DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–H005C–2006–0870]

RIN 1218–AB76

Occupational Exposure to Beryllium and Beryllium Compounds

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Proposed rule; request for comments.

SUMMARY: The Occupational Safety and Health Administration (OSHA) proposes to amend its existing exposure limits for occupational exposure in general industry to beryllium and beryllium compounds and promulgate a substance-specific standard for general industry regulating occupational exposure to beryllium and beryllium compounds. This document proposes a new permissible exposure limit (PEL), as well as ancillary provisions for employee protection such as methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping. In addition, OSHA seeks comment on a number of alternatives, including a lower PEL, that could affect construction and maritime, as well as general industry.

DATES: *Written comments.* Written comments, including comments on the information collection determination described in Section IX of the preamble (OMB Review under the Paperwork Reduction Act of 1995), must be submitted (postmarked, sent, or received) by November 5, 2015.

Informal public hearings. The Agency will schedule an informal public hearing on the proposed rule if requested during the comment period. The location and date of the hearing, procedures for interested parties to notify the Agency of their intention to participate, and procedures for participants to submit their testimony and documentary evidence will be announced in the **Federal Register** if a hearing is requested.

ADDRESSES: *Written comments.* You may submit comments, identified by Docket No. OSHA–H005C–2006–0870, by any of the following methods:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov*, which is the Federal e-Rulemaking Portal. Follow the instructions on-line for making electronic submissions. When uploading multiple attachments into Regulations.gov, please number all of your attachments because *www.Regulations.gov* will not automatically number the attachments. This will be very useful in identifying all attachments in the beryllium rule. For example, Attachment 1—title of your document, Attachment 2—title of your document, Attachment 3—title of your document, etc. Specific instructions on uploading all documents are found in the Facts, Answer, Questions portion and the commenter check list on Regulations.gov Web page.

Fax: If your submissions, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: You may submit your comments to the OSHA Docket Office, Docket No. OSHA–H005C–2006–0870, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). Deliveries (hand, express mail, messenger, or courier service) are accepted during the Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., E.S.T.

Instructions: All submissions must include the Agency name and the docket number for this rulemaking (Docket No. OSHA–H005C–2006–0870). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov*. Therefore, OSHA cautions you about submitting personal information such as Social Security numbers and birthdates.

If you submit scientific or technical studies or other results of scientific research, OSHA requests (but is not requiring) that you also provide the following information where it is available: (1) Identification of the funding source(s) and sponsoring organization(s) of the research; (2) the extent to which the research findings were reviewed by a potentially affected party prior to publication or submission to the docket, and identification of any such parties; and (3) the nature of any financial relationships (*e.g.*, consulting agreements, expert witness support, or research funding) between investigators who conducted the research and any organization(s) or entities having an interest in the rulemaking. If you are submitting comments or testimony on the Agency's scientific or technical analyses, OSHA requests that you disclose: (1) The nature of any financial relationships you may have with any organization(s) or entities having an interest in the rulemaking; and (2) the extent to which your comments or testimony were reviewed by an interested party before you submitted them. Disclosure of such information is intended to promote transparency and scientific integrity of data and technical information submitted to the record. This request is consistent with Executive Order 13563, issued on January 18, 2011, which instructs agencies to ensure the objectivity of any scientific and technological information used to support their regulatory actions. OSHA emphasizes that all material submitted to the rulemaking record will be considered by the Agency to develop the final rule and supporting analyses.

Docket: To read or download comments and materials submitted in response to this **Federal Register** notice, go to Docket No. OSHA–H005C–2006–0870 at *http://www.regulations.gov,* or to the OSHA Docket Office at the address above. All comments and submissions are listed in the *http://www.regulations.gov* index; however, some information (*e.g.*, copyrighted material) is not publicly available to read or download through that Web site. All comments and submissions are available for inspection at the OSHA Docket Office.

Electronic copies of this **Federal Register** document are available at *http://www.regulations.gov*. Copies also are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1888. This document, as well as news releases and other relevant information, is also available at OSHA's Web site at *http://www.osha.gov*.

OSHA has not provided the document ID numbers for all submissions in the record for this beryllium proposal. The proposal only contains a reference list for all submissions relied upon. The public can find all document ID numbers in an Excel spreadsheet that is posted on OSHA's rulemaking Web page (see *www.osha.gov/berylliumrulemaking*). The public will be able to locate submissions in the record in the public docked Web page: *http://www.regulations.gov*. To locate a particular submission contained in *http://www.regulations.gov*, the public should enter the full document ID number in the search bar.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Frank Meilinger, Director, Office of Communications, Room N–3647,

OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov* . For technical inquiries, contact: William Perry or Maureen Ruskin, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1955 or fax (202) 693–1678; email: *perry.bill@dol.gov*.

SUPPLEMENTARY INFORMATION:

The preamble to the proposed standard on occupational exposure to beryllium and beryllium compounds follows this outline:

Executive Summary

Executive Summary

OSHA currently enforces permissible exposure limits (PELs) for beryllium in general industry, construction, and shipyards. These PELs were adopted in 1971, shortly after the Agency was created, and have not been updated since then. The time-weighted average (TWA) PEL for beryllium is 2 micrograms per cubic meter of air (μg/m³) as an 8-hour time-weighted average. OSHA is proposing a new TWA PEL of 0.2 μg/m³ in general industry. OSHA is also proposing other elements of a comprehensive health standard, including requirements for exposure assessment, preferred methods for controlling exposure, respiratory protection, personal protective clothing and equipment (PPE), medical surveillance, medical removal, hazard communication, and recordkeeping.

OSHA's proposal is based on the requirements of the Occupational Safety and Health Act (OSH Act) and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act, OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so. See Section II of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to beryllium. The Agency has also assessed the risk of beryllium-related diseases at the current TWA PEL, the proposed TWA PEL and the alternative TWA PELs. These analyses are presented in this preamble at Section V, Health Effects, Section VI, Preliminary Risk Assessment, and Section VIII, Significance of Risk. As discussed in Section VIII of this preamble, Significance of Risk, the available evidence indicates that worker exposure to beryllium at the current PEL poses a significant risk of chronic beryllium disease (CBD) and lung cancer, and that the proposed standard will substantially reduce this risk.

Section 6(b) of the OSH Act requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the proposed rule is presented in the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA) (OSHA, 2014), and is summarized in Section IX of this preamble, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis. OSHA has preliminarily concluded that the proposed PEL of 0.2 μg/m³ is technologically feasible for all affected industries and application groups. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain beryllium exposures to the proposed PEL of 0.2 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or application group where compliance with the proposed PEL cannot be achieved even when employers implement all feasible engineering and work practice controls, the proposed standard would require employers to supplement controls with respirators.

OSHA developed quantitative estimates of the compliance costs of the proposed rule for each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide a screening analysis of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts. Industries with unusually high costs as a percentage of revenues or profits were further analyzed for possible economic feasibility issues. After performing these analyses, OSHA has preliminarily concluded that compliance with the requirements of the proposed rule would be economically feasible in every affected industry sector.

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires that OSHA either certify that a rule would not have a significant economic impact on a substantial number of small entities or prepare a regulatory flexibility analysis and hold a Small Business Advocacy Review (SBAR) Panel prior to proposing the rule. OSHA has determined that a regulatory flexibility analysis is needed and has provided this analysis in Chapter IX of the PEA (OSHA, 2014). A summary is provided in Section IX of this preamble, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis. OSHA also previously held a SBAR Panel for this rule. The recommendations of the Panel and OSHA's response to them are summarized in Section IX of this preamble.

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. The remainder of this section summarizes the key findings of the analysis with respect to costs and benefits of the proposed standard, presents alternatives to the proposed standard, and requests comments on a number of issues.

Table I–1, which is derived from material presented in the PEA, provides a summary of OSHA's best estimate of the costs and benefits of this proposed rule. As shown, this proposed rule is estimated to prevent 96 fatalities and 50 non-fatal beryllium-related illnesses annually once it is fully effective, and the monetized annualized benefits of the proposed rule are estimated to be $576 million using a 3-percent discount rate and $255 million using a 7-percent discount rate. Also as shown in Table I–1, the estimated annualized cost of the rule is $37.6 million using a 3-percent discount rate and $39.1 million using a 7-percent discount rate. This proposed rule is estimated to generate net benefits of $538 million annually using a 3-percent discount rate and $216 million annually using a 7-percent discount rate. These estimates are for informational purposes only and have not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for this proposed beryllium rule. The courts have ruled that OSHA may not use benefit-cost analysis or a criterion of maximizing net benefits as a basis for setting OSHA health standards.[1]

TABLE I–1—ANNUALIZED COSTS, BENEFITS AND NET BENEFITS OF OSHA'S PROPOSED BERYLLIUM STANDARD OF 0.2 μG/M³

Discount rate		3%	7%
Annualized Costs			
Engineering Controls		$9,540,189	$10,334,036
Respirators		249,684	252,281
Exposure Assessment		2,208,950	2,411,851
Regulated Areas and Beryllium Work Areas		629,031	652,823
Medical Surveillance		2,882,076	2,959,448
Medical Removal		148,826	166,054
Exposure Control Plan		1,769,506	1,828,766
Protective Clothing and Equipment		1,407,365	1,407,365
Hygiene Areas and Practices		389,241	389,891
Housekeeping		12,574,921	12,917,944
Training		5,797,535	5,826,975
Total Annualized Costs (Point Estimate)		37,597,325	39,147,434
Annual Benefits: Number of Cases Prevented			
Fatal Lung Cancer	4.0		
CBD-Related Mortality	92.0		
Total Beryllium Related Mortality	96.0	572,981,864	253,743,368
Morbidity	49.5	2,844,770	1,590,927
Monetized Annual Benefits (midpoint estimate)		575,826,633	255,334,295
Net Benefits		538,229,308	216,186,861

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Both the costs and benefits of Table I–1 reflect the incremental costs and benefits associated with achieving full compliance with the proposed standard. They do not include costs and benefits associated with employers' current exposure control measures or other aspects of the proposed standard they have already implemented. For example, for employers whose exposures are already below the proposed PEL, OSHA's estimated costs and benefits for the proposed standard do not include the costs of their exposure control measures or the benefits of these employers' compliance with the proposed PEL. The costs and benefits of Table I–1 also do not include costs and benefits associated with achieving compliance with existing requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

I. Issues and Alternatives

In addition to the proposed standard itself, this preamble discusses more than two dozen regulatory alternatives, including various sub-alternatives, to the proposed standard and requests comments and information on a variety of topics pertinent to the proposed standard. The regulatory alternatives OSHA is considering include alternatives to the proposed scope of the standard, regulatory alternatives to the proposed TWA PEL of 0.2 μg/m³ and proposed STEL of 2 μg/m³, a regulatory alternative that would modify the proposed methods of compliance, and regulatory alternatives that affect proposed ancillary provisions. The Agency solicits comment on the proposed phase-in schedule for the various provisions of the standard. Additional requests for comments and information follow the summaries of regulatory alternatives, under the ''Issues'' heading.

Regulatory Alternatives

OSHA believes that inclusion of regulatory alternatives serves two important functions. The first is to explore the possibility of less costly ways (than the proposed standard) to provide an adequate level of worker protection from exposure to beryllium. The second is tied to the Agency's statutory requirement, which underlies the proposed standard, to reduce significant risk to the extent feasible. Each regulatory alternative presented here is described and analyzed more fully elsewhere in this preamble or in the PEA. Where appropriate, the alternative is included in this preamble at the end of the relevant section of Section XVIII, Summary and Explanation of the Proposed Standard, to facilitate comparison of the alternative to the proposed standard. For example, alternative PELs under consideration by the Agency are presented in the discussion of paragraph (c) in Section XVIII. In addition, all

[1] *Am. Textile Mfrs. Inst., Inc.* v. *Nat'l Cotton Council of Am.*, 452 U.S. 490, 513 (1981); *Pub. Citizen Health Research Group* v. *U.S. Dep't of Labor*, 557 F.3d 165, 177 (3d Cir. 2009).

alternatives are discussed in the PEA, Chapter VIII: Regulatory Alternatives (OSHA, 2014). The costs and benefits of each regulatory alternative are presented both in Section IX of this preamble and in Chapter VIII of the PEA.

The more than two dozen regulatory alternatives, including various sub-alternatives regulatory alternatives under consideration are summarized below, and are organized into the following categories: alternatives to the proposed scope of the standard; alternatives to the proposed PELs; alternatives to the proposed methods of compliance; alternatives to the proposed ancillary provisions; and the timing of the standard.

Scope

OSHA has examined three alternatives that would alter the groups of employers and employees covered by this rulemaking. Regulatory Alternative #1a would expand the scope of the proposed standard to include all operations in general industry where beryllium exists only as a trace contaminant; that is, where the materials used contain no more than 0.1% beryllium by weight. Regulatory Alternative #1b is similar to Regulatory Alternative #1a, but exempts operations where the employer can show that employees' exposures will not meet or exceed the action level or exceed the STEL. Where the employer has objective data demonstrating that a material containing beryllium or a specific process, operation, or activity involving beryllium cannot release beryllium in concentrations at or above the proposed action level or above the proposed STEL under any expected conditions of use, that employer would be exempt from the proposed standard except for recordkeeping requirements pertaining to the objective data. Alternative #1a and Alternative #1b, like the proposed rule, would not cover employers or employees in construction or shipyards.

Regulatory Alternative #2a would expand the scope of the proposed standard to also include employers in construction and maritime. For example, this alternative would cover abrasive blasters, pot tenders, and cleanup staff working in construction and shipyards who have the potential for airborne beryllium exposure during blasting operations and during cleanup of spent media. Regulatory Alternative #2b would update §§ 1910.1000 Tables Z–1 and Z–2, 1915.1000 Table Z, and 1926.55 Appendix A so that the proposed TWA PEL and STEL would apply to all employers and employees in general industry, shipyards, and construction, including occupations where beryllium exists only as a trace contaminant. However, all other provisions of the standard would be in effect only for employers and employees that fall within the scope of the proposed rule. More detailed discussion of Regulatory Alternatives #1a, #1b, #2a, and #2b appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, Section XVIII of this preamble, Summary and Explanation, includes a discussion of paragraph (a) that describes the scope of the proposed rule, issues with the proposed scope, and Regulatory Alternatives #1a, #1b, #2a, and #2b.

Another regulatory alternative that would impact the scope of affected industries, extending eligibility for medical surveillance to employees in shipyards, construction, and parts of general industry excluded from the scope of the proposed standard, is discussed along with other medical surveillance alternatives later in this section (Regulatory Alternative #21) and in the discussion of paragraph (k) in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard.

Permissible Exposure Limits

OSHA has examined several regulatory alternatives that would modify the TWA PEL or STEL for the proposed rule. Under Regulatory Alternative #3, OSHA would adopt a STEL of 5 times the proposed PEL. Thus, this alternative STEL would be 1.0 $\mu g/m^3$ if OSHA adopts a PEL of 0.2 $\mu g/m^3$; it would be 0.5 $\mu g/m^3$ if OSHA adopts a PEL of 0.1 $\mu g/m^3$; and it would be 2.5 $\mu g/m^3$ if OSHA adopts a PEL of 0.5 $\mu g/m^3$ (see Regulatory Alternatives #4 and #5). Under Regulatory Alternative #4, the proposed PEL would be lowered from 0.2 $\mu g/m^3$ to 0.1 $\mu g/m^3$. Under Regulatory Alternative #5, the proposed PEL would be raised from 0.2 $\mu g/m^3$ to 0.5 $\mu g/m^3$. In addition, for informational purposes, OSHA examined a regulatory alternative that would maintain the TWA PEL at 2.0 $\mu g/m^3$, but all of the other proposed provisions would be required with their triggers remaining the same as in the proposed rule. This alternative is not one OSHA could legally adopt because the absence of a more protective requirement for engineering controls would not be consistent with section 6(b)(5) of the OSH Act. More detailed discussion of these alternatives to the proposed PEL appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, in Section XVIII of this preamble, Summary and Explanation of the Proposed Standard, the discussion of proposed paragraph (c) describes the proposed TWA PEL and STEL, issues with the proposed exposure limits, and Regulatory Alternatives #3, #4, and #5.

Methods of Compliance

The proposed standard would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the TWA PEL and STEL. Where engineering and work practice controls are insufficient to reduce exposures to or below the TWA PEL and STEL, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. In addition, for each operation where there is airborne beryllium exposure, the employer must ensure that one or more of the engineering and work practice controls listed in paragraph (f)(2) are in place, unless all of the listed controls are infeasible, or the employer can demonstrate that exposures are below the action level based on two samples taken seven days apart. Regulatory Alternative #6 would eliminate the engineering and work practice controls provision currently specified in paragraph (f)(2). This regulatory alternative does not eliminate the need for engineering controls to lower exposure levels to or below the TWA PEL and STEL; rather, it dispenses with the mandatory use of certain engineering controls that must be installed above the action level but at or below the TWA PEL.

More detailed discussion of Regulatory Alternative #6 appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of paragraph (f) in Section XVIII of this preamble, Summary and Explanation, provides a more detailed explanation of the proposed methods of compliance, issues with the proposed methods of compliance, and Regulatory Alternative #6.

Ancillary Provisions

The proposed rule contains several ancillary provisions, including requirements for exposure assessment, personal protective clothing and equipment (PPE), medical surveillance, medical removal, training, and regulated areas or access control. OSHA has examined a variety of regulatory alternatives involving changes to one or more of these ancillary provisions. OSHA has preliminarily determined that several of these ancillary provisions will increase the benefits of the proposed rule, for example, by helping to ensure the TWA PEL is not exceeded or by lowering the risks to workers given the significant risk remaining at the proposed TWA PEL. However, except for Regulatory Alternative #7 (involving the elimination of all ancillary provisions), OSHA did not estimate changes in monetized benefits for the regulatory alternatives that affect ancillary provisions. Two regulatory alternatives that involve all ancillary provisions are presented below (#7 and #8), followed by regulatory alternatives for exposure monitoring (#9, #10, and #11), for regulated areas (#12), for personal protective clothing and equipment (#13), for medical surveillance (#14 through #21), and for medical removal (#22).

All Ancillary Provisions

During the Small Business Regulatory Fairness Act (SBREFA) process conducted in 2007, the SBAR Panel recommended that OSHA analyze a PEL-only standard as a regulatory alternative. The Panel also recommended that OSHA consider applying ancillary provisions of the standard so as to minimize costs for small businesses where exposure levels are low (OSHA, 2008b). In response to these recommendations, OSHA analyzed Regulatory Alternative #7, a PEL-only standard, and Regulatory Alternative #8, which would only apply ancillary provisions of the beryllium standard at exposures above the proposed PEL of 0.2 μg/m³ or the proposed STEL of 2 μg/m³. Regulatory Alternative #7 would update the Z tables for § 1910.1000, so that the proposed TWA PEL and STEL would apply to all workers in general industry. All other provisions of the proposed standard would be dropped.

As indicated previously, OSHA has preliminarily determined that there is significant risk remaining at the proposed PEL of 0.2 μg/m³. However, the available evidence on feasibility suggests that 0.2 μg/m³ may be the lowest feasible PEL (see Chapter IV of the PEA, OSHA 2014). Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. In addition, the recommended standard provided to OSHA by representatives of the primary beryllium manufacturing industry and the Steelworkers Union further supports the importance of ancillary provisions in protecting workers from the harmful effects of beryllium exposure (Materion and USW, 2012).

Under Regulatory Alternative #8, several ancillary provisions that the current proposal would require under a variety of exposure conditions (*e.g.*, dermal contact; any airborne exposure; exposure at or above the action level) would instead only apply where exposure levels exceed the TWA PEL or STEL. Regulatory Alternative #8 affects the following provisions of the proposed standard:

—Exposure monitoring. Whereas the proposed standard requires annual monitoring where exposure levels are at or above the action level and at or below the TWA PEL, Alternative #8 would require annual exposure monitoring only where exposure levels exceed the TWA PEL or STEL;

— Written exposure control plan. Whereas the proposed standard requires written exposure control plans to be maintained in any facility covered by the standard, Alternative #8 would require only facilities with exposures above the TWA PEL or STEL to maintain a plan;

—PPE. Whereas the proposed standard requires PPE for employees under a variety of conditions, such as exposure to soluble beryllium or visible contamination with beryllium, Alternative #8 would require PPE only for employees exposed above the TWA PEL or STEL;

—Housekeeping. Whereas the proposed standard's housekeeping requirements apply across a wide variety of beryllium exposure conditions, Alternative #8 would limit housekeeping requirements to areas with exposures above the TWA PEL or STEL.

—Medical Surveillance. Whereas the proposed standard's medical surveillance provisions require employers to offer medical surveillance to employees with signs or symptoms of beryllium-related health effects regardless of their exposure level, Alternative #8 would make surveillance available to such employees only if they were exposed above the TWA PEL or STEL.

More detailed discussions of Regulatory Alternatives #7 and #8, including a description of the considerations pertinent to these alternatives, appear in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014).

Exposure Monitoring

OSHA has examined three regulatory alternatives that would modify the proposed standard's provisions on exposure monitoring, which require periodic monitoring annually where exposures are at or above the action level and at or below the TWA PEL. Under Regulatory Alternative #9, employers would be required to perform periodic exposure monitoring every 180 days where exposures are at or above the action level or above the STEL, and at or below the TWA PEL. Under Regulatory Alternative #10, employers would be required to perform periodic exposure monitoring every 180 days where exposures are at or above the action level or above the STEL, including where exposures exceed the TWA PEL. Under Regulatory Alternative #11, employers would be required to perform periodic exposure monitoring every 180 days where exposures are at or above the action level or above the STEL, and every 90 days where exposures exceed the TWA PEL. More detailed discussions of Regulatory Alternatives #9, #10, and #11 appear in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of proposed paragraph (d) in Section XVIII of this preamble, Summary and Explanation of the Proposed Standard, provides a more detailed explanation of the proposed requirements for exposure monitoring, issues with exposure monitoring, and the considerations pertinent to Regulatory Alternatives #9, #10, and #11.

Regulated Areas

The proposed standard would require employers to establish and maintain two types of areas: beryllium work areas, wherever employees are, or can reasonably be expected to be, exposed to any level of airborne beryllium; and regulated areas, wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. Employers are required to demarcate beryllium work areas, but are not required to restrict access to beryllium work areas or provide respiratory protection or other forms of PPE within work areas that are not also regulated areas. Employers must demarcate regulated areas, restrict access to them, post warning signs and provide respiratory protection and other PPE within regulated areas, as well as medical surveillance for employees who work in regulated areas for more than 30 days in a 12-month period. During the SBREFA process conducted in 2007, the SBAR Panel recommended that OSHA consider dropping or limiting the provision for regulated areas (OSHA, 2008b). In response to this recommendation, OSHA analyzed Regulatory Alternative #12, which would not require employers to establish regulated areas. More detailed discussion of Regulatory Alternative #12 appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of paragraph (e) in Section XVIII of this preamble, Summary and Explanation, provides a more detailed explanation of the proposed requirements for regulated areas, issues with regulated areas, and considerations pertinent to Regulatory Alternative #12.

Personal Protective Clothing and Equipment (PPE)

Regulatory Alternative #13 would modify the proposed requirements for PPE, which require PPE where exposure exceeds the TWA PEL or STEL; where employees' clothing or skin may become visibly contaminated with beryllium; and where employees may have skin contact with soluble beryllium compounds. The requirement to use PPE where work clothing or skin may become ''visibly contaminated'' with beryllium differs from prior standards that do not require contamination to be visible in order for PPE to be required. In the case of beryllium, which OSHA has preliminarily concluded can sensitize through dermal exposure, the exposure levels capable of causing adverse health effects and the PELs in effect are so low that beryllium surface contamination is unlikely to be visible (see this preamble at section V, Health Effects). OSHA is therefore considering Regulatory Alternative #13, which would require appropriate PPE wherever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. More detailed discussion of Regulatory Alternative #13 is provided in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of paragraph (h) in Section XVIII of this preamble, Summary and Explanation, provides a more detailed explanation of the proposed requirements for PPE, issues with PPE, and the considerations pertinent to Regulatory Alternative #13.

Medical Surveillance

The proposed requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are exposed to beryllium above the proposed PEL for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and (2) low-dose helical tomography (low-dose computed tomography, hereafter referred to as ''CT scans''), for employees who were exposed above the proposed PEL for more than 30 days in a 12-month period for 5 years or more. This type of CT scan is a method of detecting tumors, and is commonly used to diagnose lung cancer. The proposed standard would require periodic medical exams to be provided for employees in the medical surveillance program annually, while tests for beryllium sensitization and CT scans would be provided to eligible employees biennially.

OSHA has examined eight regulatory alternatives (#14 through #21) that would modify the proposed rule's requirements for employee eligibility, the types of exam that must be offered, and the frequency of periodic exams. Medical surveillance was a subject of special concern to SERs during the SBREFA process, and the SBREFA Panel offered many comments and recommendations related to medical surveillance for OSHA's consideration. Some of the Panel's concerns have been addressed in this proposal, which was modified since the SBREFA Panel was convened (see this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, for more detailed discussion). Several of the alternatives presented here (#16, #18, and #20) also respond to recommendations by the SBREFA Panel to reduce burdens on small businesses by dropping or reducing the frequency of medical surveillance requirements. OSHA also seeks to ensure that the requirements of the final standard offer workers adequate medical surveillance while limiting the costs to employers. Thus, OSHA requests feedback on several additional alternatives and on a variety of issues raised later in this section of the preamble.

Regulatory Alternatives #14, #15, and #21 would expand eligibility for medical surveillance to a broader group of employees than would be eligible in the proposed standard. Under Regulatory Alternative #14, medical surveillance would be available to employees who are exposed to beryllium above the proposed PEL, including employees exposed for fewer than 30 days per year. Regulatory Alternative #15 would expand eligibility for medical surveillance to employees who are exposed to beryllium above the proposed action level, including employees exposed for fewer than 30 days per year. Regulatory Alternative #21 would extend eligibility for medical surveillance as set forth in proposed paragraph (k) to all employees in shipyards, construction, and general industry who meet the criteria of proposed paragraph (k)(1) (or any of the alternative criteria under consideration). However, all other provisions of the standard would be in effect only for employers and employees that fall within the scope of the proposed rule.

