker and physician to conduct the test, shipping the sample to a lab, and analyzing and interpreting the results of the test. The cost data was obtained from a variety of sources, including CBDPP plans submitted under DOE Notice 440.1, a 1999 Environment, Safety and Health (EH) Cost Survey, contact with DOE facilities subject to the CBDPP rule, trade publications, the U.S. Office of Personnel Management (OPM) (e.g., for wage rates), and previous economic analyses of other regulations (e.g., regulatory impact analyses of OSHA health standards). This cost data was then applied to the compliance profiles to determine the costs associated with each profile, providing an estimate of the incremental cost for each requirement.

DOE-wide cost estimates for each requirement were generated by multiplying the number of units affected by each requirement by the incremental cost for each requirement. Costs estimated in this step were then annualized using a discount rate. Discount rates are used to translate costs (and benefits) that are incurred in future years into a present value. Following OMB Guidance (1992), DOE chose a 7 percent discount rate. In the analysis, DOE uses the 7 percent discount rate for three purposes: (1) To annualize the costs of equipment or other program elements that have a lifetime of more than one year, (2) to translate the costs incurred in future years into a present value, and (3) to calculate the annualized cost of initial requirements of DOE N 440.1 and the CBDPP rule.

DOE estimated the total compliance costs of the CBDPP, including the costs of the interim CBDPP under DOE Notice 440.1 and the costs of this final rule. DOE estimates an $8.54 million annualized cost on DOE contractors between July 1997 and December 1999 (compliance with DOE Notice 440.1) and a $31.55 million annualized cost on DOE contractors between December 1999 (the assumed effective date of the final rule) and December 2009. This includes an initial (i.e., startup) cost of $9.02 million incurred in July 1997 and another initial cost of $2.22 million incurred in December 1999.

DOE also assessed the potential benefits of the CBDPP for DOE, DOE contractors, and workers. DOE assessed the following benefits of the CBDPP rule: (1) Reduced medical costs; (2) reduced mortality; (3) increased quality of life; (4) increased medical surveillance for workers at risk; (5) increased work-life for beryllium workers; (6) increased productivity; (7) reduced legal costs for DOE and DOE contractors; and (8) a reduction in the externality associated with beryllium exposure through a transfer of the medical costs from workers to DOE contractors. Because sufficient information on the dose-response relationship for beryllium is not available within the scientific community, DOE could not relate reduced levels of exposure to a specific reduction in CBD and beryllium sensitization. Nevertheless, DOE estimates that the monetary benefits from reduced lifetime medical costs could range from $10,100 to $16,093 for each avoided case of beryllium sensitization or CBD.

DOE also assessed the potential economic impacts of the rule on the provision of public goods that contain beryllium and the impact on the market for beryllium. DOE assessed each of these potential impacts and determined neither will impose a significant economic impact. DOE determined that the potential reduction in the provision of beryllium-containing public goods will be minimal and, consequently, the reduction in demand for beryllium will also be small.

DOE's assessment of the potential costs and benefits of the final has been placed in the rulemaking file (Docket Number EH–RM–98–BRYLM). DOE also has placed in the rulemaking file a document that identifies the substantive changes between the draft final rule submitted to the OIRA for review and the final rule published today, including identification of the changes suggested or recommended by OIRA. These documents may be reviewed and copied at the DOE 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.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that an agency prepare a regulatory flexibility analysis and publish it at the time of publication of general notice of proposed rulemaking for the rule. This requirement does not apply if the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)).

Today's action establishes DOE's regulations for a CBDPP to reduce the number of DOE Federal and contractor workers exposed to beryllium, minimize the levels of and potential for exposure to beryllium, and establish medical surveillance requirements to ensure early detection of disease. The contractors who manage and operate DOE facilities are principally responsible for implementing the CBDPP. DOE has considered whether these contractors are ''small businesses,'' as that term is defined by the Regulatory Flexibility Act (5 U.S.C. 601(3)). The Regulatory Flexibility Act's definition incorporates the definition of ''small business concern'' in the Small Business Act, which the Small Business Administration (SBA) has developed through size standards in 13 CFR part 121. Small businesses are business concerns which, together with their affiliates, have no more than 500 to 1500 employees, varying by SIC category, and annual receipts of between $0.5 million to $25 million, again varying by SIC category. The DOE contractors subject to the CBDPP requirements exceed the SBA's size standards for small businesses. In addition, DOE contractors are reimbursed through their contracts with DOE for the costs of complying with DOE health and safety program requirements. They will not, therefore, be adversely impacted by the requirements in the rule. For these reasons, DOE certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

C. Review Under the Paperwork Reduction Act

DOE submitted the proposed collections of information in this rule to the Office of Management and Budget for review under section 3507(d) of the Paperwork Reduction Act of 1995 (42 U.S.C. 3507(d)). The information that DOE contractors are required to produce, maintain and report is necessary to permit the Department to manage and oversee the health and safety programs that control worker exposure to beryllium. The Office of Management and Budget has not yet approved the collections of information in this rule. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number (5 CFR 1320.5(b)).