Regulatory Alternatives #16 and #17 would modify the proposed standard's requirements to offer beryllium sensitization testing to eligible employees. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. Regulatory Alternative #17 would increase the frequency of periodic sensitization testing, from the proposed standard's biennial requirement to annual testing. Regulatory Alternatives #18 and #19 would similarly modify the proposed standard's requirements to offer CT scans to eligible employees. Regulatory Alternative #18 would drop the CT scan requirement from the proposed rule, whereas Regulatory Alternative #19 would increase the frequency of periodic CT scans from biennial to annual scans. Finally, under Regulatory Alternative #20, all periodic components of the medical surveillance exams would be available biennially to eligible employees. Instead of requiring employers to offer eligible employees a medical examination every year, employers would be required to offer eligible employees a medical examination every other year. The frequency of testing for beryllium sensitization and CT scans would also be biennial for eligible employees, as in the proposed standard.

More detailed discussions of Regulatory Alternatives #14, #15, #16, #17, #18, #19, #20, and #21 appear in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, Section XVIII of this preamble, Summary and Explanation, paragraph (k) provides a more detailed explanation of the proposed requirements for medical surveillance, issues with medical surveillance, and the considerations pertinent to Regulatory Alternatives #14 through #21.

Medical Removal Protection (MRP)

The proposed requirements for medical removal protection provide an option for medical removal to an employee who is working in a job with exposure at or above the action level and is diagnosed with CBD or confirmed positive for beryllium sensitization. If the employee chooses removal, the employer must either remove the employee to comparable work in a work environment where exposure is below the action level, or if comparable work is not available, must place the employee on paid leave for 6 months or until such time as comparable work becomes available. In either case, the employer must maintain for 6 months the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal. During the SBREFA process, the Panel recommended that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (OSHA, 2008b). In response to this recommendation, OSHA analyzed Regulatory Alternative #22, which would not require employers to offer MRP. More detailed discussion of Regulatory Alternative #22 appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of paragraph (l) in section XVIII of this preamble, Summary and Explanation, provides a more detailed explanation of the proposed requirements for MRP, issues with MRP, and considerations pertinent to Regulatory Alternative #22.

Timing of the Standard

The proposed standard would become effective 60 days following publication of the final standard in the **Federal Register**. The effective date is the date on which the standard imposes compliance obligations on employers. However, the standard would not become enforceable by OSHA until 90 days following the effective date for exposure monitoring, work areas and regulated areas, written exposure control plan, respiratory protection, other personal protective clothing and equipment, hygiene areas and practices (except change rooms), housekeeping, medical surveillance, and medical removal. The proposed requirement for change rooms would not be enforceable until one year after the effective date, and the requirements for engineering controls would not be enforceable until two years after the effective date. In summary, employers will have some period of time after the standard becomes effective to come into compliance before OSHA will begin enforcing it: 90 days for most provisions, one year for change rooms, and two years for engineering controls. Beginning 90 days following the effective date, during periods necessary to install or implement feasible engineering controls where exposure exceed the TWA PEL or STEL, employers must provide employees with respiratory protection as described in the proposed standard under section (g), Respiratory Protection.

OSHA invites comment and suggestions for phasing in requirements for engineering controls, medical surveillance, and other provisions of the standard. A longer phase-in time would have several advantages, such as reducing initial costs of the standard or allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However, a longer phase-in would also postpone and reduce the benefits of the standard. Suggestions for alternatives may apply to specific industries (*e.g.,* industries where first-year or annualized cost impacts are highest), specific size-classes of employers (*e.g.,* employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule.

OSHA requests comments on these regulatory alternatives, including the Agency's choice of regulatory alternatives (and whether there are other regulatory alternatives the Agency should consider) and the Agency's analysis of them. In addition, OSHA requests comments and information on a number of specific topics and issues pertinent to the proposed standard. These are summarized below.

Regulatory Issues

In this section, we solicit public feedback on issues associated with the proposed standard and request information that would help the Agency craft the final standard. In addition to the issues specified here, OSHA also raises issues for comment on technical questions and discussions of economic issues in the PEA (OSHA, 2014). OSHA requests comment on all relevant issues, including health effects, risk assessment, significance of risk, technological and economic feasibility, and the provisions of the proposed regulatory text. In addition, OSHA requests comments on all of the issues raised by the Small Business Advocacy Review (SBAR) Panel, as summarized in the SBAR report (OSHA, 2008b)

We present these issues and requests for information in the first chapter of the preamble to assist readers as they review the preamble and consider any comments they may want to submit. The issues are presented here in summary form. However, to fully understand the questions in this section and provide substantive input in response to them, the sections of the preamble relevant to these issues should be reviewed. These include: Section V, Health Effects; Section VI, the Preliminary Risk Assessment; Section VIII, Significance of Risk; Section IX, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis; and Section XVIII, Summary and Explanation of the Proposed Standard.

OSHA requests that comments be organized, to the extent possible, around the following issues and numbered questions. Comment on particular provisions should contain a heading setting forth the section and the paragraph in the proposed standard that the comment addresses. Comments addressing more than one section or paragraph will have correspondingly more headings.

Submitting comments in an organized manner and with clear reference to the issue raised will enable all participants to easily see what issues the commenter addressed and how they were addressed. Many commenters, especially small businesses, are likely to confine their comments to the issues that affect them, and they will benefit from being able to quickly identify comments on these issues in others' submissions. The Agency welcomes comments concerning all aspects of this proposal. However, OSHA is especially interested in responses, supported by evidence and reasons, to the following questions:

Health Effects

1. OSHA has described a variety of studies addressing the major adverse health effects that have been associated with exposure to beryllium. Using currently available epidemiologic and experimental studies, OSHA has made a preliminary determination that beryllium presents risks of lung cancer; sensitization; CBD at 0.1 $\mu g/m^3$; and at higher exposures acute beryllium disease, and hepatic, renal, cardiovascular and ocular diseases. Is this determination correct? Are there additional studies or other data OSHA should consider in evaluating any of these health outcomes?

2. Has OSHA adequately identified and documented all critical health impairments associated with occupational exposure to beryllium? If not, what other adverse health effects should be added? Are there additional studies or other data OSHA should consider in evaluating any of these health outcomes?

3. Are there any additional studies, other data, or information that would affect the information discussed or significantly change the determination of material health impairment?

Please submit any relevant information, data, or additional studies (or citations to studies), and explain your reasons for recommending any studies you suggest.

Risk Assessment and Significance of Risk

4. OSHA has developed an analysis of health risks associated with occupational beryllium exposure, including an analysis of sensitization and CBD based on a selection of recent

studies in the epidemiological literature, a data set on a population of beryllium machinists provided by the National Jewish Medical Research Center (NJMRC), and an assessment of lung cancer risk using an analysis provided by NIOSH. Did OSHA rely on the best available evidence in its risk assessment? Are there additional studies or other data OSHA should consider in evaluating risk for these health outcomes? Please provide the studies, citations to studies, or data you suggest.

5. OSHA preliminarily concluded that there is significant risk of material health impairment (lung cancer or CBD) from a working lifetime of occupational exposure to beryllium at the current TWA PEL of 2 μg/m³, which would be substantially reduced by the proposed TWA PEL of 0.2 μg/m³ and the alternative TWA PEL of 0.1 μg/m³. OSHA's preliminary risk assessment also concludes that there is still significant risk of CBD and lung cancer at the proposed PEL and the alternative PELs, although substantially less than at the current PEL. Are these preliminary conclusions reasonable, based on the best available evidence? If not, please provide a detailed explanation of your position, including data to support your position and a detailed analysis of OSHA's risk assessment if appropriate.

6. Please provide comment on OSHA's analysis of risk for beryllium sensitization, CBD and lung cancer. Are there important gaps or uncertainties in the analysis, such that the Agency's preliminary conclusions regarding significance of risk at the current, proposed, and alternative PELs may be in error? If so, please provide a detailed explanation and suggestions for how OSHA's analysis should be corrected or improved.

7. OSHA has made a preliminary determination that the available data are not sufficient or suitable for risk analysis of effects other than beryllium sensitization, CBD and lung cancer. Do you have, or are you aware of, studies or data that would be suitable for a risk assessment for these adverse health effects? Please provide the studies, citations to studies, or data you suggest.

(a) Scope

8. Has OSHA defined the scope of the proposed standard appropriately? Does it currently include employers who should not be covered, or exclude employers who should be covered by a comprehensive beryllium standard? Are you aware of employees in construction or maritime, or in general industry who deal with beryllium only as a trace contaminant, who may be at significant risk from occupational beryllium exposure? Please provide the basis for your response and any applicable supporting information.

(b) Definitions

9. Has OSHA defined the Beryllium lymphocyte proliferation test appropriately? If not, please provide the definition that you believe is appropriate. Please provide rationale and citations supporting your comments.

10. Has OSHA defined CBD Diagnostic Center appropriately? In particular, should a CBD diagnostic center be required to analyze biological samples on-site, or should diagnostic centers be allowed to send samples off-site for analysis? Is the list of tests and procedures a CBD Diagnostic Center is required to be able to perform appropriate? Should any of the tests or procedures be removed from the definition? Should other tests or procedures be added to the definition? Please provide rationale and information supporting your comments.

(d) Exposure Monitoring

11. Do you currently monitor for beryllium exposures in your workplace? If so, how often? Please provide the reasoning for the frequency of your monitoring. If periodic monitoring is performed at your workplace for exposures other than beryllium, with what frequency is it repeated?

12. Is it reasonable to allow discontinuation of monitoring based on one sample below the action level? Should more than one result below the action level be required to discontinue monitoring?

(e) Work Areas and Regulated Areas

The proposed standard would require employers to establish and maintain two types of areas: beryllium work areas, wherever employees are, or can reasonably be expected to be, exposed to any level of airborne beryllium; and regulated areas, wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. Employers are required to demarcate beryllium work areas, but are not required to restrict access to beryllium work areas or provide respiratory protection or other forms of PPE within work areas with exposures at or below the TWA PEL or STEL. Employers must also demarcate regulated areas, including posting warning signs; restrict access to regulated areas; and provide respiratory protection and other PPE within regulated areas.

13. Does your workplace currently have regulated areas? If so, how are regulated areas demarcated?

14. Please describe work settings where establishing regulated areas could be problematic or infeasible. If establishing regulated areas is problematic, what approaches might be used to warn employees in such work settings of high risk areas?

(f) Methods of Compliance

Paragraph (f)(2) of the proposed standard would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the TWA PEL and STEL. Where engineering and work practice controls are insufficient to reduce exposures to or below the TWA PEL and STEL, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. In addition, for each operation where there is airborne beryllium exposure, the employer must ensure that at least one of the engineering and work practice controls listed in paragraph (f)(2) is in place, unless all of the listed controls are infeasible, or the employer can demonstrate that exposures are below the action level based on no fewer than two samples taken seven days apart.

15. Do you usually use engineering or work practices controls (local exhaust ventilation, isolation, substitution) to reduce beryllium exposures? If so, which controls do you use?

16. Are the controls and processes listed in paragraph (f)(2)(i)(A) appropriate for controlling beryllium exposures? Are there additional controls or processes that should be added to paragraph (f)(2)(i)(A)?

(g) Respiratory Protection

17. OSHA's asbestos standard (CFR 1910.1001) requires employers to provide each employee with a tight-fitting, powered air-purifying respirator (PAPR) instead of a negative pressure respirator when the employee chooses to use a PAPR and it provides adequate protection to the employee. Should the beryllium standard similarly require employers to provide PAPRs (instead of allowing a negative pressure respirator) when requested by the employee? Are there other circumstances where a PAPR should be specified as the appropriate respiratory protection? Please provide the basis for your response and any applicable supporting information.

(h) Personal Protective Clothing and Equipment

18. Do you currently require specific PPE or respirators when employees are working with beryllium? If so, what type?

19. The proposal requires PPE wherever work clothing or skin may become visibly contaminated with beryllium; where employees' skin can reasonably be expected to be exposed to soluble beryllium compounds; or where employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL. The requirement to use PPE where work clothing or skin may become ''visibly contaminated'' with beryllium differs from prior standards which do not require contamination to be visible in order for PPE to be required. Is ''visibly contaminated'' an appropriate trigger for PPE? Is there reason to require PPE where employees' skin can be exposed to insoluble beryllium compounds? Please provide the basis for your response and any applicable supporting information.

(i) Hygiene Areas and Practices

20. The proposal requires employers to provide showers in their facilities if (A) Exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL; and (B) Beryllium can reasonably be expected to contaminate employees' hair or body parts other than hands, face, and neck. Is this requirement reasonable and adequately protective of beryllium-exposed workers? Should OSHA amend the provision to require showers in facilities where exposures exceed the PEL or STEL, without regard to areas of bodily contamination?

(j) Housekeeping

21. The proposed rule prohibits dry sweeping or brushing for cleaning surfaces in beryllium work areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of exposure have been tried and were not effective. Please comment on this provision. What methods do you use to clean work surfaces at your facility? Are HEPA-filtered vacuuming or other methods to minimize beryllium exposure used to clean surfaces at your facility? Have they been effective? Are there any circumstances under which dry sweeping or brushing are necessary? Please explain your response.

22. The proposed rule requires that materials designated for recycling that are visibly contaminated with beryllium particulate shall be cleaned to remove visible particulate, or placed in sealed, impermeable enclosures. However, small particles ($<10\ \mu g$) may not be visible to the naked eye, and there are studies suggesting that small particles may penetrate the skin, beyond which beryllium sensitization can occur (Tinkle et al., 2003). OSHA requests feedback on this provision. Should OSHA require that all material to be recycled be decontaminated regardless of perceived surface cleanliness? Should OSHA require that all material disposed or discarded be in enclosures regardless of perceived surface cleanliness? Please provide explanation or data to support your comments.

(k) Medical Surveillance

The proposed requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are exposed to beryllium above the proposed PEL for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and (2) CT scans for employees who were exposed above the proposed PEL for more than 30 days in a 12-month period for 5 years or more. The proposed standard would require periodic medical exams to be provided for employees in the medical surveillance program annually, while tests for beryllium sensitization and CT scans would be provided to eligible employees biennially.

23. Is medical surveillance being provided for beryllium-exposed employees at your worksite? If so:

a. Do you provide medical surveillance to employees under another OSHA standard or as a matter of company policy? What OSHA standard(s) does the program address?

b. How many employees are included, and how do you determine which employees receive medical surveillance (*e.g.*, by exposure level, other factors)?

c. Who administers and implements the medical surveillance (*e.g.*, company doctor, nurse practitioner, physician assistant, or nurse; or outside doctor, nurse practitioner, physician assistant, or nurse)?

d. What examinations, tests, or evaluations are included in the medical surveillance program, and with what frequency are they administered? Does your program include a surveillance program specifically for beryllium-related health effects (*e.g.*, the BeLPT or other tests for beryllium sensitization)?

e. If your facility offers the BeLPT, please provide feedback and data on your experience with the BeLPT, including the analytical or interpretive procedure you use and its role in your facility's exposure control program. Has identification of sensitized workers led to interventions to reduce exposures to sensitized individuals, or in the facility generally? If a worker is found to be sensitized, do you track worker health and possible progression of disease beyond sensitization? If so, how is this done?

f. What difficulties and benefits (*e.g.*, health, reduction in absenteeism, or financial) have you experienced with your medical surveillance program? If applicable, please discuss benefits and difficulties you have experienced with the use of the BeLPT, providing detailed information or examples if possible.

g. What are the costs of your medical surveillance program? How do your costs compare with OSHA's estimated unit costs for the physical examination and employee time involved in the medical surveillance program? Are OSHA's baseline assumptions and cost estimates for medical surveillance consistent with your experiences providing medical surveillance to your employees?

24. Please review paragraph (k) of the proposed rule, Medical Surveillance, and comment on the frequency and contents of medical surveillance in the proposed rule. Is 30 days from initial assignment a reasonable time at which to provide a medical exam? Should there be a requirement for beryllium sensitization testing at time of employment? Should there be a requirement for beryllium sensitization testing at an employee's exit exam, regardless of when the employee's most recent sensitization test was administered? Are the tests required and the testing frequencies specified appropriate? Should sensitized employees have the opportunity to be examined at a CBD Diagnostic Center more than once following a confirmed positive BeLPT? Are there additional tests or alternate testing schedules you would suggest? Should the skin be examined for signs and symptoms of beryllium exposure or other medical issues, as well as for breaks and wounds? Please explain the basis for your position and provide data or studies if applicable.

25. Please provide comments on the proposed requirements regarding referral of a sensitized employee to a CBD diagnostic center, which specify referral to a diagnostic center ''mutually agreed upon'' by the employer and employee. Is this requirement for mutual agreement necessary and appropriate? How should a diagnostic center be chosen if the employee and employer cannot come to agreement? Should OSHA consider alternate language, such as referral for CBD

evaluation at a diagnostic center in a reasonable location?

26. In the proposed rule, OSHA specifies that all medical examinations and procedures required by the standard must be performed by or under the direction of a licensed physician. Are physicians available in your geographic area to provide medical surveillance to workers who are covered by the proposed rule? Are other licensed health care professionals available to provide medical surveillance? Do you have access to other qualified personnel such as qualified X-ray technicians, and pulmonary specialists? Should the proposal be amended to allow examination by, or under the direction of, a physician or other licensed health care professional (PLHCP)? Please explain your position. Please note what you consider your geographic area in responding to this question.

27. The proposed standard requires the employer to obtain the Licensed Physician's Written Medical Opinion from the PLHCP within 30 days of the examination. Should OSHA revise the medical surveillance provisions of the proposed standard to allow employees to choose what, if any, medical information goes to the employer from the PLHCP? For example, the employer could instead be required to obtain a certification from the PLCHP within 30 days of the examination stating (1) when the examination took place, (2) that the examination complied with the standard, and (3) that the PLHCP provided the employee a copy of the Licensed Physician's Written Medical Opinion required by the standard. The PLHCP would need the employee's written consent to send the employer the Licensed Physician's Written Medical Opinion or any other medical information about the employee. This approach might lead to corresponding changes in proposed paragraphs (f)(1) (written exposure control program), (l) (medical removal) and (n) (recordkeeping) to reflect that employers will not automatically be receiving any medical information about employees as a result of the medical surveillance required by the proposed standard, but would instead only receive medical information the employee chooses to share with the employer. Please comment on the relative merits of the proposed standard's requirement that employers obtain the PLHCP's written opinion or an alternative that would provide employees with greater discretion over the information that goes to employers, and explain the basis for your position and the potential impact on the benefits of medical surveillance.

28. Appendix A to the proposed standard reviews procedures for conducting and interpreting the results of BeLPT testing for beryllium sensitization. Is there now, or should there be, a standard method for BeLPT laboratory procedure? If yes, please describe the existing or proposed method. Is there now, or should there be, a standard algorithm for interpreting BeLPT results to determine sensitization? Please describe the existing or proposed laboratory method or interpretation algorithm. Should OSHA require that BeLPTs performed to comply with the medical surveillance provisions of this rule adhere to the Department of Energy (DOE) analytical and interpretive specifications issued in 2001? Should interpretation of laboratory results be delegated to the employee's occupational physician or PLHCP?

29. Should OSHA require the clinical laboratories performing the BeLPT to be accredited by the College of American Pathologists or another accreditation organization approved under the Clinical Laboratory Improvement Amendments (CLIA)? What other standards, if any, should be required for clinical laboratories providing the BeLPT?

30. Are there now, or are there being developed, alternative tests to the BeLPT you would suggest? Please explain the reasons for your suggestion. How should alternative tests for beryllium sensitization be evaluated and validated? How should OSHA determine whether a test for beryllium sensitization is more reliable and accurate than the BeLPT? Please see Appendix A to the proposed standard for a discussion of the accuracy of the BeLPT.

31. The proposed rule requires employers to provide OSHA with the results of BeLPTs performed to comply with the medical surveillance provisions upon request, provided that the employer obtains a release from the tested employee. Will this requirement be unduly burdensome for employers? Are there alternative organizations that would be appropriate to send test results to?

(l) Medical Removal Protection

The proposed requirements for medical removal protection provide an option for medical removal to an employee who is working in a job with exposure at or above the action level and is diagnosed with CBD or confirmed positive for beryllium sensitization. If the employee chooses removal, the employer must remove the employee to comparable work in a work environment where exposure is below the action level, or if comparable work is not available, must place the employee on paid leave for 6 months or until such time as comparable work becomes available. In either case, the employer must maintain for 6 months the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

32. Do you provide MRP at your facility? If so, please comment on the program's benefits, difficulties, and costs, and the extent to which eligible employees make use of MRP.

33. OSHA has included requirements for medical removal protection (MRP) in the proposed rule, which includes provisions for medical removal for employees with beryllium sensitization or CBD, and an extension of removed employees' rights and benefits for six months. Are beryllium sensitization and CBD appropriate triggers for medical removal? Are there other medical conditions or findings that should trigger medical removal? For what amount of time should a removed employee's benefits be extended?

(p) Appendices

34. Some OSHA health standards include appendices that address topics such as the hazards associated with the regulated substance, health screening considerations, occupational disease questionnaires, and PLHCP obligations. In this proposed rule, OSHA has included a non-mandatory appendix to describe and discuss the BeLPT (Appendix A), and a non-mandatory appendix presenting a non-exhaustive list of engineering controls employers may use to comply with paragraph (f) (Appendix B). What would be the advantages and disadvantages of including each appendix in the final rule? What would be the advantages and disadvantages of providing this information in guidance materials?

35. What additional information, if any, should be included in the appendices? What additional information, if any, should be provided in guidance materials?

General

36. The current beryllium proposal includes triggers that require employers to initiate certain provisions, programs, and activities to protect workers from beryllium exposure. All employers covered under an OSHA health standard are required to initiate certain activities such as initial monitoring to evaluate the potential hazard to employees. OSHA health standards typically include ancillary provisions with various triggers indicating when an

employer covered under the standard would need to comply with a provision. The most common triggers are ones based an exposure level such as the PEL or action level. These exposure level triggers are sometimes combined with a minimum duration of exposure (*e.g.,* ≥ 30 days per year). Other triggers may include reasonably anticipated exposure, medical surveillance findings, certain work activities, or simply the presence of the regulated substance in the workplace.

For the current Proposal, exposures to beryllium above the TWA PEL or STEL trigger the provisions for regulated areas, additional or enhanced engineering or work practice controls to reduce airborne exposures to or below the TWA PEL and STEL, personal protective clothing and equipment, medical surveillance, showers, and respiratory protection if feasible engineering and work practice controls cannot reduce airborne exposures to or below the TWA PEL and STEL. Exposures at or above the action level in turn trigger the provisions for periodic exposure monitoring, and medical removal eligibility (along with a diagnosis of CBD or confirmed positive for beryllium sensitization). Finally, an employer covered under the scope of the proposed standard must establish a beryllium work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium regardless of the level of exposure. In beryllium work areas, employers must implement a written exposure control plan, provide washing facilities and change rooms (change rooms are only necessary if employees are required to remove their personal clothing), and follow housekeeping provisions. The employers must also implement at least one of the engineering and work practice controls listed in paragraph (f)(2) of the proposed standard. An employer is exempt from this requirement if he or she can demonstrate that such controls are not feasible or that exposures are below the action level.

Certain provisions are triggered by one condition and other provisions are triggered only if multiple conditions are present. For example, medical removal is only triggered if an employee has CBD or is confirmed positive AND the employee is exposed at or above the action level.

OSHA is requesting comment on the triggers in the proposed beryllium standard. Are the triggers OSHA has proposed appropriate? OSHA is also requesting comment on these triggers relative to the regulatory alternatives affecting the scope and PELs as described in this preamble in section I, Issues and Alternatives. For example, are the triggers in the proposed standard appropriate for Alternative #1a, which would expand the scope of the proposed standard to include all operations in general industry where beryllium exists only as a trace contaminant (less than 0.1% beryllium by weight)? Are the triggers appropriate for the alternatives that change the TWA PEL, STEL, and action level? Please specify the trigger and the alternative, if applicable, and why you agree or disagree with the trigger.

Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

37. In Section IX—Preliminary Economic Analysis under the *Initial Regulatory Flexibility Analysis,* OSHA identifies, to the extent practicable, all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule. One potential area of overlap is with the U.S. Department of Energy (DOE) beryllium program. In 1999, DOE established a chronic beryllium disease prevention program (CBDPP) to reduce the number of workers (DOE employees and DOE contractors) exposed to beryllium at DOE facilities (10 CFR part 850, published at 64 FR 68854–68914 (Dec. 8, 1999)). In establishing this program, DOE has exercised its statutory authority to prescribe and enforce occupational safety and health standards. Therefore pursuant to section 4(b)(1) of the OSH Act, 29 U.S.C. 653(b)(1), the DOE facilities are exempt from OSHA jurisdiction.

Nevertheless, under 10 CFR 850.22, DOE has included in its CBDPP regulation a requirement for compliance with the current OSHA permissible exposure limit (PEL), and any lower PEL that OSHA establishes in the future. Thus, although DOE has preempted OSHA's standard from applying at DOE facilities and OSHA cannot exercise any authority at those facilities, DOE relies on OSHA's PEL in implementing its own program. However, DOE's decision to tie its own standard to OSHA's PEL has little consequence to this rulemaking because the requirements in DOE's beryllium program (controls, medical surveillance, etc.) are triggered by DOE's action level of 0.2 μg/m^3, which is much lower than DOE's existing PEL and the same as OSHA's proposed PEL. DOE's action level is not tied to OSHA's standard, so 10 CFR 850.22 would not require the CBDPP's action level or any non-PEL requirements to be automatically adjusted as a result of OSHA's rulemaking. For this reason, DOE has indicated to OSHA that OSHA's proposed rule would not have any impact on DOE's CBDPP, particularly since 10 CFR 850.25(b), *Exposure reduction and minimization,* requires DOE contractors to reduce exposures to below the DOE's action level of 0.2 μg/m^3, if practicable.

DOE has expressed to OSHA that DOE facilities are already in compliance with 10 CFR 850 and its action level of 0.2 μg/m^3,[2] so the only potential impact on DOE's CBDPP that could flow from OSHA's rulemaking would be if OSHA ultimately adopted a PEL of 0.1 μg/m^3, as discussed in alternative #4, instead of the proposed PEL of 0.2 μg/m^3, and DOE did not make any additional adjustments to its standards. Even in that hypothetical scenario, the impact would still be limited because of the odd result that DOE's PEL would drop below its own action level, while the action level would continue to serve as the trigger for most of DOE's program requirements.

DOE also has noted some potential overlap with a separate DOE provision in 10 CFR part 851, which requires its contractors to comply with DOE's CBDPP (10 CFR 851.23(a)(1)) and also with all OSHA standards under 29 CFR part 1910 except ''Ionizing Radiation'' (§ 1910.1096) (10 CFR 851.23(a)(3)). These requirements, which DOE established in 2006 (71 FR 6858 (February 9, 2006)), make sense in light of OSHA's current regulation because OSHA's only beryllium protection is a PEL, so compliance with 10 CFR 851.23(a)(1) and (3) merely make OSHA's current PEL the relevant level for purposes of the CBDPP. However, its function would be less clear if OSHA adopts a beryllium standard as proposed. OSHA's proposed beryllium standard would establish additional substantive protections beyond the PEL. Consequently, notwithstanding the CBDPP's preemptive effect on the OSHA beryllium standard as a result of 29 U.S.C. 653(b)(1), 10 CFR 851.23(a)(3) could be read to require DOE contractors to comply with all provisions in OSHA's proposal (if finalized), including the ancillary provisions, creating a dual regulatory scheme for beryllium protection at DOE facilities.

DOE officials have indicated that this is not their intent. Instead, their intent is that DOE contractors comply solely with the CBDPP provisions in 10 CFR part 850 for protection from beryllium.

[2] This would mean the prevailing beryllium exposures at DOE facilities are at or below 0.2 μg/m^3.

Based on its discussions with DOE officials, OSHA anticipates that DOE will clarify that its contractors do not need to comply with any ancillary provisions in a beryllium standard that OSHA may promulgate.

OSHA can envision several potential scenarios developing from its rulemaking, ranging from OSHA retaining the proposed PEL of 0.2 μg/m³ and action level of 0.1 μg/m³ in the final rule to adopting the PEL of 0.1 μg/m³, as discussed in alternative #4. Because OSHA's beryllium standard does not apply directly to DOE facilities, and the only impact of its rules on those facilities is the result of DOE's regulatory choices, there is also a range of actions that DOE could take to minimize any potential impact of any change to OSHA's rules, including (1) taking no action at all, (2) simply clarifying the CBDPP, as described above, to mean that OSHA's beryllium standard (other than its PEL) does not apply to contractors, or (3) revising both parts 850 and 851 to completely disassociate DOE's regulation of beryllium at DOE facilities from OSHA's regulation of beryllium.

OSHA is aware that, in the preamble to its 1999 CBDPP rule, DOE analyzed the costs for implementing the CBDPP for action levels of 0.1 μg/m³, 0.2 μg/m³, and 0.5 μg/m³ (64 FR 68875, December 8, 1999). DOE estimated costs for periodic exposure monitoring, notifying workers of the results of such monitoring, exposure reduction and minimization, regulated areas, change rooms and showers, respiratory protection, protective clothing, and disposal of protective clothing. All of these provisions are triggered by DOE's action level (64 FR 68874, December 8, 1999). Although DOE's rule is not identical to OSHA's proposed standard, OSHA believes that DOE's costs are sufficiently representative to form the basis of a preliminary estimate of the costs that could flow from OSHA's standard, if finalized.

Based on the range of potential scenarios and the prior DOE cost estimates, OSHA estimates that the annual cost impact on DOE facilities could range from $0 to $4,065,768 (2010 dollars). The upper end of the cost range would reflect the unlikely scenario in which OSHA promulgates a final PEL of 0.1 μg/m³, 10 CFR 851.23(a)(3) is found to compel DOE contractors to comply with OSHA's comprehensive beryllium standard in addition to DOE's CBDPP, and DOE takes no action to clarify that OSHA's beryllium standard does not apply to DOE contractors. The lower end of the cost range assumes OSHA promulgates its rule as proposed with a PEL of 0.2 μg/m³ and action level of 0.1 μg/m³, and DOE clarifies that it intends its contractors to follow DOE's CBDPP and not OSHA's beryllium standard, so that the ancillary provisions of OSHA's beryllium standard do not apply to DOE facilities. Additionally, OSHA assumes that DOE contractors are in compliance with DOE's current rule and therefore took the difference in cost between implementation of an action level of 0.2 μg/m³ and an action level of 0.1 μg/m³ for the above estimates. Finally, OSHA used the GDP price deflator to present the cost estimate in 2010 dollars.

OSHA requests comment on the potential overlap of DOE's rule with OSHA's proposed rule.

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* (''the Act''), is to ''. . . assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b).

To achieve this goal Congress authorized the Secretary of Labor (the Secretary) to promulgate and enforce occupational safety and health standards. 29 U.S.C. 654(b) (requiring employers to comply with OSHA standards), 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of the Act's enactment), and 655(b) (authorizing promulgation, modification or revocation of standards pursuant to notice and comment).

The Act provides that in promulgating health standards dealing with toxic materials or harmful physical agents, such as this proposed standard regulating occupational exposure to beryllium, the Secretary, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. See 29 U.S.C. 655(b)(5).

The Supreme Court has held that before the Secretary can promulgate any permanent health or safety standard, he must make a threshold finding that significant risk is present and that such risk can be eliminated or lessened by a change in practices. *Industrial Union Dept., AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 641–42 (1980) (plurality opinion) (''*The Benzene case''*). Thus, section 6(b)(5) of the Act requires health standards to reduce significant risk to the extent feasible. *Id.*

The Court further observed that what constitutes ''significant risk'' is ''not a mathematical straitjacket'' and must be ''based largely on policy considerations.'' *The Benzene case,* 448 U.S. at 655. The Court gave the example that if,

> . . . the odds are one in a billion that a person will die from cancer . . . the risk clearly could not be considered significant. On the other hand, if the odds are one in one thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant. [*Id.*]

OSHA standards must be both technologically and economically feasible. *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1264 (D.C. Cir. 1980) (''The Lead I case''). The Supreme Court has defined feasibility as ''capable of being done.'' *Am. Textile Mfrs. Inst.* v. *Donovan,* 452 U.S. 490, 509–510 (1981) (''*The Cotton Dust case''*). The courts have further clarified that a standard is technologically feasible if OSHA proves a reasonable possibility,

> . . . within the limits of the best available evidence . . . that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations. [*See The Lead I case,* 647 F.2d at 1272]

With respect to economic feasibility, the courts have held that a standard is feasible if it does not threaten massive dislocation to or imperil the existence of the industry. *Id.* at 1265. A court must examine the cost of compliance with an OSHA standard,

> . . . in relation to the financial health and profitability of the industry and the likely effect of such costs on unit consumer prices . . . [T]he practical question is whether the standard threatens the competitive stability of an industry, . . . or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration. [*Id.* (citing *Indus. Union Dep't, AFL–CIO* v. *Hodgson,* 499 F.2d 467 (D.C. Cir. 1974))]

The courts have further observed that granting companies reasonable time to comply with new PELs may enhance economic feasibility. *The Lead I case* at 1265. While a standard must be economically feasible, the Supreme Court has held that a cost-benefit analysis of health standards is not required by the Act because a feasibility analysis is required. *The Cotton Dust case,* 453 U.S. at 509.

Finally, sections 6(b)(7) and 8(c) of the Act authorize OSHA to include among a standard's requirements labeling, monitoring, medical testing, and other information-gathering and -transmittal provisions. 29 U.S.C. 655(b)(7), 657(c).

III. Events Leading to the Proposed Standards

The first occupational exposure limit for beryllium was set in 1949 by the Atomic Energy Commission (AEC), which required that beryllium exposure in the workplaces under its jurisdiction be limited to 2 μg/m³ as an 8-hour time-weighted average (TWA), and 25 μg/m³ as a peak exposure never to be exceeded (Department of Energy, 1999). These exposure limits were adopted by all AEC installations handling beryllium, and were binding on all AEC contractors involved in the handling of beryllium.

In 1956, the American Industrial Hygiene Association (AIHA) published a Hygienic Guide which supported the AEC exposure limits. In 1959, the American Conference of Governmental Industrial Hygienists (ACGIH®) also adopted a Threshold Limit Value (TLV®) of 2 μg/m³ as an 8-hour TWA (Borak, 2006).

In 1971, OSHA adopted, under Section 6(a) of the Occupational Safety and Health Act of 1970, and made applicable to general industry, a national consensus standard (ANSI Z37.29–1970) for beryllium and beryllium compounds. The standard set a permissible exposure limit (PEL) for beryllium and beryllium compounds at 2 μg/m³ as an 8-hour TWA; 5 μg/m³ as an acceptable ceiling concentration; and 25 μg/m³ as an acceptable maximum peak above the acceptable ceiling concentration for a maximum duration of 30 minutes in an 8-hour shift (OSHA, 1971).

Section 6(a) stipulated that in the first two years after the effective date of the Act, OSHA was to promulgate ''start-up'' standards, on an expedited basis and without public hearing or comment, based on national consensus or established Federal standards that improved employee safety or health. Pursuant to that authority, in 1971, OSHA promulgated approximately 425 PELs for air contaminants, including beryllium, derived principally from Federal standards applicable to government contractors under the Walsh-Healey Public Contracts Act, 41 U.S.C. 35, and the Contract Work Hours and Safety Standards Act (commonly known as the Construction Safety Act), 40 U.S.C. 333. The Walsh-Healey Act and Construction Safety Act standards, in turn, had been adopted primarily from ACGIH®'s TLV®s.

The National Institute for Occupational Safety and Health (NIOSH) issued a document entitled *Criteria for a Recommended Standard: Occupational Exposure to Beryllium* (Criteria Document) in June 1972. OSHA reviewed the findings and recommendations contained in the Criteria Document along with the AEC control requirements for beryllium exposure. OSHA also considered existing data from animal and epidemiological studies, and studies of industrial processes of beryllium extraction, refinement, fabrication, and machining. In 1975, OSHA asked NIOSH to update the evaluation of the existing data pertaining to the carcinogenic potential of beryllium. In response to OSHA's request, the Director of NIOSH stated that, based on animal data and through all possible routes of exposure including inhalation, ''beryllium in all likelihood represents a carcinogenic risk to man.''

In October 1975, OSHA proposed a new beryllium standard for all industries based on information that beryllium caused cancer in animal experiments (40 FR 48814 (October 17, 1975)). Adoption of this proposal would have lowered the 8-hour TWA exposure limit from 2 μg/m³ to 1 μg/m³. In addition, the proposal included ancillary provisions for such topics as exposure monitoring, hygiene facilities, medical surveillance, and training related to the health hazards from beryllium exposure. The rulemaking was never completed.

In 1977, NIOSH recommended an exposure limit of 0.5 μg/m³ and identified beryllium as a potential occupational carcinogen. In December 1998, ACGIH published a Notice of Intended Change for its beryllium exposure limit. The notice proposed a lower TLV of 0.2 μg/m³ over an 8-hour TWA based on evidence of CBD and sensitization in exposed workers.

In 1999, the Department of Energy (DOE) issued a Chronic Beryllium Disease Prevention Program (CBDPP) Final Rule for employees exposed to beryllium in its facilities (DOE, 1999). The DOE rule set an action level of 0.2 μg/m³, and adopted OSHA's PEL of 2 μg/m³ or any more stringent PEL OSHA might adopt in the future. The DOE action level triggers workplace precautions and control measures such as periodic monitoring, exposure reduction or minimization, regulated areas, hygiene facilities and practices, respiratory protection, protective clothing and equipment, and warning signs (DOE, 1999).

Also in 1999, OSHA was petitioned by the Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) (OSHA, 2002) and by Dr. Lee Newman and Ms. Margaret Mroz, from the National Jewish Medical Research Center (NJMRC) (OSHA, 2002), to promulgate an Emergency Temporary Standard (ETS) for beryllium in the workplace. In 2001, OSHA was petitioned for an ETS by Public Citizen Health Research Group and again by PACE (OSHA, 2002). In order to promulgate an ETS, the Secretary of Labor must prove (1) that employees are exposed to grave danger from exposure to a hazard, and (2) that such an emergency standard is necessary to protect employees from such danger (29 U.S.C. 655(c)). The burden of proof is on the Department and because of the difficulty of meeting this burden, the Department usually proceeds when appropriate with 6(b) rulemaking rather than a 6(c) ETS. Thus, instead of granting the ETS requests, OSHA instructed staff to further collect and analyze research regarding the harmful effects of beryllium.

On November 26, 2002, OSHA published a Request for Information (RFI) for ''Occupational Exposure to Beryllium'' (OSHA, 2002). The RFI contained questions on employee exposure, health effects, risk assessment, exposure assessment and monitoring methods, control measures and technological feasibility, training, medical surveillance, and impact on small business entities. In the RFI, OSHA expressed concerns about health effects such as CBD, lung cancer, and beryllium sensitization. OSHA pointed to studies indicating that even short-term exposures below OSHA's PEL of 2 μg/m³ could lead to CBD. The RFI also cited studies describing the relationship between beryllium sensitization and CBD (67 FR at 70708). In addition, OSHA stated that beryllium had been identified as a carcinogen by organizations such as NIOSH, the International Agency for Research on Cancer (IARC), and the Environmental Protection Agency (EPA); and cancer had been evidenced in animal studies (67 FR at 70709).

On November 15, 2007, OSHA convened a Small Business Advocacy Review Panel for a draft proposed standard for occupational exposure to beryllium. OSHA convened this panel under Section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*).

The Panel included representatives from OSHA, the Solicitor's Office of the Department of Labor, the Office of Advocacy within the Small Business Administration, and the Office of Information and Regulatory Affairs of the Office of Management and Budget. Small Entity Representatives (SERs) made oral and written comments on the draft rule and submitted them to the panel.

The SBREFA Panel issued a report which included the SERs' comments on January 15, 2008. SERs expressed concerns about the impact of the ancillary requirements such as exposure monitoring and medical surveillance. Their comments addressed potential costs associated with compliance with the draft standard, and possible impacts of the standard on market conditions, among other issues. In addition, many SERs sought clarification of some of the ancillary requirements such as the meaning of ''routine'' contact or ''contaminated surfaces.''

The SBREFA Panel issued a number of recommendations, which OSHA carefully considered. In section XVIII of this preamble, Summary and Explanation, OSHA has responded to the Panel's recommendations and clarified the requirements about which SERs expressed confusion. OSHA also examined the regulatory alternatives recommended by the SBREFA Panel. The regulatory alternatives examined by OSHA are listed in section I of this preamble, Issues and Alternatives. The alternatives are discussed in greater detail in section XVIII of this preamble, Summary and Explanation, and in the PEA (OSHA, 2014). In addition, the Agency intends to develop interpretive guidance documents following the publication of a final rule.

In 2010, OSHA hired a contractor to oversee an independent scientific peer review of a draft preliminary beryllium health effects evaluation (OSHA, 2010a) and a draft preliminary beryllium risk assessment (OSHA, 2010b). The contractor identified experts familiar with beryllium health effects research and ensured that these experts had no conflict of interest or apparent bias in performing the review. The contractor selected five experts with expertise in such areas as pulmonary and occupational medicine, CBD, beryllium sensitization, the BeLPT, beryllium toxicity and carcinogenicity, and medical surveillance. Other areas of expertise included animal modeling, occupational epidemiology, biostatistics, risk and exposure assessment, exposure-response modeling, beryllium exposure assessment, industrial hygiene, and occupational/environmental health engineering.

Regarding the health effects evaluation, the peer reviewers concluded that the health effect studies were described accurately and in sufficient detail, and OSHA's conclusions based on the studies were reasonable. The reviewers agreed that the OSHA document covered the significant health endpoints related to occupational beryllium exposure. Peer reviewers considered the preliminary conclusions regarding beryllium sensitization and CBD to be reasonable and well presented in the draft health evaluation section. All reviewers agreed that the scientific evidence supports sensitization as a necessary condition in the development of CBD. In response to reviewers' comments, OSHA made revisions to more clearly describe certain sections of the health effects evaluation. In addition, OSHA expanded its discussion regarding the BeLPT.

Regarding the preliminary risk assessment, the peer reviewers were highly supportive of the Agency's approach and major conclusions. The peer reviewers stated that the key studies were appropriate and their selection clearly explained in the document. They regarded the preliminary analysis of these studies to be reasonable and scientifically sound. The reviewers supported OSHA's conclusion that substantial risk of sensitization and CBD were observed in facilities where the highest exposure generating processes had median full-shift exposures around 0.2 μg/m^3 or higher, and that the greatest reduction in risk was achieved when exposures for all processes were lowered to 0.1 μg/m^3 or below.

In February 2012 the Agency received for consideration a draft recommended standard for beryllium (Materion and USW, 2012). This draft proposal was the product of a joint effort between two stakeholders: Materion Corporation, a leading producer of beryllium and beryllium products in the United States, and the United Steelworkers, an international labor union representing workers who manufacture beryllium alloys and beryllium-containing products in a number of industries. The United Steelworkers and Materion sought to craft an OSHA-like model beryllium standard that would have support from both labor and industry. OSHA has considered this proposal along with other information submitted during the development of the Notice of Proposed Rulemaking for beryllium.

IV. Chemical Properties and Industrial Uses

Chemical and Physical Properties

Beryllium (Be; CAS Number 7440–41–7) is a silver-grey to greyish-white, strong, lightweight, and brittle metal. It is a Group IIA element with an atomic weight of 9.01, atomic number of 4, melting point of 1,287 °C, boiling point of 2,970°C, and a density of 1.85 at 20 °C (NTP 2014). It occurs naturally in rocks, soil, coal, and volcanic dust (ATSDR, 2002). Beryllium is insoluble in water and soluble in acids and alkalis. It has two common oxidation states, Be(0) and Be(+2). There are several beryllium compounds with unique CAS numbers and chemical and physical properties. Table IV–1 describes the most common beryllium compounds.

TABLE IV—1, PROPERTIES OF BERYLLIUM AND BERYLLIUM COMPOUNDS

Chemical name	CAS No.	Synonyms and trade names	Molecular weight	Melting point (°C)	Description	Density (g/cm3)	Solubility
Beryllium metal	7440–41–7	Beryllium; beryllium-9, beryllium element; beryllium metallic.	9.0122	1287	Grey, close-packed, hexagonal, brittle metal.	1.85 (20 °C).	Soluble in most dilute acids and alkali; decomposes in hot water; insoluble in mercury and cold water.
Beryllium chloride.	7787–47–5	Beryllium dichloride.	79.92	399.2	Colorless to slightly yellow; orthorhombic, deliquescent crystal.	1.899 (25 °C).	Soluble in water, ethanol, diethyl ether and pyridine; slightly soluble in benzene, carbon disulfide and chloroform; insoluble in acetone, ammonia, and toluene.

TABLE IV—1, PROPERTIES OF BERYLLIUM AND BERYLLIUM COMPOUNDS—Continued

Chemical name	CAS No.	Synonyms and trade names	Molecular weight	Melting point (°C)	Description	Density (g/cm3)	Solubility
Beryllium fluoride.	7787–49–7 (12323–05–6)	Beryllium difluoride.	47.01	555	Colorless or white, amorphous, hygroscopic solid.	1.986	Soluble in water, sulfuric acid, mixture of ethanol and diethyl ether; slightly soluble in ethanol; insoluble in hydrofluoric acid.
Beryllium hydroxide.	13327–32–7 (1304–49–0)	Beryllium dihydroxide.	43.3	138 (decomposes to beryllium oxide).	White, amorphous, amphoteric powder.	1.92	Soluble in hot concentrated acids and alkali; slightly soluble in dilute alkali; insoluble in water.
Beryllium sulfate	13510–49–1	Sulfuric acid, beryllium salt (1:1).	105.07	550–600 °C (decomposes to beryllium oxide).	Colorless crystal	2.443	Forms soluble tetrahydrate in hot water; insoluble in cold water.
Beryllium sulfate tetrhydrate.	7787–56–6	Sulfuric acid; beryllium salt (1:1), tetrahydrate.	177.14	100 °C	Colorless, tetragonal crystal.	1.713	Soluble in water; slightly soluble in concentrated sulfuric acid; insoluble in ethanol.
Beryllium Oxide	1304–56–9	Beryllia; beryllium monoxide thermalox TM.	25.01	2508–2547 °C	Colorless to white, hexagonal crystal or amorphous, amphoteric powder.	3.01 (20 °C).	Soluble in concentrated acids and alkali; insoluble in water.
Beryllium carbonate.	1319–43–3	Carbonic acid, beryllium salt, mixture with beryllium hydroxide.	112.05	No data	White powder	No data	Soluble in acids and alkali; insoluble in cold water; decomposes in hot water.
Beryllium nitrate trihydrate.	7787–55–5	Nitric acid, beryllium salt, trihydrate.	187.97	60	White to faintly yellowish, deliquescent mass.	1.56	Very soluble in water and ethanol.
Beryllium phosphate.	13598–15–7	Phosphoric acid, beryllium salt (1:1).	104.99	No data	Not reported	Not reported.	Slightly soluble in water.

ATSDR, 2002.

The physical and chemical properties of beryllium were realized early in the 20th century, and it has since gained commercial importance in a wide range of industries. Beryllium is lightweight, hard, spark resistant, non-magnetic, and has a high melting point. It lends strength, electrical and thermal conductivity, and fatigue resistance to alloys (NTP, 2014). Beryllium also has a high affinity for oxygen in air and water, which can cause a thin surface film of beryllium oxide to form on the bare metal, making it extremely resistant to corrosion. These properties make beryllium alloys highly suitable for defense, nuclear, and aerospace applications (IARC, 1993).

There are approximately 45 mineralized forms of beryllium. In the United States, the predominant mineral form mined commercially and refined into pure beryllium and beryllium alloys is bertrandite. Bertrandite, while containing less than 1% beryllium compared to 4% in beryl, is easily and efficiently processed into beryllium hydroxide (IARC, 1993). Imported beryl is also converted into beryllium hydroxide as the United States has very little beryl that can be economically mined (USGS, 2013a).

Industrial Uses

Materion Corporation, formerly called Brush Wellman, is the only producer of primary beryllium in the United States. Beryllium is used in a variety of industries, including aerospace, defense, telecommunications, automotive, electronic, and medical specialty industries. Pure beryllium metal is used in a range of products such as X-ray transmission windows, nuclear reactor neutron reflectors, nuclear weapons, precision instruments, rocket propellants, mirrors, and computers (NTP, 2014). Beryllium oxide is used in components such as ceramics, electrical insulators, microwave oven components, military vehicle armor, laser structural components, and automotive ignition systems (ATSDR, 2002). Beryllium oxide ceramics are used to produce sensitive electronic items such as lasers and satellite heat sinks.

Beryllium alloys, typically beryllium/copper or beryllium/aluminum, are manufactured as high beryllium content or low beryllium content alloys. High content alloys contain greater than 30% beryllium. Low content alloys are typically less than 3% beryllium. Beryllium alloys are used in automotive electronics (*e.g.,* electrical connectors and relays and audio components), computer components, home appliance parts, dental appliances (*e.g.,* crowns), bicycle frames, golf clubs, and other articles (NTP, 2014; Ballance et al., 1978; Cunningham et al., 1998; Mroz, et al., 2001). Electrical components and conductors are stamped and formed from beryllium alloys. Beryllium-copper alloys are used to make switches in automobiles (Ballance et al., 1978, 2002; Cunningham et al., 1998) and connectors, relays, and switches in computers, radar, satellite, and telecommunications equipment (Mroz et al., 2001). Beryllium-aluminum alloys are used in the construction of aircraft, high resolution medical and industrial X-ray equipment, and mirrors to measure weather patterns (Mroz et al., 2001). High content and low content beryllium alloys are precision machined for military and aerospace applications. Some welding consumables are also manufactured using beryllium.

Beryllium is also found as a trace metal in materials such as aluminum ore, abrasive blasting grit, and coal fly ash. Abrasive blasting grits such as coal slag and copper slag contain varying concentrations of beryllium, usually less than 0.1% by weight. The burning of bituminous and sub-bituminous coal for power generation causes the naturally occurring beryllium in coal to accumulate in the coal fly ash byproduct. Scrap and waste metal for smelting and refining may also contain beryllium. A detailed discussion of the industries and job tasks using beryllium is included in the Preliminary Economic Analysis (OSHA, 2014).

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

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

V. Health Effects

Beryllium-associated health effects, including acute beryllium disease (ABD), beryllium sensitization (also referred to in this preamble as ''sensitization''), chronic beryllium disease (CBD), and lung cancer, can lead to a number of highly debilitating and life-altering conditions including pneumonitis, loss of lung capacity (reduction in pulmonary function leading to pulmonary dysfunction), loss of physical capacity associated with reduced lung capacity, systemic effects related to pulmonary dysfunction, and decreased life expectancy (NIOSH, 1972).

This Health Effects section presents information on beryllium and its compounds, the fate of beryllium in the body, research that relates to its toxic mechanisms of action, and the scientific literature on the adverse health effects associated with beryllium exposure, including ABD, sensitization, CBD, and lung cancer. OSHA considers CBD to be a progressive illness with a continuous spectrum of symptoms ranging from no symptomatology at its earliest stage following sensitization to mild symptoms such as a slight almost imperceptible shortness of breath, to loss of pulmonary function, debilitating lung disease, and, in many cases, death. This section also discusses the nature of these illnesses, the scientific evidence that they are causally associated with occupational exposure to beryllium, and the probable mechanisms of action with a more thorough review of the supporting studies.

A. Beryllium and Beryllium Compounds

1. Particle Physical/Chemical Properties

Beryllium (Be; CAS No. 7440–41–7) is a steel-grey, brittle metal with an atomic number of 4 and an atomic weight of 9.01 (Group IIA of the periodic table). Because of its high reactivity, beryllium is not found as a free metal in nature; however, there are approximately 45 mineralized forms of beryllium. Beryllium compounds and alloys include commercially valuable metals and gemstones.