D. Review Under the National Environmental Policy Act

DOE has reviewed 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 (40 CFR parts 1500–1508), and DOE's NEPA implementing procedures (10 CFR Part 1021). DOE has completed an Environmental Assessment, and on the basis of that assessment has determined that an environmental impact statement is not required and issued a Finding of No Significant Impact (FONSI) for this rule. In the Notice of Proposed Rulemaking, the Department announced the availability of the draft Environmental Assessment and requested comments on the Assessment. DOE did not receive any comments on the draft Environmental Assessment. The Environmental Assessment updates the draft Environmental Assessment (DOE/EA 1249) to reflect changes in the final rule made in response to public comments on the rule. The Environmental Assessment and FONSI are available for inspection at the DOE Freedom of Information Reading Room, 1E–190, 1000 Independence Avenue SW, Washington, DC 20585, between the hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

E. Review Under Executive Order 13132

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

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 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 the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in an 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 Federal intergovernmental mandate,'' and requires an agency plan for giving notice and an opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. The final rule published today applies only to activities conducted by or for DOE, and its implementation will not result in an expenditure of $100 million in any year by State, local or tribal governments or the private sector. Therefore, the requirements of Title II Unfunded Mandates Reform Act of 1995 do not apply.

H. Review Under Small Business Regulatory Enforcement Fairness Act of 1996

As required by 5 U.S.C. 801, DOE will report to Congress promulgation of this rule prior to its effective date. The report will state that it has been

determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Appendix A to the Preamble References

1. ''Beryllium Disease: Reducing the Risks.'' National Jewish Medical and Research Center Website (*http://www.nationaljewish.org/beryllium/*). 1999.
2. Green DM et al. ''Agency for Toxic Substances and Disease Registry (ASTDR) Case Studies in Environmental Medicine, No.19.'' U.S. Department of Health and Human Services. 1992.
3. Hardy HL, Tabershaw IR. ''Delayed Chemical Pneumonitis Occurring in Workers Exposed to Beryllium Compounds.'' *Journal of Industrial Hygiene Toxicology*, Volume 28:197 (1946).
4. Powers MB. ''History of Beryllium.'' In *Beryllium Biomedical and Environmental Aspects*. Rossman MD, Preuss OP, and Powers MB, eds. Baltimore: Williams and Wilkins, 1991.
5. Eisenbud M et al. ''Non-occupational Berylliosis.'' *Journal of Industrial Hygiene Toxicology*, Volume 31:282–294 (1949).
6. Eisenbud M, Lisson J. ''Epidemiologic Aspects of Beryllium-Induced Nonmalignant Lung Disease: A 30–Year Update.'' *Journal of Occupational Medicine*, Volume 25:196–202 (1983).
7. Sterner JH, Eisenbud M. ''Epidemiology of Beryllium Intoxication.'' *Archives of Industrial Hygiene and Occupational Medicine*, Volume 4:123–157 (1951).
8. Newman LS, Kreiss K. ''Nonoccupational Beryllium Disease Masquerading as Sarcoidosis: Identification by Blood Lymphocyte Proliferative Response to Beryllium.'' *American Review of Respiratory Disease*, Volume 145:1212–1214 (1992).
9. Tepper LB. ''Introduction.'' In: *Beryllium Biomedical and Environmental Aspects*. Rossman MD, Preuss OP, and Powers MB, eds. Baltimore: Williams and Wilkins, 1991.
10. Sprince NL, Kazemi H. ''Beryllium Disease.'' In: *Environmental and Occupational Medicine*, 2nd ed. Room W, ed. Boston: Little, Brown, 1992.
11. Newman LS et al. ''Pathologic and Immunologic Alterations in Early Stages of Beryllium Disease. Reexamination of Disease Definition and Natural History.'' *American Review of Respiratory Disease*, Volume 139:1479–11486, (1989).
12. Kreiss K, Newman LS, Mroz MM, Campbell, PA. ''Screening Blood Test Identifies Subclinical Beryllium Disease.'' *Journal of Occupational Medicine*, Volume 31:603–608 (1989).
13. Rossman MD, Kern JA, Elias JA et al. ''Proliferative Response of Bronchoalveolar Lymphocytes to Beryllium: A Test For Chronic Beryllium Disease.'' *Annals of Internal Medicine*, Volume 108:687–693 (1988).
14. Saltini C, Winestock K, Kirby M et al. ''Maintenance of Alveolitis in Patients with Chronic Beryllium Disease by Beryllium Specific Helper T-Cells.'' *New England Journal of Medicine*, Volume 320:103–1109 (1989).
15. Cullen MR et al. ''Chronic Beryllium Disease in a Metal Refinery. Clinical Epidemiologic and Immunologic Evidence for Continuing Risk from Exposure to Low Level Beryllium Fume.'' *American Review of Respiratory Disease*, Volume 135(1):201–208 (1987).
16. Kreiss K, Mroz MM, Zhen B et al. ''Epidemiology of Beryllium Sensitization and Disease in Nuclear Workers.'' *American Review of Respiratory Disease*, Volume 148:985–991 (1993).
17. Kreiss K et al. ''Beryllium Disease Screening in the Ceramics Industry.'' *Journal of Occupational Medicine*, Volume 35:267–274 (1993).
18. *Health Assessment Document for Beryllium* [Publication No. EPA/600/8–84/026F] U.S. Environmental Protection Agency. (1987).
19. Stange AW et al. ''Possible Health Risks from Low Level Exposure to Beryllium.'' *Toxicology,* Volume 111:213–224 (1996).
20. Barnard AE, et al. ''Retrospective Beryllium Exposure Assessment at the Rocky Flats Environmental Technology Site.'' *American Industrial Hygiene Association Journal,* Volume 57:804–808 (1996).
21. Kreiss K et al. ''Machining Risk of Beryllium Disease and Sensitization with Median Exposures Below 2 $\mu g/m^3$,'' *American Journal of Industrial Medicine,* Volume 30:16–25 (1996).
22. Kreiss K, Mroz M, Zhen B, Wiedemann H, Barna B. Risks of beryllium disease related to work processes at a metal, alloy, and oxide production plant. Occupational and Environmental Medicine, Volume 54:605–612 (1997).
23. Cohen BS. ''Air Sampling.'' In: *Beryllium Biomedical and Environmental Aspects*. Rossman MD, Preuss OP, and Powers MB, eds. Baltimore: Williams and Wilkins, 1991.
24. Finch GL. ''In Vitro Dissolution Characteristics of Beryllium Oxide and Beryllium Metal Aerosols.'' *Journal of Aerosols Science,* Volume 19:333–342 (1988).
25. Newman LS. ''To Be^{2+} or Not to Be^{2+} : Immunogenetics and Occupational Exposure.'' *Science,* Volume 262:197–198 (8 October 1993).
26. Haley PJ. ''Mechanisms of Granulomatous Lung Disease from Inhaled Beryllium: The Role of Antigenicity in Granuloma Formation.'' *Toxicologic Pathology,* Volume 19:514–525 (1991).
27. Finch GL. ''Clearance, Translocation, and Excretion of Beryllium Following Inhalation of Beryllium Oxide by Beagle Dogs.'' *Fundamentals of Applied Toxicology,* Volume 15:231–241 (1990).
28. Richeldi L et al. ''HLA-DPB1 Glutamate 69: A Genetic Marker of Beryllium Disease.'' *Science,* Volume 262:242–244 (8 October 1993).
29. Eisenbud M. ''The Standard for Control of Chronic Beryllium Disease.'' *Applied Occupational Environmental Hygiene,* Volume 13(1):25–31 (January 1998).
30. Pappas GP et al. ''Early Pulmonary Physiologic Abnormalities in Beryllium Disease.'' *American Review of Respiratory Disease,* Volume 148:661–666 (1993).
31. Yoshida T et. al. ''A Study on the Beryllium Lymphocyte Transformation Test and the Beryllium Levels in Working Environment.'' *Industrial Health,* Volume 35(3):374–9 (Jul 1997).
32. Threshold Limit Value for Chemical Substances and Physical Agents and Biological Exposure Indices, Notice of Intended Change (1999).
33. U.S. Environmental Protection Agency: Integrated Risk Information System, Substance File—Beryllium and Compounds, CASRN 7440–41; U.S. Environmental Protection Agency, Washington, DC (1998).
34. Epstein WL. ''Cutaneous Effects of Beryllium.'' In: *Beryllium Biomedical and Environmental Aspects*. Rossman MD, Preuss OP, and Powers MB, eds. Baltimore: Williams and Wilkins, 1991.
35. Sanderson WT et. al. ''Beryllium Contamination Inside Vehicles of Machine Shop Workers.'' *Applied Occupational Environmental Hygiene,* Volume 14:223–230 (1999).