Beryllium has two oxidative states: Be(0) and Be(2^+) Agency for Toxic Substance and Disease Registry (ATSDR) 2002). It is likely that the Be(2^+) state is the most biologically reactive and able to form a bond with peptides leading to it becoming antigenic (Snyder *et al.,* 2003). This will be discussed in more detail in the Beryllium Sensitization section below. Beryllium has a high charge-to-radius ratio and in addition to forming various types of ionic bonds, beryllium has a strong tendency for covalent bond formation (*e.g.,* it can form organometallic compounds such as $Be(CH_3)_2$ and many other complexes) (ATSDR, 2002; Greene *et al.,* 1998). However, it appears that few, if any, toxicity studies exist for the organometallic compounds. Additional physical/chemical properties for beryllium compounds that may be important in their biological response are summarized in Table 1 below. This information was obtained from their International Chemical Safety Cards (ICSC) (beryllium metal (ICSC 0226), beryllium oxide (ICSC 1325), beryllium sulfate (ICSC 1351), beryllium nitrate (ICSC 1352), beryllium carbonate (ICSC 1353), beryllium chloride (ICSC 1354), beryllium fluoride (ICSC 1355)) and from the hazardous substance data bank (HSDB) for beryllium hydroxide (CASRN: 13327–32–7), and beryllium phosphate (CASRN: 13598–15–7). Additional information on chemical and physical properties as well as industrial uses for beryllium can be found in this preamble at Section IV, Chemical Properties and Industrial Uses.

TABLE 1—PHYSICAL/CHEMICAL PROPERTIES OF BERYLLIUM AND COMPOUNDS

Compound name	Physical appearance	Chemical formula	Molecular mass	Acute physical hazards	Solubility in water at 20 °C
Beryllium Metal	Grey to White Powder.	Be	9.0	Combustible; Finely dispersed particles—Explosive.	None.
Beryllium Oxide	White Crystals or Powder.	BeO	25.0	Not combustible or explosive	Very sparingly soluble.
Beryllium Carbonate	White Powder	$Be_2CO_3(OH)/Be_2CO_5H_2$.	181.07	Not combustible or explosive	None.
Beryllium Sulfate	Colorless Crystals	$BeSO_4$	105.1	Not combustible or explosive	Slightly soluble.
Beryllium Nitrate	White to Yellow Solid.	$BeN_2O_6/Be(NO_3)_2$	133.0	Enhances combustion of other substances.	Very soluble (1.66 $\times 10^6$ mg/L).
Beryllium Hydroxide	White amorphous powder or crystalline solid.	$Be(OH)_2$	43.0	Not reported	Slightly soluble 0.8 $\times 10^{-4}$ mol/L (3.44 mg/L).
Beryllium Chloride	Colorless to Yellow Crystals.	$BeCl_2$	79.9	Not combustible or explosive	Soluble.
Beryllium Fluoride	Colorless Lumps	BeF_2	47.0	Not combustible or explosive	Very soluble.

TABLE 1—PHYSICAL/CHEMICAL PROPERTIES OF BERYLLIUM AND COMPOUNDS—Continued

Compound name	Physical appearance	Chemical formula	Molecular mass	Acute physical hazards	Solubility in water at 20 °C
Beryllium Phosphate	White solid	$Be_3(PO_4)_2$	271.0	Not reported	Soluble.

Source: International Chemical Safety Cards (except beryllium phosphate and hydroxide—HSDB).

Beryllium shows a high affinity for oxygen in air and water, resulting in a thin surface film of beryllium oxide on the bare metal. If the surface film is disturbed, it may become airborne or dermal exposure may occur. The solubility, particle surface area, and particle size of some beryllium compounds are examined in more detail below. These properties have been evaluated in many toxicological studies. In particular, the properties related to the calcination (firing temperatures) and differences in crystal size and solubility are important aspects in their toxicological profile.

2. Factors Affecting Potency and Effect of Beryllium Exposure

The effect and potency of beryllium and its compounds, as for any toxicant, immunogen, or immunotoxicant, may be dependent upon the physical state in which they are presented to a host. For occupational airborne materials and surface contaminants, it is especially critical to understand those physical parameters in order to determine the extent of exposure to the respiratory tract and skin since these are generally the initial target organs for either route of exposure.

For example, large particles may have less of an effect in the lung than smaller particles due to reduced potential to stay airborne to be inhaled or be deposited along the respiratory tract. In addition, once inhalation occurs particle size is critical in determining where the particle will deposit along the respiratory tract. Solubility also has an important part in determining the toxicity and bioavailability of airborne materials as well. Respiratory tract retention and skin penetration are directly influenced by the solubility and reactivity of airborne material.

These factors may be responsible, at least in part, for the process by which beryllium sensitization progresses to CBD in exposed workers. Other factors influencing beryllium-induced toxicity include the surface area of beryllium particles and their persistence in the lung. With respect to dermal exposure, the physical characteristics of the particle are important as well since they can influence skin absorption and bioavailability. This section addresses certain physical characteristics (*i.e.*, solubility, particle size, particle surface area) that are important in influencing the toxicity of beryllium materials in occupational settings.

a. Solubility

Solubility may be an important determinant of the toxicity of airborne materials, influencing the deposition and persistence of inhaled particles in the respiratory tract, their bioavailability, and the likelihood of presentation to the immune system. A number of chemical agents, including metals that contact and penetrate the skin, are able to induce an immune response, such as sensitization (Boeniger, 2003; Mandervelt *et al.*, 1997). Similar to inhaled agents, the ability of materials to penetrate the skin is also influenced by solubility since dermal absorption may occur at a greater rate for soluble materials than insoluble materials (Kimber *et al.*, 2011).

This section reviews the relevant information regarding solubility, its importance in a biological matrix and its relevance to sensitization and beryllium lung disease. The weight of evidence presented below suggests that both soluble and non-soluble forms of beryllium can induce a sensitization response and result in progression of lung disease.

Beryllium salts, including the chloride ($BeCl_2$), fluoride (BeF_2), nitrate ($Be(NO_3)_2$), phosphate ($Be_3(PO_4)_2$), and sulfate (tetrahydrate) ($BeSO_4 \cdot 4H_2O$) salts, are all water soluble. However, soluble beryllium salts can be converted to less soluble forms in the lung (Reeves and Vorwald, 1967). Aqueous solutions of the soluble beryllium salts are acidic as a result of the formation of $Be(OH_2)_4$ 2^+, the tetrahydrate, which will react to form insoluble hydroxides or hydrated complexes within the general physiological range of pH values (between 5 and 8) (EPA, 1998). This may be an important factor in the development of CBD since lower-solubility forms of beryllium have been shown to persist in the lung for longer periods of time and persistence in the lung may be needed in order for this disease to occur (NAS, 2008).

Beryllium oxide (BeO), hydroxide ($Be(OH)_2$), carbonate ($Be_2CO_3(OH)_2$), and sulfate (anhydrous) ($BeSO_4$) are either insoluble, slightly soluble, or considered to be sparingly soluble (almost insoluble or having an extremely slow rate of dissolution). The solubility of beryllium oxide, which is prepared from beryllium hydroxide by calcining (heating to a high temperature without fusing in order to drive off volatile chemicals) at temperatures between 500 and 1,750 °C, has an inverse relationship with calcination temperature. Although the solubility of the low-fired crystals can be as much as 10 times that of the high-fired crystals, low-fired beryllium oxide is still only sparingly soluble (Delic, 1992). In a study that measured the dissolution kinetics (rate to dissolve) of beryllium compounds calcined at different temperatures, Hoover *et al.*, compared beryllium metal to beryllium oxide particles and found them to have similar solubilities. This was attributed to a fine layer of beryllium oxide that coats the metal particles (Hoover *et al.*, 1989). A study conducted by Deubner *et al.*, (2011) determined ore materials to be more soluble than beryllium oxide at pH 7.2 but similar in solubility at pH 4.5. Beryllium hydroxide was more soluble than beryllium oxide at both pHs (Deubner *et al.*, 2011).

Investigators have also attempted to determine how biological fluids can dissolve beryllium materials. In two studies, insoluble beryllium, taken up by activated phagocytes, was shown to be ionized by myeloperoxidases (Leonard and Lauwerys, 1987; Lansdown, 1995). The positive charge resulting from ionization enabled the beryllium to bind to receptors on the surface of cells such as lymphocytes or antigen-presenting cells which could make it more biologically active (NAS, 2008). In a study utilizing phagolysosomal-simulating fluid (PSF) with a pH of 4.5, both beryllium metal and beryllium oxide dissolved at a greater rate than that previously reported in water or SUF (simulant fluid) (Stefaniak *et al.*, 2006), and the rate of dissolution of the multi-constituent (mixed) particles was greater than that of the single-constituent beryllium oxide powder. The authors speculated that copper in the particles rapidly dissolves, exposing the small inclusions of beryllium oxide, which have higher specific surface areas (SSA) and therefore dissolve at a higher rate. A follow-up study by the same investigational team (Duling *et al.*, 2012) confirmed dissolution of beryllium oxide by PSF and determined the release rate was biphasic (initial rapid diffusion followed by a latter slower surface reaction-driven release). During the latter phase, dissolution half-times were 1,400 to 2,000 days. The authors speculated this indicated bertrandite was persistent in the lung (Duling *et al.*, 2012).

In a recent study investigating the dissolution and release of beryllium ions for 17 beryllium-containing materials (ore, hydroxide, metal, oxide, alloys, and processing intermediates) using artificial human airway epithelial lining fluid, Stefaniak *et al.*, (2011) found release of beryllium ions within 7 days (beryl ore melter dust). The authors calculated dissolution half-times ranging from 30 days (reduction furnace material) to 74,000 days (hydroxide). Stefaniak *et al.*, (2011) speculated that despite the rapid mechanical clearance, billions of beryllium ions could be released in the respiratory tract via dissolution in airway lining fluid (ALF). Under this scenario beryllium-containing particles depositing in the respiratory tract dissolving in ALF could provide beryllium ions for absorption in the lung and interact with immune cells in the respiratory tract (Stefaniak *et al.*, 2011).

Huang *et al.*, (2011) investigated the effect of simulated lung fluid (SLF) on dissolution and nanoparticle generation and beryllium-containing materials. Bertrandite-containing ore, beryl-containing ore, frit (a processing intermediate), beryllium hydroxide (a processing intermediate) and silica (used as a control), were equilibrated in SLF at two pH values (4.5 and 7.2) to reflect inter- and intra-cellular environments in the lung tissue. Concentrations of beryllium, aluminum, and silica ions increased linearly during the first 20 days in SLF, rose slowly thereafter, reaching equilibrium over time. The study also found nanoparticle formation (in the size range of 10–100 nm) for all materials (Huang *et al.*, 2011).

In an *in vitro* skin model, Sutton *et al.*, (2003) demonstrated the dissolution of beryllium compounds (insoluble beryllium hydroxide, soluble beryllium phosphate) in a simulated sweat fluid. This model showed beryllium can be dissolved in biological fluids and be available for cellular uptake in the skin. Duling *et al.*, (2012) confirmed dissolution and release of ions from bertrandite ore in an artificial sweat model (pH 5.3 and pH 6.5).

b. Particle Size

The toxicity of beryllium as exemplified by beryllium oxide also is dependent, in part, on the particle size, with smaller particles (<10 µm) able to penetrate beyond the larynx (Stefaniak *et al.*, 2008). Most inhalation studies and occupational exposures involve quite small (<1–2 µm) beryllium oxide particles that can penetrate to the pulmonary regions of the lung (Stefaniak *et al.*, 2008). In inhalation studies with beryllium ores, particle sizes are generally much larger, with deposition occurring in several areas throughout the respiratory tract for particles <10 µm.

The temperature at which beryllium oxide is calcined influences its particle size, surface area, solubility, and ultimately its toxicity (Delic, 1992). Low-fired (500 °C) beryllium oxide is predominantly made up of poorly crystallized small particles, while higher firing temperatures (1000—1750 °C) result in larger particle sizes (Delic, 1992).

In order to determine the extent to which particle size plays a role in the toxicity of beryllium in occupational settings, several key studies are reviewed and detailed below. The findings on particle size have been related, where possible, to work process and biologically relevant toxicity endpoints of either sensitization or CBD.

Numerous studies have been conducted evaluating the particle size generated during basic industrial and machining operations. In a study by Cohen *et al.*, (1983), a multi-cyclone sampler was utilized to measure the size mass distribution of the beryllium aerosol at a beryllium-copper alloy casting operation. Briefly, Cohen *et al.*, (1983) found variable particle size generation based on the operations being sampled with particle size ranging from 3 to 16 µm. Hoover *et al.*, (1990) also found variable particle sizes being generated based on operations. In general, Hoover *et al.*, (1990) found that milling operations generated smaller particle sizes than sawing operations. Hoover *et al.*, (1990) also found that beryllium metal generated higher concentrations than metal alloys. Martyny *et al.*, (2000) characterized generation of particle size during precision beryllium machining processes. The study found that more than 50 percent of the beryllium machining particles collected in the breathing zone of machinists were less than 10 µm in aerodynamic diameter with 30 percent of that fraction being particles of less than 0.6 µm. A study by Thorat *et al.*, (2003) found similar results with ore mixing, crushing, powder production and machining ranging from 5.0 to 9.5 µm. Kent *et al.*, (2001) measured airborne beryllium using size-selective samplers in five furnace areas at a beryllium processing facility. A statistically significant linear trend was reported between the above alveolar-deposited particle mass concentration and prevalence of CBD and sensitization in the furnace production areas. The study authors suggested that the concentration of alveolar-deposited particles (*e.g.*, <3.5 µm) may be a better predictor of sensitization and CBD than the total mass concentration of airborne beryllium.

A recent study by Virji et al. (2011) evaluated particle size distribution, chemistry and solubility in areas with historically elevated risk of sensitization and CBD at a beryllium metal powder, beryllium oxide, and alloy production facility. The investigators observed that historically, exposure-response relationships have been inconsistent when using mass concentration to identify process-related risk, possibly due to incomplete particle characterization. Two separate exposure surveys were conducted in March 1999 and June–August 1999 using multi-stage personal impactor samplers (to determine particle size distribution) and personal 37 mm closed face cassette (CFC) samplers, both located in workers' breathing zones. One hundred and ninety eight time-weighted-average (TWA) personal impactor samples were analyzed for representative jobs and processes. A total of 4,026 CFC samples were collected over the 5-month collection period and analyzed for mass concentration, particle size, chemical content and solubility and compared to process areas with high risk of sensitization and CBD. The investigators found that total beryllium concentration varied greatly between workers and among process areas. Analysis of chemical form and solubility also revealed wide variability among process areas, but high risk process areas had exposures to both soluble and insoluble forms of beryllium. Analysis of particle size revealed most process areas had particles ranging from 5–14 µm mass median aerodynamic diameter (MMAD). Rank order correlating jobs to particle size showed high overall consistency (Spearman r=0.84) but moderate correlation (Pearson r=0.43). The investigators concluded that consideration of relevant aspects of exposure such as particle size distribution, chemical form, and solubility will likely improve exposure assessments (Virji et al., 2011)

c. Particle Surface Area.

Particle surface area has been postulated as an important metric for beryllium exposure. Several studies have demonstrated a relationship between the inflammatory and tumorigenic potential of ultrafine particles and their increased surface area (Driscoll, 1996; Miller, 1995; Oberdorster *et al.*, 1996). While the exact mechanism explaining how particle surface area influences its biological activity is not known, a greater particle surface area has been shown to increase inflammation, cytokine production, anti-oxidant defenses and apoptosis (Elder *et al.*, 2005; Carter *et al.*, 2006; Refsne *et al.*, 2006).

Finch *et al.*, (1988) found that beryllium oxide calcined at 500 °C had 3.3 times greater specific surface area (SSA) than beryllium oxide calcined at 1000 °C, although there was no difference in size or structure of the particles as a function of calcining temperature. The beryllium-metal aerosol (airborne beryllium particles), although similar to the beryllium oxide aerosols in aerodynamic size, had an SSA about 30 percent that of the beryllium oxide calcined at 1000 °C. As discussed above, a later study by Delic (1992) found calcining temperatures had an effect on SSA as well as particle size.

Several studies have investigated the lung toxicity of beryllium oxide calcined at different temperatures and generally had found that those calcined at lower temperatures have greater toxicity and effect than materials calcined at higher temperatures. This may be because beryllium oxide fired at the lower temperature has a loosely formed crystalline structure with greater specific surface area than the fused crystal structure of beryllium oxide fired at the higher temperature. For example, beryllium oxide calcined at 500 °C has been found to have stronger pathogenic effects than material calcined at 1,000 °C, as shown in several of the beagle dog, rat, mouse and guinea pig studies discussed in the section on CBD pathogenesis that follows (Finch *et al.*, 1988; Polak *et al.*, 1968; Haley *et al.*, 1989; Haley *et al.*, 1992; Hall *et al.*, 1950). Finch *et al.* have also observed higher toxicity of beryllium oxide calcined at 500 °C, an observation they attribute to the greater surface area of beryllium particles calcined at the lower temperature (Finch *et al.*, 1988). These authors found that the *in vitro* cytotoxicity to Chinese hamster ovary (CHO) cells and cultured lung epithelial cells of 500 °C beryllium oxide was greater than that of 1,000 °C beryllium oxide, which in turn was greater than that of beryllium metal. However, when toxicity was expressed in terms of particle surface area, the cytotoxicity of all three forms was similar. Similar results were observed in a study comparing the cytotoxicity of beryllium metal particles of various sizes to cultured rat alveolar macrophages, although specific surface area did not entirely predict cytotoxicity (Finch *et al.*, 1991).

Stefaniak *et al.*, (2003b) investigated the particle structure and surface area of particles (powder and process-sampled) of beryllium metal, beryllium oxide, and copper-beryllium alloy. Each of these samples was separated by aerodynamic size, and their chemical compositions and structures were determined with x-ray diffraction and transmission electron microscopy, respectively. In summary, beryllium-metal powder varied remarkably from beryllium oxide powder and alloy particles. The metal powder consisted of compact particles, in which SSA decreases with increasing surface diameter. In contrast, the alloys and oxides consisted of small primary particles in clusters, in which the SSA remains fairly constant with particle size. SSA for the metal powders varied based on production and manufacturing process with variations among samples as high as a factor of 37. Stefaniak *et al.* (2003b) found lesser variation in SSA for the alloys or oxides. This is consistent with data from other studies summarized above showing that process may affect particle size and surface area. Particle size and/or surface area may explain differences in the rate of BeS and CBD observed in some epidemiological studies. However, these properties have not been consistently characterized in most studies.

B. Kinetics and Metabolism of Beryllium

Beryllium enters the body by inhalation, ingestion, or absorption through the skin. For occupational exposure, the airways and the skin are the primary routes of uptake.

1. Exposure via the Respiratory System

The respiratory tract, especially the lung, is the primary target of inhalation exposure in workers. Inhaled beryllium particles are deposited along the respiratory tract in a size dependent manner. In general, particles larger than 10 μm tend to deposit in the upper respiratory tract or nasal region and do not appreciably penetrate lower in the tracheobronchial or pulmonary regions (Figure 1). Particles less than 10 μm increasingly penetrate and deposit in the tracheobronchial and pulmonary regions with peak deposition in the pulmonary region occurring below 5 μm in particle diameter. The CBD pathology of concern is found in the pulmonary region. For particles below 1 μm, regional deposition changes dramatically. Ultrafine particles (generally considered to be 100 nm or lower) have a higher rate of deposition along the entire respiratory system (ICRP model, 1994). Those particles depositing in the lung and along the entire respiratory tract may encounter immunologic cells or may move into the vascular system where they are free to leave the lung and can contribute to systemic beryllium concentrations.

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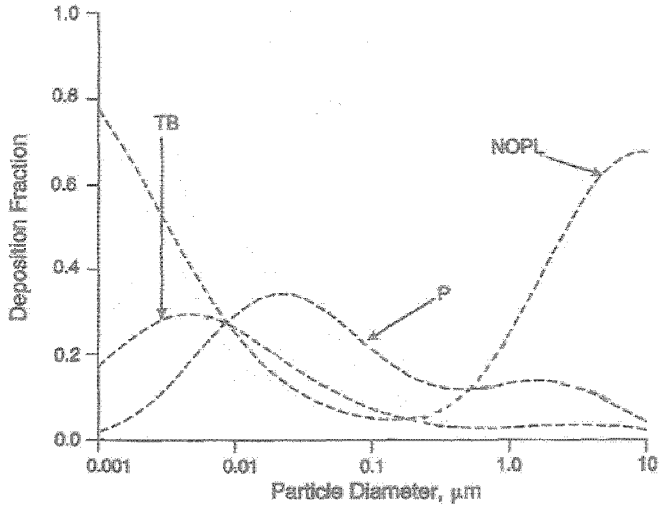

Figure 1, ICRP model: Regional Depostion Model in Humans (Adapted from Yeh et al., 1996)

NOPL - naso-oral-pharynolaryngeal region

TB – tracheobronchial region

P – pulmonary region

Beryllium is removed from the respiratory tract by various clearance mechanisms. Soluble beryllium is removed from the respiratory tract via absorption. Sparingly soluble or insoluble beryllium may remain in the lungs for many years after exposure, as has been observed in workers (Schepers, 1962). Clearance mechanisms for sparingly soluble or insoluble beryllium particles include: In the nasal passage, sneezing, mucociliary transport to the throat, or dissolution; in the tracheobronchial region, mucociliary transport, coughing, phagocytosis, or dissolution; in the pulmonary or alveolar region, phagocytosis, movement through the interstitium (translocation), or dissolution (Schlesinger, 1997).

Clearance mechanisms may occur slowly in humans, which is consistent with some animal studies. For example, subjects in the Beryllium Case Registry (BCR), which identifies and tracks cases of acute and chronic beryllium diseases, had elevated concentrations of beryllium in lung tissue (*e.g.,* 3.1 µg/g of dried lung tissue and 8.5 µg/g in a mediastinal node) more than 20 years after termination of short-term (generally between 2 and 5 years) occupational exposure to beryllium (Sprince *et al.,* 1976).

Clearance rates may depend on the solubility, dose, and size of the beryllium particles inhaled as well as the sex and species of the animal tested. As reviewed in a WHO Report (2001), more soluble beryllium compounds generally tend to be cleared from the respiratory system and absorbed into the bloodstream more rapidly than less soluble compounds (Van Cleave and Kaylor, 1955; Hart *et al.,* 1980; Finch *et al.,* 1990). Animal inhalation or intratracheal instillation studies administering soluble beryllium salts demonstrated significant absorption of approximately 20 percent of the initial lung burden, while sparingly soluble compounds such as beryllium oxide demonstrated that absorption was slower and less significant (Delic, 1992). Additional animal studies have demonstrated that clearance of soluble and sparingly soluble beryllium compounds was biphasic: A more rapid initial mucociliary transport phase of particles from the tracheobronchial tree to the gastrointestinal tract, followed by a slower phase via translocation to tracheobronchial lymph nodes, alveolar macrophages uptake, and beryllium particles dissolution (Camner *et al.,* 1977; Sanders *et al.,* 1978; Delic, 1992; WHO, 2001). Confirmatory studies in rats have shown the half-time for the rapid phase between 1–60 days, while the slow phase ranged from 0.6–2.3 years. It was also shown that this process was influenced by the solubility of the beryllium compounds: Weeks/months for soluble compounds, months/years for sparingly soluble compounds (Reeves and Vorwald, 1967; Reeves *et al.,* 1967; Zorn *et al.,* 1977; Rhoads and Sanders, 1985). Studies in guinea-pigs and rats indicate that 40–50 percent of the inhaled soluble beryllium salts are retained in the respiratory tract. Similar data could not be found for the sparingly or less soluble beryllium compounds or metal administered by this exposure route. (WHO, 2001; ATSDR, 2002).

Evidence from animal studies suggests that greater amounts of beryllium deposited in the lung may result in slower clearance times. A comparative study of rats and mice using a single dose of inhaled aerosolized beryllium metal demonstrated that an acute inhalation exposure to beryllium metal can slow particle clearance and induce lung damage in rats (Haley *et al.,* 1990) and mice (Finch *et al.,* 1998a). In another study Finch *et al.* (1994) exposed male F344/N rats to beryllium metal at concentrations resulting in beryllium lung burdens of 1.8, 10, and 100 µg. These exposure levels resulted in an estimated clearance half-life ranging from 250–380 days for the three concentrations. For mice (Finch *et al.,* 1998a), lung clearance half-lives were 91–150 days (for 1.7- and 2.6-μg lung burden groups) or 360–400 days (for 12- and 34-μg lung burden groups). While the lower exposure groups were quite different for rats and mice, the highest groups were similar in clearance half-lives for both species.

Beryllium absorbed from the respiratory system is mainly distributed to the tracheobronchial lymph nodes via the lymph system, bloodstream, and skeleton, which is the ultimate site of beryllium storage (Stokinger *et al.,* 1953; Clary *et al.,* 1975; Sanders *et al.,* 1975; Finch *et al.,* 1990). Trace amounts are distributed throughout the body (Zorn *et al.,* 1977; WHO, 2001). Studies in rats have demonstrated accumulation of beryllium chloride in the skeletal system following intraperitoneal injection (Crowley *et al.,* 1949; Scott *et al.,* 1950) and accumulation of beryllium phosphate and beryllium sulfate in both nonparenchymal and parenchymal cells of the liver after intravenous administration in rats (Skilleter and Price, 1978). Studies have also demonstrated intracellular accumulation of beryllium oxide in bone marrow throughout the skeletal system after intravenous administration to rabbits (Fodor, 1977; WHO, 2001).

Systemic distribution of the more soluble compounds appears to be greater than that of the insoluble compounds (Stokinger *et al.*, 1953). Distribution has also been shown to be dose dependent in research using intravenous administration of beryllium in rats; small doses were preferentially taken up in the skeleton, while higher doses were initially distributed preferentially to the liver. Beryllium was later mobilized from the liver and transferred to the skeleton (IARC, 1993). A half-life of 450 days has been estimated for beryllium in the human skeleton (ICRP, 1960). This indicates the skeleton may serve as a repository for beryllium that may later be reabsorbed by the circulatory system, making beryllium available to the immunological system.

2. Dermal Exposure

Beryllium compounds have been shown to cause skin irritation and sensitization in humans and certain animal models (Van Orstrand *et al.*, 1945; de Nardi *et al.*, 1953; Nishimura 1966; Epstein 1990; Belman, 1969; Tinkle *et al.*, 2003; Delic, 1992). The Agency for Toxic Substances and Disease Registry (ATSDR) estimated that less than 0.1 percent of beryllium compounds are absorbed through the skin (ATSDR, 2002). However, even minute contact and absorption across the skin may directly elicit an immunological sensitization response (Deubner *et al.*, 2001; Toledo *et al.*, 2011). Recent studies by Tinkle *et al.* (2003) showed that penetration of beryllium oxide particles was possible *ex vivo* for human intact skin at particle sizes of ≤ 1μm, as confirmed by scanning electron microscopy. Using confocal microscopy, Tinkle *et al.* demonstrated that surrogate fluorescent particles up to 1 μm in size could penetrate the mouse epidermis and dermis layers in a model designed to mimic the flexing and stretching of human skin in motion. Other poorly soluble particles, such as titanium dioxide, have been shown to penetrate normal human skin (Tan *et al.*, 1996) suggesting the flexing and stretching motion as a plausible mechanism for dermal penetration of beryllium as well. As earlier summarized, insoluble forms of beryllium can be solubilized in biological fluids (*e.g.*, sweat) making them available for absorption through intact skin (Sutton *et al.*, 2003; Stefaniak *et al.*, 2011; Duling *et al.*, 2012).

Although its precise role remains to be elucidated, there is evidence to indicate that dermal exposure can contribute to beryllium sensitization. As early as the 1940s it was recognized that dermatitis experienced by workers in primary beryllium production facilities was linked to exposures to the soluble beryllium salts. Except in cases of wound contamination, dermatitis was rare in workers whose exposures were restricted to exposure to poorly soluble beryllium-containing particles (Van Ordstrand *et al.*, 1945). Further investigation by McCord in 1951 indicated that direct skin contact with soluble beryllium compounds, but not beryllium hydroxide or beryllium metal, caused dermal lesions (reddened, elevated, or fluid-filled lesions on exposed body surfaces) in susceptible persons. Curtis, in 1951, demonstrated skin sensitization to beryllium with patch testing using soluble and insoluble forms of beryllium in beryllium-naïve subjects. These subjects later developed granulomatous skin lesions with the classical delayed-type contact dermatitis following repeat challenge (Curtis, 1951). These lesions appeared after a latent period of 1–2 weeks, suggesting a delayed allergic reaction. The dermal reaction occurred more rapidly and in response to smaller amounts of beryllium in those individuals previously sensitized (Van Ordstrand *et al.*, 1945). Contamination of cuts and scrapes with beryllium can result in the beryllium becoming embedded within the skin causing a granuloma to develop in the skin (Epstein, 1991). Introduction of soluble or insoluble beryllium compounds into or under the skin as a result of abrasions or cuts at work has been shown to result in chronic ulcerations with granuloma formation (Van Orstrand *et al.*, 1945; Lederer and Savage, 1954). Beryllium absorption through bruises and cuts has been demonstrated as well (Rossman *et al.*, 1991). In a study by Invannikov *et al.*, (1982), beryllium chloride was applied directly to the skin of live animals with three types of wounds: abrasions (superficial skin trauma), cuts (skin and superficial muscle trauma), and penetration wounds (deep muscle trauma). The percentage of the applied dose absorbed into the systemic circulation during a 24-hour exposure was significant, ranging from 7.8 percent to 11.4 percent for abrasions, from 18.3 percent to 22.9 percent for cuts, and from 34 percent to 38.8 percent for penetration wounds (WHO, 2001).

A study by Deubner *et al.*, (2001) concluded that exposure across damaged skin can contribute as much systemic loading of beryllium as inhalation (Deubner *et al.*, 2001). Deubner *et al.*, (2001) estimated dermal loading (amount of particles penetrating into the skin) in workers as compared to inhalation exposure. Deubner's calculations assumed a dermal loading rate for beryllium on skin of 0.43 μg/cm², based on the studies of loading on skin after workers cleaned up (Sanderson *et al.*, 1999), multiplied by a factor of 10 to approximate the workplace concentrations and the very low absorption rate of 0.001 percent (taken from EPA estimates). It should be noted that these calculations did not take into account absorption of soluble beryllium salts that might occur across nasal mucus membranes, which may result from contact between contaminated skin and the nose (EPA, 1998).

A study conducted by Day *et al.* (2007) evaluated the effectiveness of a dermal protection program implemented in a beryllium alloy facility in 2002. The investigators evaluated levels of beryllium in air, on workplace surfaces, on cotton gloves worn over nitrile gloves, and on the necks and faces of workers over a six day period. The investigators found a good correlation between air samples and work surface contamination at this facility. The investigators also found measurable levels of beryllium on the skin of workers as a result of work processes even from workplace areas promoted as ''visually clean'' by the company housekeeping policy. Importantly, the investigators found that the beryllium contamination could be transferred from body region to body region (*e.g.*, hand to face, neck to face). The investigators demonstrated multiple pathways of exposure which could lead to sensitization, increasing risk for developing CBD (Day, *et al.*, 2007).

The same group of investigators (Armstrong *et al.*, 2014) extended their work on investigating multiple exposure pathways contributing to sensitization and CBD. The investigators evaluated four different beryllium manufacturing and processing facilities to assess the contribution of various exposure pathways on worker exposure. Airborne, work surface and cotton glove beryllium concentrations were evaluated. The investigators found strong correlations between air-surface concentrations, glove-surface concentrations, and air-glove concentrations at this facility. This work confirms findings from Day et al. (2007) demonstrating the importance of airborne beryllium concentrations to surface contamination and dermal exposure even at exposures below the current OSHA PEL (Armstrong et al., 2014).

3. Oral and Gastrointestinal Exposure

According to the WHO Report (2001), gastrointestinal absorption of beryllium can occur by both the inhalation and oral routes of exposure. Through inhalation exposure, a fraction of the inhaled material is transported to the gastrointestinal tract by the mucociliary escalator or by the swallowing of the insoluble material deposited in the upper respiratory tract (WHO, 2001). Gastrointestinal absorption of beryllium can occur by both the inhalation and oral routes of exposure. In the case of inhalation, a portion of the inhaled material is transported to the gastrointestinal tract by the mucociliary escalator or by the swallowing of the insoluble material deposited in the upper respiratory tract (Schlesinger, 1997). Animal studies have shown oral administration of beryllium compounds to result in very limited absorption and storage (as reviewed by U.S. EPA, 1998). In animal ingestion studies using radio-labeled beryllium chloride in rats, mice, dogs, and monkeys, the vast majority of the ingested dose passed through the gastrointestinal tract unabsorbed and was excreted in the feces. In most studies, <1 percent of the administered radioactivity was absorbed into the bloodstream and subsequently excreted in the urine (Crowley *et al.*, 1949; Furchner *et al.*, 1973; LeFevre and Joel, 1986). Research using soluble beryllium sulfate has shown that as the compound passes into the intestine, which has a higher pH than the stomach (approximate pH of 6 to 8 for the intestine, pH of 1 or 2 for the stomach), the beryllium is precipitated as the insoluble phosphate and thus is no longer available for absorption (Reeves, 1965; WHO, 2001).

Urinary excretion of beryllium has been shown to correlate with the amount of occupational exposure (Klemperer *et al.*, 1951). Beryllium that is absorbed into the bloodstream is excreted primarily in the urine (Crowley *et al.*, 1949; Scott *et al.*, 1950; Furchner *et al.*, 1973; Stiefel *et al.*, 1980), whereas excretion of unabsorbed beryllium is primarily via the fecal route (Hart *et al.*, 1980; Finch *et al.*, 1990). A far higher percentage of the beryllium administered parenterally in various animal species was eliminated in the urine than in the feces (Crowley *et al.*, 1949; Scott *et al.*, 1950; Furchner *et al.*, 1973), confirming that beryllium found in the feces following oral exposure is primarily unabsorbed material. A study using percutaneous incorporation of soluble beryllium nitrate in rats similarly demonstrated that more than 90 percent of the beryllium in the bloodstream was eliminated via urine (Zorn *et al.*, 1977; WHO, 2001). More than 99 percent of ingested beryllium chloride was excreted in the feces (Mullen *et al.*, 1972). Elimination half-times of 890–1,770 days (2.4–4.8 years) were calculated for mice, rats, monkeys, and dogs injected intravenously with beryllium chloride (Furchner *et al.*, 1973). Mean daily excretion of beryllium metal was 4.6×10^{-5} percent of the dose administered by intratracheal instillation in baboons and 3.1×10^{-5} percent in rats (Andre *et al.*, 1987).

4. Metabolism

Beryllium and its compounds are not metabolized or biotransformed, but soluble beryllium salts may be converted to less soluble forms in the lung (Reeves and Vorwald, 1967). As stated earlier, solubility is an important factor for persistence of beryllium in the lung. Insoluble beryllium, engulfed by activated phagocytes, can be ionized by an acidic environment and by myeloperoxidases (Leonard and Lauwerys, 1987; Lansdown, 1995; WHO, 2001), and this positive charge could potentially make it more biologically reactive because it may allow the beryllium to bind to a peptide or protein and be presented to the T cell receptor or antigen-presenting cell (Fontenot, 2000).

5. Preliminary Conclusion for Particle Characterization and Kinetics of Beryllium

The forms and concentrations of beryllium across the workplace vary substantially based upon location, process, production and work task. Many factors influence the potency of beryllium including concentration, composition, structure, size and surface area of the particle.

Studies have demonstrated that beryllium sensitization can occur via the skin or inhalation from soluble or poorly soluble beryllium particles. Beryllium must be presented to a cell in a soluble form for activation of the immune system (NAS, 2008), and this will be discussed in more detail in the section to follow. Poorly soluble beryllium can be solubilized via intracellular fluid, lung fluid and sweat (Sutton *et al.*, 2003; Stefaniak *et al.*, 2011). For beryllium to persist in the lung it needs to be insoluble. However, soluble beryllium has been shown to precipitate in the lung to form insoluble beryllium (Reeves and Vorwald, 1967).

Some animal and epidemiological studies suggest that the form of beryllium may affect the rate of development of BeS and CBD. Beryllium in an inhalable form (either as soluble or insoluble particles or mist) can deposit in the respiratory tract and interact with immune cells located along the entire respiratory tract (Scheslinger, 1997). However, more study is needed to precisely determine the physiochemical characteristics of beryllium that influence toxicity and immunogenicity.

C. Acute Beryllium Diseases

Acute beryllium disease (ABD) is a relatively rapid onset inflammatory reaction resulting from breathing high airborne concentrations of beryllium. It was first reported in workers extracting beryllium oxide (Van Ordstrand *et al.*, 1943). Since the Atomic Energy Commission's adoption of occupational exposure limits for beryllium beginning in 1949, cases of ABD have been rare. According to the World Health Organization (2001), ABD is generally associated with exposure to beryllium levels at or above 100 μg/m³ and may be fatal in 10 percent of cases. However, cases have been reported with beryllium exposures below 100 μg/m³ (Cummings *et al.*, 2009). The disease involves an inflammatory reaction that may include the entire respiratory tract, involving the nasal passages, pharynx, bronchial airways and alveoli. Other tissues including skin and conjunctivae may be affected as well. The clinical features of

ABD include a nonproductive cough, chest pain, cyanosis, shortness of breath, low-grade fever and a sharp drop in functional parameters of the lungs. Pathological features of ABD include edematous distension, round cell infiltration of the septa, proteinaceous materials, and desquamated alveolar cells in the lung. Monocytes, lymphocytes and plasma cells within the alveoli are also characteristic of the acute disease process (Freiman and Hardy, 1970).

Two types of acute beryllium disease have been characterized in the literature: a rapid and severe course of acute fulminating pneumonitis generally developing within 48 to 72 hours of a massive exposure, and a second form that takes several days to develop from exposure to lower concentrations of beryllium (still above the levels set by regulatory and guidance agencies) (Hall, 1950; DeNardi *et al.*, 1953; Newman and Kreiss, 1992). Evidence of a dose-response relationship to the concentration of beryllium is limited (Eisenbud *et al.*, 1948; Stokinger, 1950; Sterner and Eisenbud, 1951). Recovery from either type of ABD is generally complete after a period of several weeks or months (DeNardi *et al.*, 1953). However, deaths have been reported in more severe cases (Freiman and Hardy, 1970). There have been documented cases of progression to CBD (ACCP, 1965; Hall, 1950) suggesting the possibility of an immune component to this disease (Cummings *et al.*, 2009) as well. According to the BCR, in the United States, approximately 17 percent of ABD patients developed CBD (BCR, 2010). The majority of ABD cases occurred between 1932 and 1970 (Eisenbud, 1983; Middleton, 1998). ABD is extremely rare in the workplace today due to more stringent exposure controls implemented following occupational and environmental standards set in 1970–1972 (OSHA, 1971; ACGIH, 1971; ANSI, 1970) and 1974 (EPA, 1974).

D. Chronic Beryllium Disease

This section provides an overview of the immunology and pathogenesis of BeS and CBD, with particular attention to the role of skin sensitization, particle size, beryllium compound solubility, and genetic variability in individuals' susceptibility to beryllium sensitization and CBD.

Chronic beryllium disease (CBD), formerly known as ''berylliosis'' or ''chronic berylliosis,'' is a granulomatous disorder primarily affecting the lungs. CBD was first described in the literature by Hardy and Tabershaw (1946) as a chronic granulomatous pneumonitis. It was proposed as early as 1951 that CBD could be a chronic disease resulting from an immune sensitization to beryllium (Sterner and Eisenbud, 1951; Curtis, 1959; Nishimura, 1966). However, for a time, there remained some controversy as to whether CBD was a delayed-onset hypersensitivity disease or a toxicant-induced disease (NAS, 2008). Wide acceptance of CBD as a hypersensitivity lung disease did not occur until bronchoscopy studies and bronchoalveolar lavage (BAL) studies were performed demonstrating that BAL cells from CBD patients responded to beryllium challenge (Epstein *et al.*, 1982; Rossman *et al.*, 1988; Saltini *et al.*, 1989).

CBD shares many clinical and histopathological features with pulmonary sarcoidosis, a granulomatous lung disease of unknown etiology. This includes such debilitating effects as airway obstruction, diminishment of physical capacity associated with reduced lung function, possible depression associated with decreased physical capacity, and decreased life expectancy. Without appropriate information, CBD may be difficult to distinguish from sarcoidosis. It is estimated that up to 6 percent of all patients diagnosed with sarcoidosis may actually have CBD (Fireman *et al.*, 2003; Rossman and Kreiber, 2003). Among patients diagnosed with sarcoidosis in which beryllium exposure can be confirmed, as many as 40 percent may actually have CBD (Muller-Quernheim *et al.*, 2006; Cherry *et al.*, 2015).

Clinical signs and symptoms of CBD may include, but are not limited to, a simple cough, shortness of breath or dypsnea, fever, weight loss or anorexia, skin lesions, clubbing of fingers, cyanosis, night sweats, cor pulmonale, tachycardia, edema, chest pain and arthralgia. Changes or loss of pulmonary function also occur with CBD such as decrease in vital capacity, reduced diffusing capacity, and restrictive breathing patterns. The signs and symptoms of CBD constitute a continuum of symptoms that are progressive in nature with no clear demarcation between any stages in the disease (Rossman, 1996; NAS, 2008). Besides these listed symptoms from CBD patients, there have been reported cases of CBD that remained asymptomatic (Muller-Querheim, 2005; NAS, 2008).

Unlike ABD, CBD can result from inhalation exposure to beryllium at levels below the current OSHA PEL, can take months to years after initial beryllium exposure before signs and symptoms of CBD occur (Newman 1996, 2005 and 2007; Henneberger, 2001; Seidler *et al.*, 2012; Schuler *et al.*, 2012), and may continue to progress following removal from beryllium exposure (Newman, 2005; Sawyer *et al.*, 2005; Seidler *et al.*, 2012). Patients with CBD can progress to a chronic obstructive lung disorder resulting in loss of quality of life and the potential for decreased life expectancy (Rossman, *et al.*, 1996; Newman *et al.*, 2005). The NAS report (2008) noted the general lack of published studies on progression of CBD from an early asymptomatic stage to functionally significant lung disease (NAS, 2008). The report emphasized that risk factors and time course for clinical disease have not been fully delineated. However, for people now under surveillance, clinical progression from immunological sensitization and early pathological lesions (*i.e.*, granulomatous inflammation) prior to onset of symptoms to symptomatic disease appears to be slow, although more follow-up is needed (NAS, 2008). A study by Newman (1996) emphasized the need for prospective studies to determine the natural history and time course from BeS and asymptomatic CBD to full-blown disease (Newman, 1996). Drawing from his own clinical experience, Newman was able to identify the sequence of events for those with symptomatic disease as follows: Initial determination of beryllium sensitization; gradual emergence of chronic inflammation of the lung; pathologic alterations with measurable physiologic changes (*e.g.*, pulmonary function and gas exchange); progression to a more severe lung disease (with extrapulmonary effects such as clubbing and cor pulmonale in some cases); and finally death in some cases (reported between 5.8 to 38 percent) (NAS, 2008; Newman, 1996).

In contrast to some occupationally related lung diseases, the early detection of chronic beryllium disease may be useful since treatment of this condition can lead not only to regression of the signs and symptoms, but also may prevent further progression of the disease in certain individuals (Marchand-Adam, 2008; NAS, 2008). The management of CBD is based on the hypothesis that suppression of the hypersensitivity reaction (*i.e.*, granulomatous process) will prevent the development of fibrosis. However, once fibrosis has developed, therapy cannot reverse the damage.

To date, there have been no controlled studies to determine the optimal treatment for CBD (Rossman, 1996; NAS 2008; Sood, 2009). Management of CBD is generally modeled after sarcoidosis treatment. Oral corticosteroid treatment can be initiated in patients with evidence of disease (either by bronchoscopy or other diagnostic measures before progression of disease or after clinical signs of pulmonary deterioration occur). This includes treatment with other anti-inflammatory agents (NAS, 2008; Maier *et al.*, 2012; Salvator *et al.*, 2013) as well. It should be noted, however, that treatment with corticosteroids has side-effects of their own that need to be measured against the possibility of progression of disease (Gibson *et al.*, 1996; Zaki *et al.*, 1987). Alternative treatments such as azathiopurine and infliximab, while successful at treating symptoms of CBD, have been demonstrated to have side-effects as well (Pallavicino *et al.*, 2013; Freeman, 2012).

1. Development of Beryllium Sensitization

Sensitization to beryllium is an essential step for worker development of CBD. Sensitization to beryllium can result from inhalation exposure to beryllium (Newman *et al.,* 2005; NAS, 2008), as well as from skin exposure to beryllium (Curtis, 1951; Newman *et al.,* 1996; Tinkle *et al.,* 2003). Sensitization is currently detected using a laboratory blood test described in Appendix A. Although there may be no clinical symptoms associated with BeS, a sensitized worker's immune system has been activated to react to beryllium exposures such that subsequent exposure to beryllium can progress to serious lung disease (Kreiss *et al.,* 1996; Kreiss *et al.,* 1997; Kelleher *et al.,* 2001; and Rossman, 2001). Since the pathogenesis of CBD involves a beryllium-specific, cell-mediated immune response, CBD cannot occur in the absence of sensitization (NAS, 2008). Various factors, including genetic susceptibility, have been shown to influence risk of developing sensitization and CBD (NAS 2008) and will be discussed later in this section.

While various mechanisms or pathways may exist for beryllium sensitization, the most plausible mechanisms supported by the best available and most current science are discussed below. Sensitization occurs via the formation of a beryllium-protein complex (an antigen) that causes an immunological response. In some instances, onset of sensitization has been observed in individuals exposed to beryllium for only a few months (Kelleher *et al.,* 2001; Henneberger *et al.,* 2001). This suggests the possibility that relatively brief, short-term beryllium exposures may be sufficient to trigger the immune hypersensitivity reaction. Several studies (Newman et al., 2001; Henneberger et al., 2001; Rossman, 2001; Schuler et al., 2005; Donovan et al., 2007, Schuler et al., 2012) have detected a higher prevalence of sensitization among workers with less than one year of employment compared to some cross-sectional studies which, due to lack of information regarding initial exposure, cannot determine time of sensitization (Kreiss et al., 1996; Kreiss et al., 1997). While only very limited evidence has described humoral changes in certain patients with CBD (Cianciara *et al.,* 1980), clear evidence exists for an immune cell-mediated response, specifically the T-cell (NAS, 2008). Figure 2 delineates the major steps required for progression from beryllium contact to sensitization to CBD.

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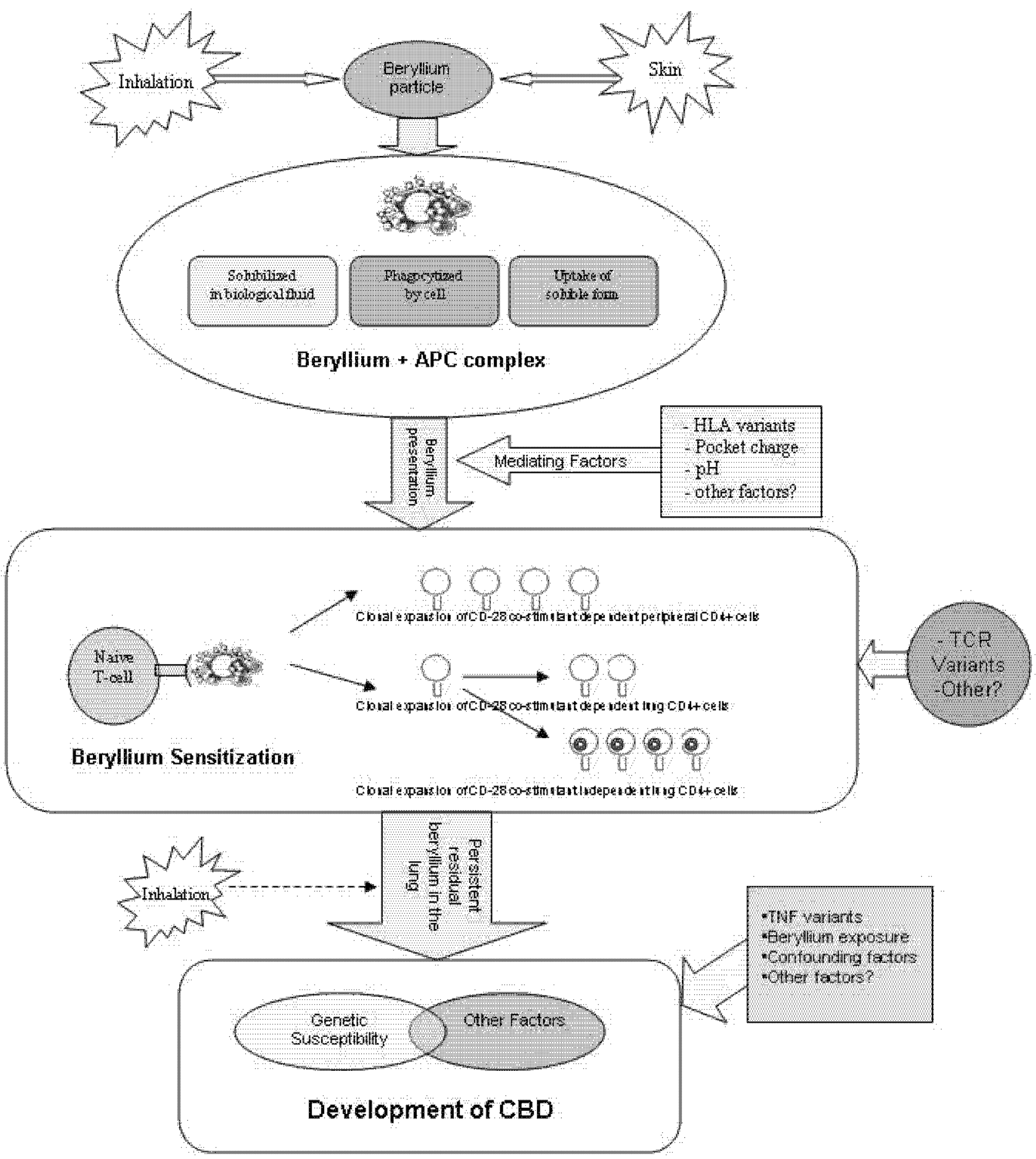
Figure 2 – Schematic of beryllium presentation through to formation of CBD



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Beryllium presentation to the immune system is believed to occur either by direct presentation or by antigen processing. It has been postulated that beryllium must be presented to the immune system in an ionic form for cell-mediated immune activation to occur (Kreiss *et al.,* 2007). Some soluble forms of beryllium are readily presented, since the soluble beryllium form disassociates into its ionic components. However, for insoluble forms, dissolution may need to occur. A study by Harmsen *et al.* (1986) suggested that a sufficient rate of dissolution of small amounts of poorly soluble beryllium compounds might occur in the lungs to allow persistent low-level beryllium presentation to the immune system. Stefaniak *et al.* (2005 and 2012) reported that insoluble beryllium particles phagocytized by macrophages were dissolved in phagolysomal fluid (Stefaniak *et al.,* 2005; Stefaniak *et al.,* 2012) and that the dissolution rate stimulated by phagolysomal fluid was different for various forms of beryllium (Stefaniak *et al.,* 2006; Duling *et al.,* 2012). Several studies have demonstrated that macrophage uptake of beryllium can induce aberrant apoptotic processes leading to the continued release of beryllium ions which will continually stimulate T-cell activation (Sawyer *et al.,* 2000; Sawyer *et al.,* 2004; Kittle *et al.,* 2002). Antigen processing can be mediated by antigen-presenting cells (APC). These may include macrophages, dendritic cells, or other antigen-presenting cells, although this has not been well defined in most studies (NAS, 2008).