Appendix B to the Preamble—Questions and Answers Concerning the Beryllium-Induced Lymphocyte Proliferation Test (Be-LPT), Medical Records, and the Department of Energy (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 the beryllium in a specific way, the test results are ''positive.'' If they do not react to 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 that 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 a person is not sensitive or allergic to beryllium. 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 that 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.

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.

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. Your employer will pay for all tests.

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. If you have a positive Be-LPT or have been diagnosed with CBD, your employer may inform you that the SOMD has recommended that you be temporarily or permanently removed from working with beryllium. You will be given information and counseling to help you decide whether to accept medical removal. If you agree to medical removal, every effort will be made to offer you another job that you are qualified (or can be trained for in a short period) to perform and where the beryllium exposures will be as low as possible, but in no case above the action level.

If you are temporarily removed, you will maintain your total normal earnings, seniority, and other benefits until you are placed in another job for 1 year, whichever comes first. If you are permanently removed, you will maintain your total normal earnings, seniority, and other benefits until you are placed in another job or for 2 years, whichever comes first. 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 Normal 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 Be-LPT and other screening tests will be made available to you and, with your consent, to your physician. The information also will become part of your medical record, which the clinic keeps.

The results of tests and examinations in your medical record will be available to the physicians and nurses in this clinic, and possibly to scientists conducting health studies. The test results in your medical records 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; and
4. The Centers for Disease Control and Prevention and the 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.

What Laws Protect Me if I Consent To Participate in the Blood Be-LPT Testing 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. It would also be available as the Freedom of Information Act or Privacy Act provide, such as to Congress, to an individual upon a showing of compelling circumstances affecting the health and safety of an individual, etc. 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.

What Is the DOE Beryllium Registry?

Your health and the health of all workers is a major concern to DOE. There is a need to learn more about chronic beryllium disease and what causes some individuals to react more strongly than others do. A DOE beryllium registry has been established to collect and maintain information on workers who are exposed to beryllium. This registry is a tool that 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 this information in conformance with the Privacy Act of 1974, the Americans with Disabilities Act, and other applicable laws. Your employer will establish a unique identifier for you that will be included in the registry instead of your personal identifying information (such as your name and social security number). The unique identifier will be used to inform your employer of any study results that you and your employer's Site Occupational Medical Director (SOMD) should know about. The SOMD will know to whom the unique identifier refers and will notify you of these results. At no time will your name or other personal identifying information be included in any report. The confidentiality of personal information in DOE records is protected under the Privacy Act of 1974.

List of Subjects in 10 CFR Part 850

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

Issued in Washington, D.C., on November 24, 1999.

Bill Richardson,

Secretary of Energy.

For the reason set forth in the preamble, Title 10, Chapter III of the Code of Federal Regulations is amended by adding a new part 850 as set forth below.

PART 850—CHRONIC BERYLLIUM DISEASE PREVENTION PROGRAM

Subpart A—General Provisions

Sec.

Subpart B—Administrative Requirements

Subpart C—Specific Program Requirements

Authority: 42 U.S.C. 2201(i)(3), (p); 29 U.S.C. 668; E.O. 12196, 3 CFR 1981 comp., p. 145 as amended.

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 operations or activities that involve present or past exposure, or the potential for exposure, to beryllium at DOE facilities;

(2) DOE contractors with operations or activities that involve present or past exposure, or the potential for exposure, to beryllium at DOE facilities; and

(3) Any current DOE employee, DOE contractor employee, or other worker at a DOE facility who is or was exposed or potentially exposed to beryllium at a DOE facility.

(b) This part does not apply to:

(1) Beryllium articles; and

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

§ 850.3 Definitions.

(a) As used in this part:

Action level means the level of airborne concentration of beryllium established pursuant to section 850.23 of this part that, if met or 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 activity means an activity taken for, or by, DOE at a DOE facility that can expose workers to airborne beryllium, including but not limited to design, construction, operation, maintenance, or decommissioning, and which may involve one DOE facility or operation or a combination of facilities and operations.

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

(1) A beryllium worker;

(2) A current worker whose work history shows that the worker may have been exposed to airborne concentrations of beryllium at a DOE facility;

(3) A current worker who exhibits signs or symptoms of beryllium exposure; and

(4) A current worker who is receiving medical removal protection benefits.

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