Because of their strong positive charge, beryllium ions have the ability to haptenate and alter the structure of peptides occupying the antigen-binding cleft of major histocompatibility complex (MHC) class II on antigen-presenting cells (APC). The MHC class II antigen-binding molecule for beryllium is the human leukocyte antigen (HLA) with specific alleles (*e.g.,* HLA–DP, HLA–DR, HLA–DQ) associated with the progression to CBD (NAS, 2008; Yucesoy and Johnson, 2011). Several studies have also demonstrated that the electrostatic charge of HLA may be a factor in binding beryllium (Snyder *et al.,* 2003; Bill *et al.,* 2005; Dai *et al.,* 2010). The strong positive ionic charge of the beryllium ion would have a strong attraction for the negatively charged patches of certain HLA alleles (Snyder *et al.,* 2008; Dai *et al.,* 2010). Alternatively, beryllium oxide has been demonstrated to bind to the MHC class II receptor in a neutral pH. The six carboxylates in the amino acid sequence of the binding pocket provide a stable bond with the Be-O-Be molecule when the pH of the substrate is neutral (Keizer *et al.,* 2005). The direct binding of BeO may eliminate the biological requirement for antigen processing or dissolution of beryllium oxide to activate an immune response.

Next in sequence is the beryllium-MHC–APC complex binding to a T-cell receptor (TCR) on a naïve T-cell which stimulates the proliferation and accumulation of beryllium-specific $CD4^+$ (cluster of differentiation 4^+) T-cells (Saltini *et al.,* 1989 and 1990; Martin *et al.,* 2011) as depicted in Figure 3. Fontenot *et al.* (1999) demonstrated that diversely different variants of TCR were expressed by $CD4^+$ T-cells in peripheral blood cells of CBD patients. However, the $CD4^+$ T-cells from the lung were more homologous in expression of TCR variants in CBD patients, suggesting clonal expansion of a subset of T-cells in the lung (Fontenot *et al.,* 1999). This may also indicate a pathogenic potential for subsets of T-cell clones expressing this homologous TCR (NAS, 2008). Fontenot *et al.* (2006) reported beryllium self-presentation by HLA–DP expressing BAL $CD4^+$ T-cells. Self-presentation by BAL T-cells in the lung granuloma may result in activation-induced cell death, which may then lead to oligoclonality of the T-cell population characteristic of CBD (NAS, 2008).

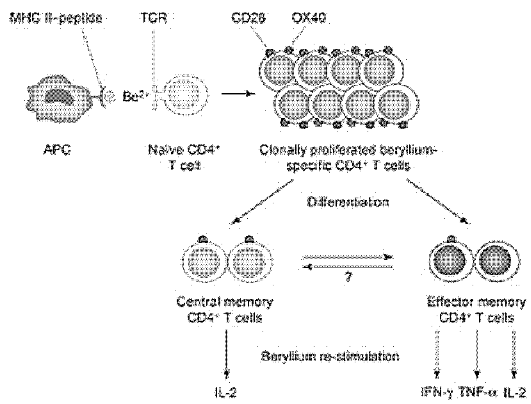

FIGURE 3 - Immune response to beryllium. Source: Fontenot and Maier 2005. Reprinted with permission; copyright 2005, Trends in Immunology.

As $CD4^+$ T-cells proliferate, clonal expansion of various subsets of the $CD4^+$ beryllium specific T-cells occurs (Figure 3). In the peripheral blood, the beryllium-specific $CD4^+$ T cells require co-stimulation with a co-stimulant CD28 (cluster of differentiation 28). During the proliferation and differentiation process $CD4^+$ T-cells secrete pro-inflammatory cytokines that may influence this process (Sawyer *et al.,* 2004; Kimber *et al.,* 2011).

2. Development of CBD

The continued persistence of residual beryllium in the lung leads to a T-cell maturation process. A large portion of beryllium-specific $CD4^+$ T cells were shown to cease expression of CD28 mRNA and protein, indicating these cells no longer required co-stimulation with the CD28 ligand (Fontenot *et al.,* 2003). This change in phenotype correlated with lung inflammation (Fontenot *et al.,* 2003). The $CD4^+$ independent cells continued to secrete cytokines necessary for additional recruitment of inflammatory and immunological cells; however, they were less proliferative and less susceptible to cell death compared to the CD28 dependent cells (Fontenot *et al.,* 2005; Mack *et al.,* 2008). These beryllium-specific $CD4^+$ independent cells are considered to be mature memory effector cells (Ndejembi *et al.,* 2006; Bian *et al.,* 2005). Repeat exposure to beryllium in the lung resulting in a mature population of T cell development independent of co-stimulation by CD28 and development of a population of T effector memory cells (T_{em} cells) may be one of the mechanisms that lead to the more severe reactions observed specifically in the lung (Fontenot *et al.,* 2005).

$CD4^+$ T cells created in the sensitization process recognize the beryllium antigen, and respond by proliferating and secreting cytokines and inflammatory mediators, including IL–2, IFN-γ, and TNF-α (Tinkle *et al.,* 1997a and b; Fontenot *et al.,* 2002) and MIP–1α and GRO–1 (Hong-Geller, 2006). This also results in the accumulation of various types of inflammatory cells including mononuclear cells (mostly $CD4^+$ T cells) in the bronchoalveolar lavage fluid (BAL fluid) (Saltini *et al.,* 1989, 1990).

The development of granulomatous inflammation in the lung of CBD patients has been associated with the accumulation of beryllium responsive $CD4^+$ T_{em} cells in BAL fluid (NAS, 2008). The subsequent release of pro-inflammatory cytokines, chemokines and reactive oxygen species by these cells may lead to migration of additional inflammatory/immune cells and the development of a microenvironment that contributes to the development of CBD (Sawyer *et al.,* 2005; Tinkle *et al.,* 1996; Hong-Geller *et al.,* 2006; NAS, 2008).

The cascade of events described above results in the formation of a noncaseating granulomatous lesion.

Release of cytokines by the accumulating T cells leads to the formation of granulomatous lesions that are characterized by an outer ring of histiocytes surrounding non-necrotic tissue with embedded multi-nucleated giant cells (Saltini *et al.,* 1989, 1990).

Over time, the granulomas spread and can lead to lung fibrosis and abnormal pulmonary function, with symptoms including a persistent dry cough and shortness of breath (Saber and Dweik, 2000). Fatigue, night sweats, chest and joint pain, clubbing of fingers (due to impaired oxygen exchange), loss of appetite or unexplained weight loss, and cor pulmonale have been experienced in certain patients as the disease progresses (Conradi *et al.,* 1971; ACCP, 1965; Kriebel *et al.,* 1988a and b). While CBD primarily affects the lungs, it can also involve other organs such as the liver, skin, spleen, and kidneys (ATSDR, 2002).

As previously mentioned, the uptake of beryllium may lead to an aberrant apoptotic process with rerelease of beryllium ions and continual stimulation of beryllium-responsive $CD4^+$ cells in the lung (Sawyer *et al.,* 2000; Kittle *et al.,* 2002; Sawyer *et al.,* 2004). Several research studies suggest apoptosis may be one mechanism that enhances inflammatory cell recruitment, cytokine production and inflammation, thus creating a scenario for progressive granulomatous inflammation (Palmer *et al.,* 2008; Rana, 2008). Macrophages and neutrophils can phagocytize beryllium particles in an attempt to remove the beryllium from the lung (Ding, *et al.,* 2009). Multiple studies (Sawyer *et al.,* 2004; Kittle *et al.,* 2002) using BAL cells (mostly macrophages and neutrophils) from patients with CBD found that *in vitro* stimulation with beryllium sulfate induced the production of TNF-α (one of many cytokines produced in response to beryllium), and that production of TNF-α might induce apoptosis in CBD and sarcoidosis patients (Bost *et al.,* 1994; Dai *et al.,* 1999). The stimulation of CBD-derived macrophages by beryllium sulphate resulted in cells becoming apoptotic, as measured by propidium iodide. These results were confirmed in a mouse macrophage cell-line (p388D1) (Sawyer *et al.,* 2000). However, other factors may influence the development of CBD and are outlined in the following section.

3. Genetic and Other Susceptibility Factors

Evidence from a variety of sources indicates genetic susceptibility may play an important role in the development of CBD in certain individuals, especially at levels low enough not to invoke a response in other individuals. Early occupational studies proposed that CBD was an immune reaction based on the high susceptibility of some individuals to become sensitized and progress to CBD and the lack of CBD in others who were exposed to levels several orders of magnitude higher (Sterner and Eisenbud, 1951). Additional *in vitro* human research has identified genes coding for specific protein molecules on the surface of their immune cells that place carriers at greater risk of becoming sensitized to beryllium and developing CBD (McCanlies *et al.,* 2004). Recent studies have confirmed genetic susceptibility to CBD involves either HLA variants, T-cell receptor clonality, tumor necrosis factor (TNF-α) polymorphisms and/or transforming growth factor-beta (TGF-β) polymorphisms (Fontenot *et al.,* 2000; Amicosante *et al.,* 2005; Tinkle *et al.,* 1996; Gaede *et al.,* 2005; Van Dyke *et al.,* 2011; Silveira *et al.,* 2012).

Single Nucleotide Polymorphisms (SNPs) have been studied with regard to genetic variations associated with increased risk of developing CBD. SNPs are the most abundant type of human genetic variation. Polymorphisms in MHC class II and pro-inflammatory genes have been shown to contribute to variations in immune responses contributing to the susceptibility and resistance in many diseases including auto-immunity, and beryllium sensitization and CBD (McClesky et al., 2009). Specific SNPs have been evaluated as a factor in Glu69 variant from the HLA–DPB1 locus (Richeldi et al., 1993; Cai et al., 2000; Saltini et al., 2001; Silviera et al., 2012; Dai et al., 2013), HLA–DRPheβ47 (Amicosante et al., 2005).

HLA–DPB1 with a glutamic acid at amino position 69 (Glu 69) has been shown to confer increased risk of beryllium sensitization and CBD (Richeldi *et al.,* 1993; Saltini *et al.,* 2001; Amicosante *et al.,* 2005; Van Dyke *et al.,* 2011; Silveira *et al.,* 2012). Fontenot *et al.* (2000) demonstrated that beryllium presentation by certain alleles of the class II human leukocyte antigen-DP (HLA–DP) to CD4+ T cells is the mechanism underlying the development of CBD. Richeldi *et al.* (1993) reported a strong association between the MHC class II allele HLA–DP 1 and the development of CBD in beryllium-exposed workers from a Tucson, AZ facility. This marker was found in 32 of the 33 workers who developed CBD, but in only 14 of 44 similarly exposed workers without CBD. The more common allele of the HLA–DP 1 variant is negatively charged at this site and could directly interact with the positively charged beryllium ion. The high percentage (~30 percent) of beryllium-exposed workers without CBD who had this allele indicates that other factors also contribute to the development of CBD (EPA, 1998). Additional studies by Amicosante *et al.* (2005) using blood lymphocytes derived from beryllium-exposed workers found a high frequency of this gene in those sensitized to beryllium. In a study of 82 CBD patients (beryllium-exposed workers), Stubbs *et al.* (1996) also found a relationship between the HLA–DP 1 allele and BeS. The glutamate-69 allele was present in 86 percent of sensitized subjects, but in only 48 percent of beryllium-exposed, non-sensitized subjects. Some variants of the HLA–DPB1 allele convey higher risk of BeS and CBD than others. For example, HLA–DPB1*0201 yielded an approximately 3-fold increase in disease outcome relative to controls; HLA–DPB1*1901 yielded an approximately 5-fold increase, and HLA–DPB1*1701 an approximately 10-fold increase (Weston *et al.,* 2005; Snyder *et al.,* 2008). By assigning odds ratios for specific alleles on the basis of previous studies discussed above, the researchers found a strong correlation (88 percent) between the reported risk of CBD and the predicted surface electrostatic potential and charge of the isotypes of the genes. They were able to conclude that the alleles associated with the most negatively charged proteins carry the greatest risk of developing beryllium sensitization and CBD. This confirms the importance of beryllium charge as a key factor in haptogenic potential.

In contrast, the HLA–DRB1 allele, which lacks Glu 69, has also been shown to increase the risk of developing sensitization and CBD (Amicosante *et al.,* 2005; Maier *et al.,* 2003). Bill *et al.* (2005) found that HLA–DR has a glutamic acid at position 71 of the β chain, functionally equivalent to the Glu 69 of HLA–DP (Bill *et al.,* 2005). Associations with BeS and CBD have also been reported with the HLA–DQ markers (Amicosante *et al.,* 2005; Maier *et al.,* 2003). Stubbs *et al.* also found a biased distribution of the MHC class II HLA–DR gene between sensitized and non-sensitized subjects. Neither of these markers was completely specific for CBD, as each study found beryllium sensitization or CBD among individuals without the genetic risk factor. While there remains uncertainty as to which of the MHC class II genes interact directly with the beryllium ion, antibody inhibition data suggest that the HLA–DR gene product may be involved in the presentation of beryllium to T lymphocytes (Amicosante *et al.,* 2002). In addition, antibody blocking experiments revealed that anti-HLA–DP strongly reduced proliferation responses and cytokine secretion by BAL CD4 T cells (Chou *et al.,* 2005). In the study by Chou (2005), anti-HLA–DR ligand antibodies mainly affected beryllium-induced proliferation responses with little impact on cytokines other than IL–2, thus implying that nonproliferating BAL CD4 T cells may still contribute to inflammation leading to the progression of CBD (Chou *et al.,* 2005).

TNF alpha (TNF-α) polymorphisms and TGF beta (TGF-β) polymorphisms have also been shown to confer a genetic susceptibility for developing CBD in certain individuals. TNF-α is a pro-inflammatory cytokine associated with a more severe pulmonary disease in CBD (NAS, 2008). Beryllium exposure has been shown to upregulate transcription factors AP–1 and NF-κB (Sawyer *et al.,* 2007) inducing an inflammatory response by stimulating production of pro-inflammatory cytokines such as TNF-α by inflammatory cells. Polymorphisms in the 308 position of the TNF-α gene have been demonstrated to increase production of the cytokine and increase severity of disease (Maier *et al.,* 2001; Saltini *et al.,* 2001; Dotti *et al.,* 2004). While a study by McCanlies *et al.* (2007) found no relationship between TNF-α polymorphism and BeS or CBD, the inconsistency may be due to misclassification, exposure differences or statistical power (NAS, 2008).

Other genetic variations have been shown to be associated with increased risk of beryllium sensitization and CBD (NAS, 2008). These include TGF-β (Gaede *et al.,* 2005), angiotensin-1 converting enzyme (ACE) (Newman *et al.,* 1992; Maier *et al.,* 1999) and an enzyme involved in glutathione synthesis (glutamate cysteine ligase) (Bekris *et al.,* 2006). McCanlies *et al.* (2010) evaluated the association between polymorphisms in a select group of interleukin genes (IL–1A; IL–1B, IL–1RN, IL–2, IL–9, IL–9R) due to their role in immune and inflammatory processes. The study evaluated SNPs in three groups of workers from large beryllium manufacturing facilities in OH and AZ. The investigators found a significant association between variants IL–1A–1142, IL–1A–3769 and IL–1A–4697 and CBD but not with beryllium sensitization. However, these still require confirmation in larger studies (NAS, 2008).

In addition to the genetic factors which may contribute to the susceptibility and severity of disease, other factors such as smoking and gender may play a role in the development of CBD (NAS, 2008). A recent longitudinal cohort study by Mroz *et al.* (2009) of 229 individuals identified with beryllium sensitization or CBD through workplace medical surveillance found that the prevalence of CBD among ever smokers was significantly lower than among never smokers (38.1 percent versus 49.4 percent, p=0.025). BeS subjects that never smoked were found to be more likely to develop CBD over the course of the study compared to current smokers (12.6 percent versus 6.4 percent, p=0.10). The authors suggested smoking may confer a protective effect against development of lung granulomas as has been demonstrated with hypersensitivity pneumonitis (Mroz *et al.,* 2009).

4. Beryllium Sensitization and CBD in the Workforce

Sensitization to beryllium is currently detected in the workforce with the beryllium lymphocyte proliferation test (BeLPT), a laboratory blood test developed in the 1980s, also referred to as the LTT (Lymphocyte Transformation Test) or BeLT (Beryllium Lymphocyte Transformation Test). In this test, lymphocytes obtained from either bronchoalveolar lavage fluid (the BAL BeLPT) or from peripheral blood (the blood BeLPT) are cultured *in vitro* and exposed to beryllium sulfate to stimulate lymphocyte proliferation. The observation of beryllium-specific proliferation indicates beryllium sensitization. Hereafter, ''BeLPT'' generally refers to the blood BeLPT, which is typically used in screening for beryllium sensitization. This test is described in more detail in subsection D.5.b.

CBD can be detected at an asymptomatic stage by a number of techniques including bronchoalveolar lavage and biopsy (Cordeiro *et al.,* 2007; Maier, 2001). Bronchoalveolar lavage is a method of ''washing'' the lungs with fluid inserted via a flexible fiberoptic instrument known as a bronchoscope, removing the fluid and analyzing the content for the inclusion of immune cells reactive to beryllium exposure, as described earlier in this section. Fiberoptic bronchoscopy can be used to detect granulomatous lung inflammation prior to the onset of CBD symptoms as well, and has been used in combination with the BeLPT to diagnose pre-symptomatic CBD in a number of recent screening studies of beryllium-exposed workers, which are discussed in the following section detailing diagnostic procedures. Of workers who were found to be sensitized and underwent clinical evaluation, 31–49 percent of them were diagnosed with CBD (Kreiss *et al.,* 1993; Newman *et al.,* 1996, 2005, 2007; Mroz, 2009), however some estimate that with increased surveillance the percent could be much higher (Newman, 2005; Mroz, 2009). It has been estimated from ongoing surveillance studies of sensitized individuals with an average follow-up time of 4.5 years that 31 percent of beryllium-sensitized employees were estimated to progress to CBD (Newman *et al.,* 2005). A study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that only 20 percent of sensitized workers employed less than 5 years eventually were diagnosed with CBD, while 40 percent of sensitized workers employed 10 years or more developed CBD (Stange *et al.,* 2001). One limitation for all these studies is lack of long-term follow-up. It may be necessary to continue to monitor these workers in order to determine whether all BeS workers will develop CBD (Newman *et al.,* 2005).

CBD has a clinical spectrum ranging from evidence of beryllium sensitization and granulomas in the lung with little symptomatology to loss of lung function and end stage disease which may result in the need for lung transplantation and decreased life expectancy. Unfortunately, there are very few published clinical studies describing the full range and progression of CBD from the beginning to the end stages and very few of the risk factors for progression of disease have been delineated (NAS, 2008). Clinical management of CBD is modeled after sarcoidosis where oral corticosteroid treatment is initiated in patients who have evidence of progressive lung disease, although progressive lung disease has not been well defined (NAS, 2008). In advanced cases of CBD, corticosteroids are the standard treatment (NAS, 2008). No comprehensive studies have been published measuring the overall effect of removal of workers from beryllium exposure on sensitization and CBD (NAS, 2008) although this has been suggested as part of an overall treatment regime for CBD (Mapel *et al.,* 2002; Sood *et al.,* 2004; Maier *et al.,* 2006; Sood, 2009; Maier *et al.,* 2012). Sood *et al.* reported that cessation of exposure can sometimes have beneficial effects on lung function (Sood et al., 2004). However, this was based on anecdotal evidence from six patients with CBD, so more research is needed to better determine the relationship between exposure duration and disease progression

5. Human Epidemiological Studies

This section describes the human epidemiological data supporting the mechanistic overview of beryllium-induced disease in workers. It has been divided into reviews of epidemiological studies performed prior to development and implementation of the BeLPT in the late 1980s and after wide use of the BeLPT for screening purposes. Use of the BeLPT has allowed investigators to screen for beryllium sensitization and CBD prior to the onset of clinical symptoms, providing a more sensitive and thorough analysis of the worker population. The discussion of the studies has been further divided by manufacturing processes that may have similar exposure profiles. Table A.1 in the Appendix summarizes the prevalence of beryllium sensitization and CBD, range of exposure measurements, and other salient information from the key epidemiological studies.

It has been well-established that beryllium exposure, either via inhalation or skin, may lead to beryllium sensitization, or, with inhalation exposure, may lead to the onset and progression of CBD. The available published epidemiological literature discussed below provides strong evidence of beryllium sensitization and CBD in workers exposed to airborne beryllium well below the current OSHA PEL of 2 μg/m³. Several studies demonstrate the prevalence of sensitization and CBD is related to the level of airborne exposure, including a cross-sectional survey of employees at a beryllium ceramics plant in Tucson, AZ (Henneberger *et al.,* 2001), case-control studies of workers at the Rocky Flats nuclear weapons facility (Viet *et al.,* 2000), and workers from a beryllium machining plant in Cullman, AL (Kelleher *et al.,* 2001). The prevalence of beryllium sensitization also may be related to dermal exposure. An increased risk of CBD has been reported in workers with skin lesions, potentially increasing the uptake of beryllium (Curtis, 1951; Johnson *et al.,* 2001; Schuler *et al.,* 2005). Three studies describe comprehensive preventive programs, which included expanded respiratory protection, dermal protection, and improved control of beryllium dust migration, that substantially reduced the rate of beryllium sensitization among new hires (Cummings *et al.,* 2007; Thomas *et al.,* 2009; Bailey *et al.,* 2010; Schuler *et al.,* 2012).

Some of the epidemiological studies presented in this review suffer from challenges common to many published epidemiological studies: Limitations in study design (particularly cross-sectional); small sample size; lack of personal and/or short-term exposure data, particularly those published before the late 1990s; and incomplete information regarding specific chemical form and/or particle characterization. Challenges that are specific to beryllium epidemiological studies include: uncertainty regarding the contribution of dermal exposure; use of various BeLPT protocols; a variety of case definitions for determining CBD; and use of various exposure sampling/assessment methods (*e.g.,* daily weighted average (DWA), lapel sampling). Even with these limitations, the epidemiological evidence presented in this section clearly demonstrates that beryllium sensitization and CBD are continuing to occur from present-day exposures below OSHA's PEL. The available literature also indicates that the rate of BeS can be substantially lowered by reducing inhalation exposure and minimizing dermal contact.

a. Studies Conducted Prior to the BeLPT

First reports of CBD came from studies performed by Hardy and Tabershaw (1946). Cases were observed in industrial plants that were refining and manufacturing beryllium metal and beryllium alloys and in plants manufacturing fluorescent light bulbs (NAS, 2008). From the late 1940s through the 1960s, clusters of non-occupational CBD cases were identified around beryllium refineries in Ohio and Pennsylvania, and outbreaks in family members of beryllium factory workers were assumed to be from exposure to contaminated clothes (Hardy, 1980). It had been established that the risk of disease among beryllium workers was variable and generally rose with the levels of airborne concentrations (Machle *et al.,* 1948). And while there was a relationship between air concentrations of beryllium and risk of developing disease both in and surrounding these plants, the disease rates outside the plants were higher than expected and not very different from the rate of CBD within the plants (Eisenbud *et al.,* 1949; Lieben and Metzner, 1959). There remained considerable uncertainty regarding diagnosis due to lack of well-defined cohorts, modern diagnostic methods, or inadequate follow-up. In fact, many patients with CBD may have been misdiagnosed with sarcoidosis (NAS, 2008).

The difficulties in distinguishing lung disease caused by beryllium from other lung diseases led to the establishment of the BCR in 1952 to identify and track cases of ABD and CBD. A uniform diagnostic criterion was introduced in 1959 as a way to delineate CBD from sarcoidosis. Patient entry into the BCR required either: documented past exposure to beryllium or the presence of beryllium in lung tissue as well as clinical evidence of beryllium disease (Hardy *et al.,* 1967); or any three of the six criteria listed below (Hasan and Kazemi, 1974). Patients identified using the above criteria were registered and added to the BCR from 1952 through 1983 (Eisenbud and Lisson, 1983).

The BCR listed the following criteria for diagnosing CBD (Eisenbud and Lisson, 1983):

(1) Establishment of significant beryllium exposure based on sound epidemiologic history;

(2) Objective evidence of lower respiratory tract disease and clinical course consistent with beryllium disease;

(3) Chest X-ray films with radiologic evidence of interstitial fibronodular disease;

(4) Evidence of restrictive or obstructive defect with diminished carbon monoxide diffusing capacity (DL_{CO}) by physiologic studies of lung function;

(5) Pathologic changes consistent with beryllium disease on examination of lung tissue; and

(6) Presence of beryllium in lung tissue or thoracic lymph nodes.

Prevalence of CBD in workers during the time period between the 1940s and 1950s was estimated to be between 1–10% (Eisenbud and Lisson, 1983). In a 1969 study, Stoeckle *et al.* presented 60 case histories with a selective literature review utilizing the above criteria except that urinary beryllium was substituted for lung beryllium to demonstrate beryllium exposure. Stoeckle *et al.* (1969) were able to demonstrate corticosteroids as a successful treatment option in one case of confirmed CBD. This study also presented a 28 percent mortality rate from complications of CBD at the time of publication. However, even with the improved methodology for determining CBD based on the BCR criteria, these studies suffered from lack of well-defined cohorts, modern diagnostic techniques or adequate follow-up.

b. Criteria for Beryllium Sensitization and CBD Case Definition Following the Development of the BeLPT

The criteria for diagnosis of CBD have evolved over time as more advanced diagnostic technology, such as the (blood) BeLPT and BAL BeLPT, has become available. More recent diagnostic criteria have both higher specificity than earlier methods and higher sensitivity, identifying subclinical effects. Recent studies typically use the following criteria (Newman *et al.,* 1989; Pappas and Newman, 1993; Maier *et al.,* 1999):

(1) History of beryllium exposure;

(2) Histopathological evidence of noncaseating granulomas or mononuclear cell infiltrates in the absence of infection; and

(3) Positive blood or BAL BeLPT (Newman *et al.,* 1989).

The availability of transbronchial lung biopsy facilitates the evaluation of the second criterion, by making histopathological confirmation possible in almost all cases.

A significant component for the identification of CBD is the demonstration of a confirmed abnormal BeLPT result in a blood or BAL sample (Newman, 1996). Since the development of the BeLPT in the 1980s, it has been used to screen beryllium-exposed workers for sensitization in a number of studies to be discussed below. The BeLPT is a non-invasive *in vitro* blood test which measures the beryllium antigen-specific T-cell mediated immune response and is the most commonly available diagnostic tool for identifying beryllium sensitization. The BeLPT measures the degree to which beryllium stimulates lymphocyte proliferation under a specific set of conditions, and is interpreted based upon the number of stimulation indices that exceed the normal value. The 'cut-off' is based on the mean value of the peak stimulation index among controls plus 2 or 3 standard deviations. This methodology was modeled into a statistical method known as the ''least absolute values'' or ''statistical-biological positive'' method and relies on natural log modeling of the median stimulation index values (DOE, 2001; Frome, 2003). In most applications, two or more stimulation indices that exceed the cut-off constitute an abnormal test.

Early versions of the BeLPT test had high variability, but the use of tritiated thymidine to identify proliferating cells has led to a more reliable test (Mroz *et al.,* 1991; Rossman *et al.,* 2001). In recent years, the peripheral blood test has been found to be as sensitive as the BAL assay, although larger abnormal responses have been observed with the BAL assay (Kreiss *et al.,* 1993; Pappas and Newman, 1993). False negative results have also been observed with the BAL BeLPT in cigarette smokers who have marked excess of alveolar macrophages in lavage fluid (Kreiss *et al.,* 1993). The BeLPT has also been a useful tool in animal studies to identify those species with a beryllium-specific immune response (Haley *et al.,* 1994).

Screenings for beryllium sensitization have been conducted using the BeLPT in several occupational surveys and surveillance programs, including nuclear weapons facilities operated by the Department of Energy (Viet *et al.,* 2000; Strange *et al.,* 2001; DOE/HSS Report, 2006), a beryllium ceramics plant in Arizona (Kreiss *et al.,* 1996; Henneberger *et al.,* 2001; Cummings *et al.,* 2007), a beryllium production plant in Ohio (Kreiss *et al.,* 1997; Kent *et al.,* 2001), a beryllium machining facility in Alabama (Kelleher *et al.,* 2001; Madl *et al.,* 2007), a beryllium alloy plant (Schuler *et al.,* 2005, Thomas *et al.,* 2009), and another beryllium processing plant (Rosenman *et al.,* 2005) in Pennsylvania. In most of these studies, individuals with an abnormal BeLPT result were retested and were identified as sensitized (*i.e.,* confirmed positive) if the abnormal result was repeated.

There has been criticism regarding the reliability and specificity of the BeLPT as a screening tool (Borak *et al.,* 2006). Stange *et al.* (2004) studied the reliability and laboratory variability of the BeLPT by splitting blood samples and sending samples to two laboratories simultaneously for BeLPT analysis. Stange *et al.* found the range of agreement on abnormal (positive BeLPT) results was 26.2—61.8 percent depending upon the labs tested (Stange *et al.,* 2004). Borak *et al.* (2006) contended that the positive predictive value (PPV) (PPV is the portion of patients with positive test result correctly diagnosed) is not high enough to meet the criteria of a good screening tool. Middleton *et al.* (2008) used the data from the Stange *et al.* (2004) study to estimate the PPV and determined that the PPV of the BeLPT could be improved from 0.383 to 0.968 when an abnormal BeLPT result is confirmed with a second abnormal result (Middleton *et al.,* 2008). However, an apparent false positive can occur in people not occupationally exposed to beryllium (NAS, 2008). An analysis of survey data from the general workforce and new employees at a beryllium manufacturer was performed to assess the reliability of the BeLPT (Donovan *et al.* 2007). Donovan *et al.* analyzed more than 10,000 test results from nearly 2400 participants over a 12-year period. Donovan *et al.* found that approximately 2 percent of new employees had at least one positive BeLPT at the time of hire and 1 percent of new hires with no known occupational exposure were confirmed positive at the time of hire with two BeLPTs. Since there are currently no alternatives to the BeLPT in a screening program many programs rely on a second test to confirm a positive result (NAS, 2008).

The epidemiological studies presented in this section utilized the BeLPT as either a surveillance tool or a screening tool for determining sensitization status and/or sensitization/CBD prevalence in workers for inclusion in the published studies. Most epidemiological studies have reported rates of sensitization and disease based on a single screening of a working population ('cross-sectional' or 'population prevalence' rates). Studies of workers in a beryllium machining plant and a nuclear weapons facility have included follow-up of the population originally screened, resulting in the detection of additional cases of sensitization over several years (Newman *et al.,* 2001, Stange *et al.,* 2001). OSHA regards the BeLPT as a reliable medical surveillance tool. The BeLPT is discussed in more detail in Non-Mandatory Appendix A to the proposed standard, Immunological Testing for the Determination of Beryllium Sensitization.

c. Beryllium Mining and Extraction

Mining and extraction of beryllium usually involves the two major beryllium minerals, beryl (an aluminosilicate containing up to 4 percent beryllium) and bertrandite (a beryllium silicate hydrate containing generally less than 1 percent beryllium) (WHO, 2001). The United States is the world leader in beryllium extraction and also leads the world in production and use of beryllium and its alloys (WHO, 2001). Most exposures from mining and extraction come in the form of beryllium ore, beryllium salts, beryllium hydroxide (NAS 2008) or beryllium oxide (Stefaniak *et al.,* 2008).

Deubner *et al.* published a study of 75 workers employed at a beryllium mining and extraction facility in Delta, UT (Deubner *et al.,* 2001b). Of the 75 workers surveyed for sensitization with the BeLPT, three were identified as sensitized by an abnormal BeLPT result. One of those found to be sensitized was diagnosed with CBD. Exposures at the facility included primarily beryllium ore and salts. General area (GA), breathing zone (BZ), and personal lapel (LP) exposure samples were collected from 1970 to 1999. Jobs involving beryllium hydrolysis and wet-grinding activities had the highest air concentrations, with an annual median GA concentration ranging from 0.1 to 0.4 μg/m³. Median BZ concentrations were higher than either LP or GA. The average duration of exposure for beryllium sensitized workers was 21.3 years (27.7 years for the worker with CBD), compared to an average duration for all workers of 14.9 years. However, these exposures were less than either the Elmore, OH, or Tucson, AZ, facilities described below, which also had higher reported rates of BeS and CBD. A study by Stefaniak *et al.* (2008) demonstrated that beryllium was present at the mill in three forms: mineral, poorly crystalline oxide, and hydroxide.

There was no sensitization or CBD among those who worked only at the mine where exposure to beryllium resulted solely from working with bertrandite ore. The authors concluded that the results of this study indicated that beryllium ore and salts may pose less of a hazard than beryllium metal and beryllium hydroxide. These results are consistent with the previously discussed animal studies examining solubility and particle size.

d. Beryllium Metal Processing and Alloy Production

Kreiss *et al.* (1997) conducted a study of workers at a beryllium production facility in Elmore, OH. The plant, which opened in 1953 and initially specialized in production of beryllium-copper alloy, later expanded its operations to include beryllium metal, beryllium oxide, and beryllium-aluminum alloy production; beryllium and beryllium alloy machining; and beryllium ceramics production, which was moved to a different factory in the early 1980s. Production operations included a wide variety of jobs and processes, such as work in arc furnaces and furnace rebuilding, alloy melting and casting, beryllium powder processing, and work in the pebble plant. Non-production work included jobs in the analytical laboratory, engineering research and development, maintenance, laundry, production-area management, and office-area administration. While the publication refers to the use of respiratory protection in some areas, such as the pebble plant, the extent of its use across all jobs or time periods was not reported. Use of dermal PPE was not reported.

The authors characterized exposures at the plant using industrial hygiene (IH) samples collected between 1980 and 1993. The exposure samples and the plant's formulas for estimating workers' DWA exposures were used, together with study participants' work histories, to estimate their cumulative and average beryllium exposure levels. Exposure concentrations reflected the high exposures found historically in beryllium production and processing. Short-term BZ measurements had a median of 1.4, with 18.5 percent of samples exceeding OSHA's STEL of 5.0 μg/m^3. Particularly high beryllium concentrations were reported in the areas of beryllium powder production, laundry, alloy arc furnace (approximately 40 percent of DWA estimates over 2.0 μg/m^3) and furnace rebuild (28.6 percent of short-term BZ samples over the OSHA STEL of 5 μg/m^3). LP samples (n = 179), which were available from 1990 to 1992, had a median value of 1 μg/m^3.

Of 655 workers employed at the time of the study, 627 underwent BeLPT screening. Blood samples were divided and split between two labs for analysis, with repeat testing for results that were abnormal or indeterminate. Thirty-one workers had an abnormal blood test upon initial testing and at least one of two subsequent tests was classified as sensitized. These workers, together with 19 workers who had an initial abnormal result and one subsequent indeterminate result, were offered clinical evaluation for CBD including the BAL-BeLPT and transbronchial lung biopsy. Nine with an initial abnormal test followed by two subsequent normal tests were not clinically evaluated, although four were found to be sensitized upon retesting in 1995. Of 47 workers who proceeded with evaluation for CBD (3 of the 50 initial workers with abnormal results declined to participate), 24 workers were diagnosed with CBD based on evidence of granulomas on lung biopsy (20 workers) or on other findings consistent with CBD (4 workers) (Kreiss *et al.,* 1997). After including five workers who had been diagnosed prior to the study, a total of 29 (4.6 percent) current workers were found to have CBD. In addition, the plant medical department identified 24 former workers diagnosed with CBD before the study.

Kreiss *et al.* reported that the highest prevalence of sensitization and CBD occurred among workers employed in beryllium metal production, even though the highest airborne total mass concentrations of beryllium were generally among employees operating the beryllium alloy furnaces in a different area of the plant (Kreiss *et al.,* 1997). Preliminary follow-up investigations of particle size-specific sampling at five furnace sites within the plant determined that the highest respirable (*e.g.,* particles <10 μm in diameter as defined by the authors) and alveolar-deposited (*e.g.,* particles <1 μm in diameter as defined by the authors) beryllium mass and particle number concentrations, as collected by a general area impactor device, were measured at the beryllium metal production furnaces rather than the beryllium alloy furnaces (Kent *et al.,* 2001; McCawley *et al.,* 2001). A statistically significant linear trend was reported between the above alveolar-deposited particle mass concentration and prevalence of CBD and sensitization in the furnace production areas. The authors concluded that alveolar-deposited particles may be a more relevant exposure metric for predicting the incidence of CBD or sensitization than the total mass concentration of airborne beryllium.

Bailey *et al.* (2010) evaluated the effectiveness of a workplace preventive program in lowering BeS at the beryllium metal, oxide, and alloy production plant studied by Kreiss *et al.* (1997). The preventive program included use of administrative and PPE controls (*e.g.,* improved training, skin protection and other PPE, half-mask or air-purified respirators, medical surveillance, improved housekeeping standards, clean uniforms) as well as engineering controls (*e.g.,* migration controls, physical separation of administrative offices from production facilities) implemented over the course of five years.

In a cross-sectional/longitudinal hybrid study, Bailey *et al.* compared rates of sensitization in pre-program workers to those hired after the preventive program began. Pre-program workers were surveyed cross-sectionally in 1993–1994, and again in 1999 using the BeLPT to determine sensitization and CBD prevalence rates. The 1999 cross-sectional survey was conducted to determine if improvements in engineering and administrative controls were successful, however, results indicated no improvement in reducing rates of sensitization or CBD.

An enhanced preventive program including particle migration control, respiratory and dermal protection, and process enclosure was implemented in 2000, with continuing improvements made to the program in 2001, 2002–2004, and 2005. Workers hired during this period were longitudinally surveyed for sensitization using the BeLPT. Both the pre-program and program survey of worker sensitization status utilized split-sample testing to verify positive test results using the BeLPT. Of the total 660 workers employed at the production plant, 258 workers participated from the pre-program group while 290 participated from the program group (206 partial program, 84 full program). Prevalence comparisons of the pre-program and program groups (partial and full) were performed by calculating prevalence ratios. A 95 percent confidence interval (95 percent CI) was derived using a cohort study method that accounted for the variance in survey techniques (cross-sectional versus longitudinal) (Bailey *et al.,* 2010). The sensitization prevalence of the pre-program group was 3.8 times higher (95 percent CI, 1.5–9.3) than the program group, 4.0 times higher (95 percent CI, 1.4–11.6) than the partial program subgroup, and 3.3 times higher (95 percent CI, 0.8–13.7) than the full program subgroup indicating that a comprehensive preventive program can reduce, but not eliminate, occurrence of sensitization among non-sensitized workers (Bailey *et al.,* 2010).

Rosenman *et al.* (2005) studied a group of several hundred workers who had been employed at a beryllium production and processing facility that operated in eastern Pennsylvania between 1957 and 1978. Of 715 former workers located, 577 were screened for BeS with the BLPT and 544 underwent chest radiography to identify cases of BeS and CBD. Workers were reported to have exposure to beryllium dust and fume in a variety of chemical forms including beryl ore, beryllium metal, beryllium fluoride, beryllium hydroxide, and beryllium oxide.

Rosenman *et al.* used the plant's DWA formulas to assess workers' full-shift exposure levels, based on IH data collected between 1957–1962 and 1971–1976, to calculate exposure metrics including cumulative, average, and peak for each worker in the study. The DWA was calculated based on air monitoring that consisted of GA and short-term task-based BZ samples. Workers' exposures to specific chemical and physical forms of beryllium were assessed, including insoluble beryllium (metal and oxide), soluble beryllium (fluoride and hydroxide), mixed soluble and insoluble beryllium, beryllium dust (metal, hydroxide, or oxide), fume (fluoride), and mixed dust and fume. Use of respiratory or dermal protection by workers was not reported. Exposures in the plant were high overall. Representative task-based IH samples ranged from 0.9 $\mu g/m^3$ to 84 $\mu g/m^3$ in the 1960s, falling to a range of 0.5–16.7 $\mu g/m^3$ in the 1970s. A large number of workers' mean DWA estimates (25 percent) were above the OSHA PEL of 2.0 $\mu g/m^3$, while most workers had mean DWA exposures between 0.2 and 2.0 $\mu g/m^3$ (74 percent) or below 0.02 $\mu g/m^3$ (1 percent) (Rosenman *et al.,* Table 11; revised erratum April, 2006).

Blood samples for the BeLPT were collected from the former workers between 1996 and 2001 and were evaluated at a single laboratory. Individuals with an abnormal test result were offered repeat testing, and were classified as sensitized if the second test was also abnormal. Sixty workers with two positive BeLPTs and 50 additional workers with chest radiography suggestive of disease were offered clinical evaluation, including bronchoscopy with bronchial biopsy and BAL-BeLPT. Seven workers met both criteria. Only 56 (51 percent) of these workers proceeded with clinical evaluation, including 57 percent of those referred on the basis of confirmed abnormal BeLPT and 47 percent of those with abnormal radiographs.

Of those workers who underwent bronchoscopy, 32 (5.5 percent) with evidence of granulomas were classified as ''definite'' CBD cases. Twelve (2.1 percent) additional workers with positive BAL-BeLPT or confirmed positive BeLPT and radiographic evidence of upper lobe fibrosis were classified as ''probable'' CBD cases. Forty workers (6.9 percent) without upper lobe fibrosis who had confirmed abnormal BeLPT, but who were not biopsied or who underwent biopsy with no evidence of granuloma, were classified as sensitized without disease. It is not clear how many of the 40 workers underwent biopsy. Another 12 (2.1 percent) workers with upper lobe fibrosis and negative or unconfirmed positive BeLPT were classified as ''possible'' CBD cases. Nine additional workers who were diagnosed with CBD before the screening were included in some parts of the authors' analysis.

The authors reported a total prevalence of 14.5 percent for CBD (definite and probable) and sensitization. This rate, considerably higher than the overall prevalence of sensitization and disease in several other worker cohorts as described earlier in this section, reflects in part the very high exposures experienced by many workers during the plant's operation in the 1950s, 1960s and 1970s. A total of 115 workers had mean DWAs above the OSHA PEL of 2 $\mu g/m^3$. Of those, 7 (6.0 percent) had definite or probable CBD and another 13 (11 percent) were classified as sensitized without disease. The true prevalence of CBD in the group may be higher than reported, due to the low rate of clinical evaluation among sensitized workers.

Although most of the workers in this study had high exposures, sensitization and CBD also were observed within the small subgroup of participants believed to have relatively low beryllium exposures. Thirty-three cases of CBD and 24 additional cases of sensitization occurred among 339 workers with mean DWA exposures below OSHA's PEL of 2.0 $\mu g/m^3$ (Rosenman *et al.,* Table 11, erratum 2006). Ten cases of sensitization and five cases of CBD were found among office and clerical workers, who were believed to have low exposures (levels not reported).

Follow-up time for sensitization screening of workers in this study who became sensitized during their employment had a minimum of 20 years to develop CBD prior to screening. In this sense the cohort is especially well suited to compare the exposure patterns of workers with CBD and those sensitized without disease, in contrast to several other studies of workers with only recent beryllium exposures. Rosenman *et al.* characterized and compared the exposures of workers with definite and probable CBD, sensitization only, and no disease or sensitization using chi-squared tests for discrete outcomes and analysis of variance (ANOVA) for continuous variables (cumulative, mean, and peak exposure levels). Exposure-response relationships were further examined with logistic regression analysis, adjusting for potential confounders including smoking, age, and beryllium exposure from outside of the plant. The authors found that cumulative, peak, and duration of exposure were significantly higher for workers with CBD than for sensitized workers without disease ($p < 0.05$), suggesting that the risk of progressing from sensitization to CBD is related to the level or extent of exposure a worker experiences. The risk of developing CBD following sensitization appeared strongly related to exposure to insoluble forms of beryllium, which are cleared slowly from the lung and increase beryllium lung burden more rapidly than quickly mobilized soluble forms. Individuals with CBD had higher exposures to insoluble beryllium than those classified as sensitized without disease, while exposure to soluble beryllium was higher among sensitized individuals than those with CBD.

Cumulative, mean, peak, and duration of exposure were found to be comparable for workers with CBD and workers without sensitization or CBD (''normal'' workers). Cumulative, peak, and duration of exposure were significantly lower for sensitized workers without disease than for normal workers. Rosenman *et al.* suggested that genetic predisposition to sensitization and CBD may have obscured an exposure-response relationship in this study, and plan to control for genetic risk factors in future studies. Exposure misclassification from the 1950s and 1960s may have been another limitation in this study, introducing bias that could have influenced the lack of exposure response. It is also unknown if the 25 percent who died from CBD-related conditions may have had higher exposures.

A follow-up was conducted of the cross-sectional study of a population of workers first evaluated by Kreiss et al. (1997) and Rosenman et al. (2005) at a beryllium production and processing facility in eastern Pennsylvania by Schuler et al. (2012), and in a companion study by Virji et al. (2012). Schuler et al. evaluated the worker population employed in 1999 with six years or less work tenure in a cross-sectional study. The investigators evaluated the worker population by administering a work history questionnaire with a follow-up examination for sensitization and CBD. A job-exposure matrix (JEM) was combined with work histories to create individual estimates of average, cumulative, and highest-job-related exposure for total, respirable, and sub-micron beryllium mass concentration. Of the 291 eligible workers, 90.7 percent (264) participated in the study. Sensitization prevalence was 9.8 percent (26/264) with CBD prevalence of 2.3 percent (6/264). The investigators found a general pattern of increasing sensitization prevalence as the exposure quartile increased indicating an exposure-response relationship. The investigators found positive associations with both total and respirable mass concentration with sensitization (average and highest job) and CBD (cumulative). Increased sensitization prevalence was observed with metal oxide production alloy melting and casting, and maintenance. CBD was associated with melting and casting. The investigators summarized that both total and respirable mass concentration were relevant predictors of risk (Schuler *et al.,* 2012).

In the companion study by Virji et al. (2012), the investigators reconstructed historical exposure from 1994 to 1999 utilizing the personal sampling data collected in 1999 as baseline exposure estimates (BEE). The study evaluated techniques for reconstructing historical data to evaluate exposure-response relationships for epidemiological studies. The investigators constructed JEMs using the BEE and estimates of annual changes in exposure for 25 different process areas. The investigators concluded these reconstructed JEMs could be used to evaluate a range of exposure parameters from total, respirable and submicron mass concentration including cumulative, average, and highest exposure. These two studies demonstrate that high-quality exposure estimates can be developed both for total mass and respirable mass concentrations.

e. Beryllium Machining Operations

Newman *et al.* (2001) and Kelleher *et al.* (2001) studied a group of 235 workers at a beryllium metal machining plant. Since the plant opened in 1969, its primary operations have been machining and polishing beryllium metal and high-beryllium content composite materials, with occasional machining of beryllium oxide/metal matrix ('E-metal'), and beryllium alloys. Other functions include machining of metals other than beryllium; receipt and inspection of materials; acid etching; final inspection, quality control, and shipping of finished materials; tool making; and engineering, maintenance, administrative and supervisory functions (Newman *et al.,* 2001; Madl *et al.,* 2007). Machining operations, including milling, grinding, lapping, deburring, lathing, and electrical discharge machining (EDM), were performed in an open-floor plan production area. Most non-machining jobs were located in a separate, adjacent area; however, non-production employees had access to the machining area.

Engineering and administrative measures, rather than PPE, were primarily used to control beryllium exposures at the plant (Madl *et al.,* 2007). Based on interviews with long-standing employees of the plant, Kelleher *et al.* reported that work practices were relatively stable until 1994, when a worker was diagnosed with CBD and a new exposure control program was initiated. Between 1995 and 1999 new engineering and work practice controls were implemented, including removal of pressurized air hoses and discouragement of dry sweeping (1995), enclosure of deburring processes (1996), mandatory uniforms (1997), and installation or updating of local exhaust ventilation (LEV) in EDM, lapping, deburring, and grinding processes (1998) (Madl *et al.,* 2007). Throughout the plant's history, respiratory protection was used mainly for ''unusually large, anticipated exposures'' to beryllium (Kelleher *et al.,* 2001), and was not routinely used otherwise (Newman *et al.,* 2001).

All workers at the plant participated in a beryllium disease surveillance program initiated in 1994, and were screened for beryllium sensitization with the BeLPT beginning in 1995. A BeLPT result was considered abnormal if two or more of six stimulation indices exceeded the normal range (see section on BeLPT testing above), and was considered borderline if one of the indices exceeded the normal range. A repeat BeLPT was conducted for workers with abnormal or borderline initial results. Workers were identified as beryllium sensitized and referred for a clinical evaluation, including bronchoalveolar lavage (BAL) and transbronchial lung biopsy, if the repeat test was abnormal. CBD was diagnosed upon evidence of sensititization with granulomas or mononuclear cell infiltrates in the lung tissue (Newman *et al.,* 2001). Following the initial plant-wide screening, plant employees were offered BeLPT testing at two-year intervals. Workers hired after the initial screening were offered a BeLPT within 3 months of their hire date, and at 2-year intervals thereafter (Madl *et al.,* 2007).

Kelleher *et al.* performed a nested case-control study of the 235 workers evaluated in Newman *et al.* (2001) to evaluate the relationship between beryllium exposure levels and risk of sensitization and CBD (Kelleher *et al.,* 2001). The authors evaluated exposures at the plant using IH samples they had collected between 1996 and 1999, using personal cascade impactors designed to measure the mass of beryllium particles less than 6 μm, particles less than 1 μm in diameter, and total mass. The great majority of workers' exposures were below the OSHA PEL of 2 μg/m³. However, a few higher levels were observed in machining jobs including deburring, lathing, lapping, and grinding. Based on a statistical comparison between their samples and historical data provided by the plant, the authors concluded that worker beryllium exposures across all time periods could be approximated using the 1996–1999 data. They estimated workers' cumulative and 'lifetime weighted' (LTW) beryllium exposure based on the exposure samples they collected for each job in 1996–1999 and company records of each worker's job history.

Twenty workers with beryllium sensitization or CBD (cases) were compared to 206 workers (controls) for the case-control analysis from the study evaluating workers originally conducted by Newman *et al.* Thirteen workers were diagnosed with CBD based on lung biopsy evidence of granulomas and/or mononuclear cell infiltrates (11) or positive BAL results with evidence of lymphocytosis (2). Seven were evaluated for CBD and found to be sensitized only, thus twenty composing the case group. Nine of the remaining 215 workers first identified in original study (Newman *et al.,* 2001) were excluded due to incomplete job history information, leaving 206 workers in the control group.

Kelleher *et al.'*s analysis included comparisons of the case and control groups' median exposure levels; calculation of odds ratios for workers in high, medium, and low exposure groups; and logistic regression testing of the association of sensitization or CBD with exposure level and other variables. Median cumulative exposures for total mass, particles <6 μ m, and particles <1 μm were approximately three times higher among the cases than controls, although the relationships observed were not statistically significant (p values ~ 0.2). No clear difference between cases and controls was observed for the median LTW exposures. Odds ratios with sensitization and CBD as outcomes were elevated in high (upper third) and intermediate exposure groups relative to low (lowest third) exposure groups for both cumulative and LTW exposure, though the results were not statistically significant (p > 0.1). In the logistic regression analysis, only machinist work history was a significant predictor of case status in the final model. Quantitative exposure measures were not significant predictors of sensitization or disease risk.

Citing an 11.5 percent prevalence of beryllium sensitization or CBD among machinists as compared with 2.9 percent prevalence among workers with no machinist work history, the authors concluded that the risk of sensitization and CBD is increased among workers who machine beryllium. Although differences between cases and controls in median cumulative exposure did not achieve conventional thresholds for statistical significance, the authors noted that cumulative exposures were consistently higher among cases than controls for all categories of exposure estimates and for all particle sizes, suggesting an effect of cumulative exposure on risk. The levels at which workers developed CBD and sensitization were predominantly below OSHA's current PEL of 2 μ g/m^3, and no cases of sensitization or CBD were observed among workers with LTW exposure <0.02 μg/m^3. Twelve (60 percent) of the 20 sensitized workers had LTW exposures > 0.20 μ g/m^3.

In 2007, Madl *et a*l. published an additional study of 27 workers at the machining plant who were found to be sensitized or diagnosed with CBD between the start of medical surveillance in 1995 and 2005. As previously described, workers were offered a BeLPT in the initial 1995 screening (or within 3 months of their hire date if hired after 1995) and at 2-year intervals after their first screening. Workers with two positive BeLPTs were identified as sensitized and offered clinical evaluation for CBD, including bronchoscopy with BAL and transbronchial lung biopsy. The criteria for CBD in this study were somewhat stricter than those used in the Newman *et al.* study, requiring evidence of granulomas on lung biopsy or detection of X-ray or pulmonary function changes associated with CBD, in combination with two positive BeLPTs or one positive BAL-BeLPT.

Based on the history of the plant's control efforts and their analysis of historical IH data, Madl *et al.* identified three ''exposure control eras'': A relatively uncontrolled period from 1980–1995; a transitional period from 1996 to 1999; and a relatively well-controlled ''modern'' period from 2000–2005. They found that the engineering and work practice controls instituted in the mid-1990s reduced workers' exposures substantially, with nearly a 15-fold difference in reported exposure levels between the pre-control and the modern period (Madl *et al.,* 2007). Madl *et al.* estimated workers' exposures using LP samples collected between 1980 and 2005, including those collected by Kelleher *et al.,* and work histories provided by the plant. As described more fully in the study, they used a variety of approaches to describe individual workers' exposures, including approaches designed to characterize the highest exposures workers were likely to have experienced. Their exposure-response analysis was based primarily on an exposure metric they derived by identifying the year and job of each worker's pre-diagnosis work history with the highest reported exposures. They used the upper 95th percentile of the LP samples collected in that job and year (in some cases supplemented with data from other years) to characterize the worker's upper-level exposures.

Based on their estimates of workers' upper level exposures, Madl *et al.* concluded that workers with sensitization or CBD were likely to have been exposed to airborne beryllium levels greater than 0.2 μg/m^3 as an 8-hour TWA at some point in their history of employment in the plant. They also concluded that most sensitization and CBD cases were likely to have been exposed to levels greater than 0.4 μg/m^3 at some point in their work at the plant. Madl *et al.* did not reconstruct exposures for workers at the plant who did not have sensitization or CBD and therefore could not determine whether non-cases had upper-bound exposures lower than these levels. They found that upper-bound exposure estimates were generally higher for workers with CBD than for those who were sensitized but not diagnosed with CBD at the conclusion of the study (Madl *et al.,* 2007). Because CBD is an immunological disease and beryllium sensitization has been shown to occur within a year of exposure for some workers, Madl *et al.* argued that their estimates of workers' short-term upper-bound exposures may better capture the exposure levels that led to sensitization and disease than estimates of long-term cumulative or average exposures such as the LTW exposure measure constructed by Kelleher *et al.* (Madl *et al.,* 2007).

f. Beryllium Oxide Ceramics

Kreiss *et al.* (1993) conducted a screening of current and former workers at a plant that manufactured beryllium ceramics from beryllium oxide between 1958 and 1975, and then transitioned to metalizing circuitry onto beryllium ceramics produced elsewhere. Of the plant's 1,316 current and 350 retired workers, 505 participated who had not previously been diagnosed with CBD or sarcoidosis, including 377 current and 128 former workers. Although beryllium exposure was not estimated quantitatively in this survey, the authors conducted a questionnaire to assess study participants' exposures qualitatively. Results showed that 55 percent of participants reported working in jobs with exposure to beryllium dust. Close to 25 percent of participants did not know if they had exposure to beryllium, and just over 20 percent believed they had not been exposed.

BeLPT tests were administered to all 505 participants in the 1989–1990 screening period and evaluated at a single lab. Seven workers had confirmed abnormal BeLPT results and were identified as sensitized; these workers were also diagnosed with CBD based on findings of granulomas upon clinical evaluation. Radiograph screening led to clinical evaluation and diagnosis of two additional CBD cases, who were among three participants with initially abnormal BeLPT results that could not be confirmed on repeat testing. In addition, nine workers had been previously diagnosed with CBD, and another five were diagnosed shortly after the screening period, in 1991–1992.

Eight (3.7 percent of the screening population) of the nine CBD cases identified in the screening population were hired before the plant stopped producing beryllium ceramics in 1975, and were among the 216 participants who had reported having been near or exposed to beryllium dust. Particularly high CBD rates of 11.1–15.8 percent were found among screening participants who had worked in process development/engineering, dry pressing, and ventilation maintenance jobs believed to have high or uncontrolled dust exposure. One case (0.6 percent) of CBD was diagnosed among the 171 study participants who had been hired after the plant stopped producing beryllium ceramics. Although this worker was hired eight years after the end of ceramics production, he had worked in an area later found to be contaminated with beryllium dust. The authors concluded that the study results suggested an exposure-response relationship between beryllium exposure and CBD, and recommended beryllium exposure control to reduce workers' risk of CBD.

Kreiss *et al.* later published a study of workers at a second ceramics plant located in Tucson, AZ (Kreiss *et al.,* 1996), which since 1980 had produced beryllium ceramics from beryllium oxide powder manufactured elsewhere. IH measurements collected between 1981 and 1992, primarily GA or short-term BZ samples and a few (<100) LP samples, were available from the plant. Airborne beryllium exposures were generally low. The majority of area samples were below the analytical detection limit of 0.1 μg/m³, while LP and short-term BZ samples had medians of 0.3 μg/m³. However, 3.6 percent of short-term BZ samples and 0.7 percent of GA samples exceeded 5.0 μg/mg³, while LP samples ranged from 0.1 to 1.8 μg/m³. Machining jobs had the highest beryllium exposure levels among job tasks, with short-term BZ samples significantly higher for machining jobs than for non-machining jobs (median 0.6 μg/m³ vs. 0.3 μg/mg³, $p = 0.0001$). The authors used DWA formulas provided by the plant to estimate workers' full-shift exposure levels, and to calculate cumulative and average beryllium exposures for each worker in the study. The median cumulative exposure was 591.7 mg-days/m³ and the median average exposure was 0.35 μg/m³.

One hundred thirty-six of the 139 workers employed at the plant at the time of the Kreiss *et al.* (1996) study underwent BeLPT screening and chest radiographs in 1992. Blood samples were split between two laboratories. If one or both test results were abnormal, an additional sample was collected and split between the labs. Seven workers with an abnormal result on two draws were initially identified as sensitized. Those with confirmed abnormal BeLPTs or abnormal chest X-rays were offered clinical evaluation for CBD, including transbronchial lung biopsy and BAL BeLPT. CBD was diagnosed based on observation of granulomas on lung biopsy, in five of the six sensitized workers who accepted evaluation. An eighth case of sensitization and sixth case of CBD were diagnosed in one worker hired in October 1991 whose initial BeLPT was normal, but who was confirmed as sensitized and found to have lung granulomas less than two years later, after sustaining a beryllium-contaminated skin wound. The plant medical department reported 11 additional cases of CBD among former workers (Kreiss *et al.,* 1996). The overall prevalence of sensitization in the plant was 5.9 percent, with a 4.4 percent prevalence of CBD.

Kreiss *et al.* reported that six (75 percent) of the eight sensitized workers were exposed as machinists during or before the period October 1985–March 1988, when measurements were first available for machining jobs. The authors reported that 14.3 percent of machinists were sensitized, compared to 1.2 percent of workers who had never been machinists ($p < 0.01$). Workers' estimated cumulative and average beryllium exposures did not differ significantly for machinists and non-machinists, or for cases and non-cases. As in the previous study of the same ceramics plant published by Kreiss *et al.* in 1993, one case of CBD was diagnosed in a worker who had never been employed in a production job. This worker was employed in administration, a job with a median DWA of 0.1 μg/m³ (range 0.1–0.3).

In 1998, Henneberger *et al.* conducted a follow-up cross-sectional survey of 151 employees employed at the beryllium ceramics plant studied by Kreiss *et al.* (1996) (Henneberger *et al.,* 2001). Employees were eligible who either had not participated in the Kreiss *et al.* survey (''short-term workers''—74 of those studied by Henneberger *et al.*), or who had participated and were not found to have sensitization or disease (''long-term workers''—77 of those studied by Henneberger *et al.*).

The authors estimated workers' cumulative, average, and peak beryllium exposures based on the plant's formulas for estimating job-specific DWA exposures, participants' work histories, and area and short-term task-specific BZ samples collected from the start of full production at the plant in 1981 to 1998. The long-term workers, who were hired before the 1992 study was conducted, had generally higher estimated exposures (median of average exposures—0.39 μg/m³; mean—14.9 μg/m³) than the short-term workers, who were hired after 1992 (median 0.28 μg/m³, mean 6.1 μg/m³).

Fifteen cases of sensitization were found, including eight among short-term and seven among long-term workers. Eight of the 15 workers were found to have CBD. Of the workers diagnosed with CBD, seven (88 percent) were long-term workers. One non-sensitized long-term worker and one sensitized long-term worker declined clinical examination.

Henneberger *et al.* reported a higher prevalence of sensitization among long-term workers with ''high'' (greater than median) peak exposures compared to long-term workers with ''low'' exposures; however, this relationship was not statistically significant. No association was observed for average or cumulative exposures. The authors reported higher prevalence of sensitization (but not statistically significant) among short-term workers with ''high'' (greater than median) average, cumulative, and peak exposures compared to short-term workers with ''low'' exposures of each type.

The cumulative incidence of sensitization and CBD was investigated in a cohort of 136 workers at the beryllium ceramics plant previously studied by the Kreiss and Henneberger groups (Schuler *et al.,* 2008). The study cohort consisted of those who participated in the plant-wide BeLPT screening in 1992. Both current and former workers from this group were invited to participate in follow-up BeLPT screenings in 1998, 2000, and 2002–03. A total of 106 of the 128 non-sensitized individuals in 1992 participated in the 11-year follow-up. Sensitization was defined as a confirmed abnormal BeLPT based on the split blood sample-dual laboratory protocol described earlier. CBD was diagnosed in sensitized individuals based on pathological findings from transbronchial biopsy and BAL fluid analysis. The 11-year crude cumulative incidence of sensitization and CBD was 13 percent (14 of 106) and 8 percent (9 of 106) respectively. The cumulative prevalence was about triple the point prevalences determined in the initial 1992 cross-sectional survey. The corrected cumulative prevalences for those that ever worked in machining were nearly twice that for non-machinists. The data illustrate the value of longitudinal medical screening over time to obtain a more accurate estimate of the occurrence of sensitization and CBD among an exposed working population.

Following the 1998 survey, the company continued efforts to reduce exposures and risk of sensitization and CBD by implementing additional engineering, administrative, and PPE measures (Cummings *et al.,* 2007). Respirator use was required in production areas beginning in 1999, and latex gloves were required beginning in 2000. The lapping area was enclosed in 2000, and enclosures were installed for all mechanical presses in 2001. Between 2000 and 2003, water-resistant or water-proof garments, shoe covers, and taped gloves were incorporated to keep beryllium-containing fluids from wet machining processes off the skin. The new engineering measures did not appear to substantially reduce airborne beryllium levels in the plant. LP samples collected between 2000 and 2003 had a median of 0.18 μg/m³, similar to the 1994–1999 samples. However, respiratory protection requirements to control workers' airborne beryllium exposures were instituted prior to the 2000 sample collections.

To test the efficacy of the new measures instituted after 1998, in January 2000 the company began screening new workers for sensitization at the time of hire and at 3, 6, 12, 24, and 48 months of employment. These more stringent measures appear to have substantially reduced the risk of sensitization among new employees. Of 126 workers hired between 2000 and 2004, 93 completed BeLPT testing at hire and at least one additional test at 3 months of employment. One case of sensitization was identified at 24 months of employment (1 percent). This worker had experienced a rash after an incident of dermal exposure to lapping fluid through a gap between his glove and uniform sleeve, indicating that he may have become sensitized via the skin. He was tested again at 48 months of employment, with an abnormal result.

A second worker in the 2000–2004 group had two abnormal BeLPT tests at the time of hire, and a third had one abnormal test at hire and a second abnormal test at 3 months. Both had normal BeLPTs at 6 months, and were not tested thereafter. A fourth worker had one abnormal BeLPT result at the time of hire, a normal result at 3 months, an abnormal result at 6 months, and a normal result at 12 months. Four additional workers had one abnormal result during surveillance, which could not be confirmed upon repeat testing.

Cummings *et al.* calculated two sensitization rates based on these screening results: (1) a rate using only the sensitized worker identified at 24 months, and (2) a rate including all four workers who had repeated abnormal results. They reported a sensitization incidence rate (IR) of 0.7 per 1,000 person-months to 2.7 per 1,000 person-months for the workers hired between 2000 and 2004, using the sum of sensitization-free months of employment among all 93 workers as the denominator.

The authors also estimated an incidence rate (IR) of 5.6 per 1,000 person-months for workers hired between 1993 and the 1998 survey. This estimated IR was based on one BeLPT screening, rather than BeLPTs conducted throughout the workers' employment. The denominator in this case was the total months of employment until the 1998 screening. Because sensitized workers may have been sensitized prior to the screening, the denominator may overestimate sensitization-free time in the legacy group, and the actual sensitization IR for legacy workers may be somewhat higher than 5.6 per 1,000 person-months. Based on comparison of the IRs, the authors concluded that the addition of respirator use, dermal protection, and housekeeping improvements appeared to have reduced the risk of sensitization among workers at the plant, even though airborne beryllium levels in some areas of the plant had not changed significantly since the 1998 survey.

g. Copper-Beryllium Alloy Processing and Distribution

Schuler *et al.* (2005) studied a group of 152 workers at a facility processing copper-beryllium alloys and small quantities of nickel-beryllium alloys, and converting semi-finished alloy strip and wire into finished strip, wire and rod. Production activities included annealing, drawing, straightening, point and chamfer, rod and wire packing, die grinding, pickling, slitting, and degreasing. Periodically in the plant's history, they also did salt baths, cadmium plating, welding and deburring. Since the late 1980s, rod and wire production processes were physically segregated from strip metal production. Production support jobs included mechanical maintenance, quality assurance, shipping and receiving, inspection, and wastewater treatment. Administration was divided into staff primarily working within the plant and personnel who mostly worked in office areas (Schuler, *et al.,* 2005). Workers' respirator use was limited, mostly to occasional tasks where high exposures were anticipated.

Following the 1999 diagnosis of a worker with CBD, the company surveyed the workforce, offering all current employees BeLPT testing in 2000 and offering sensitized workers clinical evaluation for CBD, including BAL and transbronchial biopsy. Of the facility's 185 employees, 152 participated in the BeLPT screening. Samples were split between two laboratories, with additional draws and testing for confirmation if conflicting tests resulted in the initial draw. Ten participants (7 percent) had at least two abnormal BeLPT results. The results of nine workers who had abnormal BeLPT results from only one laboratory were not included because the authors believed it was experiencing technical problems with the test (Schuler *et al.,* 2005). CBD was diagnosed in six workers (4 percent) on evidence of pathogenic abnormalities (*e.g.,* granulomas) or evidence of clinical abnormalities consistent with CBD based on pulmonary function testing, pulmonary exercise testing, and/or chest radiography. One worker diagnosed with CBD had been exposed to beryllium during previous work at another copper-beryllium processing facility.

Schuler *et al.* evaluated airborne beryllium levels at the plant using IH samples collected between 1969 and 2000, including 4,524 GA samples, 650 LP samples and 815 short-duration (3–5 min) high volume (SD–HV) BZ task-specific samples. Occupational exposures to airborne beryllium were generally low. Ninety-nine percent of all LP measurements were below the current OSHA PEL of 2.0 μg/m³ (8-hr TWA); 93 percent were below the DOE action level of 0.2 μg/m³; and the median value was 0.02 μg/m³. The SD–HV BZ samples had a median value of 0.44 μg/m³, with 90 percent below the OSHA Short-Term Exposure Limit (STEL) of 5.0 μg/m³. The highest levels of beryllium were found in rod and wire production, particularly in wire annealing and pickling, the only production job with a median personal sample measurement greater than 0.1 μg/m³ (median 0.12 μg/m³; range 0.01–7.8 μg/m³) (Schuler *et al.,* Table 4). These concentrations were significantly higher than the exposure levels in the strip metal area (median 0.02, range 0.01–0.72 μg/m³), in production support jobs (median 0.02, range <0.01–0.33 μg/m³), plant administration (median 0.02, range <0.01–0.11 μg/m³), and office administration jobs (median 0.01, range <0.01–0.06 μg/m³).

The authors reported that eight of the ten sensitized employees, including all six CBD cases, had worked in both major production areas during their tenure with the plant. The 7 percent prevalence (6 of 81 workers) of CBD among employees who had ever worked in rod and wire was statistically significantly elevated compared with employees who had never worked in rod and wire ($p < 0.05$), while the 6 percent prevalence (6 of 94 workers) among those who had worked in strip metal was not significantly elevated compared to non-strip metal workers ($p > 0.1$). Based on these results, together with the higher exposure levels reported for the rod and wire production area, Schuler *et al.* concluded that work in rod and wire was a key risk factor for CBD in this population. Schuler *et al.* also found a high prevalence (13 percent) of sensitization among workers who had been exposed to beryllium for less than a year at the time of the screening, a rate similar to that found by Henneberger *et al.* among beryllium ceramics workers exposed for one year or less (16 percent, Henneberger *et al.,* 2001). All four workers who were sensitized without disease had been exposed 5 years or less; conversely, all six of the workers with CBD had first been exposed to beryllium at least five years prior to the screening (Schuler *et al.,* Table 2).

As has been seen in other studies, beryllium sensitization and CBD were found among workers who were typically exposed to low time-weighted average airborne concentrations of beryllium. While jobs in the rod and wire area had the highest exposure levels in the plant, the median personal sample value was only 0.12 μg/m³. However, workers may have occasionally been exposed to higher beryllium levels for short periods during specific tasks. A small fraction of personal samples recorded in rod and wire were above the OSHA PEL of 2.0 μg/m³, and half of workers with sensitization or CBD reported that they had experienced a ''high-exposure incident'' at some point in their work history (Schuler *et al.,* 2005). The only group of workers with no cases of sensitization or CBD, a group of 26 office administration workers, was the group with the lowest recorded exposures (median personal sample 0.01 μg/m³, range <0.01–0.06 μg/m³).

After the BeLPT screening was conducted in 2000, the company began implementing new measures to further reduce workers' exposure to beryllium (Thomas *et al.,* 2009). Requirements designed to minimize dermal contact with beryllium, including long-sleeve facility uniforms and polymer gloves, were instituted in production areas in 2000. In 2001 the company installed LEV in die grinding and polishing. LP samples collected between June 2000 and December 2001 show reduced exposures plant-wide. Of 2,211 exposure samples collected, 98 percent were below 0.2 μg/m³, and 59 percent below the limit of detection (LOD), which was either 0.02 μg/m³ or 0.2 μg/m³ depending on the method of sample analysis (Thomas *et al.,* 2009). Median values below 0.03 μg/m³ were reported for all processes except the wire annealing and pickling process. Samples for this process remained somewhat elevated, with a median of 0.1 μg/m³. In January 2002, the plant enclosed the wire annealing and pickling process in a restricted access zone (RAZ), requiring respiratory PPE in the RAZ and implementing stringent measures to minimize the potential for skin contact and beryllium transfer out of the zone. While exposure samples collected by the facility were sparse following the enclosure, they suggest exposure levels comparable to the 2000–01 samples in areas other than the RAZ. Within the RAZ, required use of powered air-purifying respirators indicates that respiratory exposure was negligible.

To test the efficacy of the new measures in preventing sensitization and CBD, in June 2000 the facility began an intensive BeLPT screening program for all new workers. The company screened workers at the time of hire; at intervals of 3, 6, 12, 24, and 48 months; and at 3-year intervals thereafter. Among 82 workers hired after 1999, three (3.7 percent) cases of sensitization were found. Two (5.4 percent) of 37 workers hired prior to enclosure of the wire annealing and pickling process were found to be sensitized within 3 and 6 months of beginning work at the plant. One (2.2 percent) of 45 workers hired after the enclosure was confirmed as sensitized.

Thomas *et al.* calculated a sensitization IR of 1.9 per 1,000 person-months for the workers hired after the exposure control program was initiated in 2000 (''program workers''), using the sum of sensitization-free months of employment among all 82 workers as the denominator (Thomas *et al.,* 2009). They calculated an estimated IR of 3.8 per 1,000 person-months for 43 workers hired between 1993 and 2000 who had participated in the 2000 BeLPT screening (''legacy workers''). This estimated IR was based on one BeLPT screening, rather than BeLPTs conducted throughout the legacy workers' employment. The denominator in this case is the total months of employment until the 2000 screening. Because sensitized workers may have been sensitized prior to the screening, the denominator may overestimate sensitization-free time in the legacy group, and the actual sensitization IR for legacy workers may be somewhat higher than 3.8 per 1,000 person-months. Based on comparison of the IRs and the prevalence rates discussed previously, the authors concluded that the combination of dermal protection, respiratory protection, housekeeping improvements and engineering controls implemented beginning in 2000 appeared to have reduced the risk of sensitization among workers at the plant. However, they noted that the small size of the study population and the short follow-up time for the program workers suggested that further research is needed to confirm the program's efficacy (Thomas *et al.,* 2009).

Stanton *et al.* (2006) conducted a study of workers in three different copper-beryllium alloy distribution centers in the United States. The distribution centers, including one bulk products center established in 1963 and strip metal centers established in 1968 and 1972, sell products received from beryllium production and finishing facilities and small quantities of copper-beryllium, aluminum-beryllium, and nickel-beryllium alloy materials. Work at distribution centers does not require large-scale heat treatment or manipulation of material typical of beryllium processing and machining plants, but involves final processing steps that can generate airborne beryllium. Slitting, the main production activity at the two strip product distribution centers, generates low levels of airborne beryllium particles, while operations such as tensioning and welding used more frequently at the bulk products center can generate somewhat higher levels. Non-production jobs at all three centers included shipping and receiving, palletizing and wrapping, production-area administrative work, and office-area administrative work.

The authors estimated workers' beryllium exposures using IH data from company records and job history information collected through interviews conducted by a company occupational health nurse. Stanton *et al.* evaluated airborne beryllium levels in various jobs based on 393 full-shift LP samples collected from 1996 to 2004. Airborne beryllium levels at the plant were generally very low, with 54 percent of all samples at or below the LOD, which ranged from 0.02 to 0.1 μg/m³. The authors reported a median of 0.03 μg/m³ and an arithmetic mean of 0.05 μg/m³ for the 393 full-shift LP samples, where samples below the LOD were assigned a value of half the applicable LOD. Median and geometric mean values for specific jobs ranged from 0.01–0.07 and 0.02–0.07 μg/m³, respectively. All measurements were below the OSHA PEL of 2.0 μg/m^3 and 97 percent were below the DOE action level of 0.2 μg/m^3. The paper does not report use of respiratory or skin protection. Exposure conditions may have changed somewhat over the history of the plant due to changes in exposure control measures, including improvements to product and container cleaning practices instituted during the 1990s.

Eighty-eight of the 100 workers (88 percent) employed at the three centers at the time of the study participated in screening for beryllium sensitization. Blood samples were collected between November 2000 and March 2001 by the company's medical staff. Samples collected from employees of the strip metal centers were split and evaluated at two laboratories, while samples from the bulk product center workers were evaluated at a single laboratory. Participants were considered to be ''sensitized'' to beryllium if two or more BeLPT results, from two laboratories or from repeat testing at the same laboratory, were found to be abnormal. One individual was found to be sensitized and was offered clinical evaluation, including BAL and fiberoptic bronchoscopy. He was found to have lung granulomas and was diagnosed with CBD.

The worker diagnosed with CBD had been employed at a strip metal distribution center from 1978 to 2000 as a shipper and receiver, loading and unloading trucks delivering materials from a beryllium production facility and to the distribution center's customers. Although the LP samples collected for his job between 1996 and 2000 were generally low (n = 35, median 0.01, range < 0.02–0.13 μg/m^3), it is not clear whether these samples adequately characterize his exposure conditions over the course of his work history. He reported that early in his work history, containers of beryllium oxide powder were transported on the trucks he entered. While he did not recall seeing any breaks or leaks in the beryllium oxide containers, some containers were known to have been punctured by forklifts on trailers used by the company during the period of his employment, and could have contaminated trucks he entered. With 22 years of employment at the facility, this worker had begun beryllium-related work earlier and performed it longer than about 90 percent of the study population (Stanton *et al.,* 2006).

h. Nuclear Weapons Production Facilities & Cleanup of Former Facilities

Primary exposure from nuclear weapons production facilities comes from beryllium metal and beryllium alloys. A study conducted by Kreiss *et al.* (1989) documented sensitization and CBD among beryllium-exposed workers in the nuclear industry. A company medical department identified 58 workers with beryllium exposure among a work force of 500, of whom 51 (88 percent) participated in the study. Twenty-four workers were involved in research and development (R&D), while the remaining 27 were production workers. The R&D workers had a longer tenure with a mean time from first exposure of 21.2 years, compared to a mean time since first exposure of 5 years among the production workers. The number of workers with abnormal BeLPT readings was 6, with 4 being diagnosed with CBD. This resulted in an estimated 11.8 percent prevalence of sensitization.

Kreiss *et al.* (1993) expanded the work of Kreiss *et al.* (1989) by performing a cross-sectional study of 895 (current and former) beryllium workers in the same nuclear weapons plant. Participants were placed in qualitative exposure groups (''no exposure,'' ''minimal exposure,'' ''intermittent exposure,'' and ''consistent exposure'') based on questionnaire responses. The number of workers with abnormal BeLPT totaled 18 with 12 being diagnosed with CBD. Three additional workers with sensitization developed CBD over the next 2 years. Sensitization occurred in all of the qualitatively defined exposure groups. Individuals who had worked as machinists were statistically overrepresented among beryllium-sensitized cases, compared with non-cases. Cases were more likely than non-cases to report having had a measured overexposure to beryllium (p = 0.009), a factor which proved to be a significant predictor of sensitization in logistic regression analyses, as was exposure to beryllium prior to 1970. Beryllium sensitized cases were also significantly more likely to report having had cuts that were delayed in healing (p = 0.02). The authors concluded that individual variability and susceptibility along with exposure circumstances are important factors in developing beryllium sensitization and CBD.

In 1991, the Beryllium Health Surveillance Program (BHSP) was established at the Rocky Flats Nuclear Weapons Facility to offer BLPT screening to current and former employees who may have been exposed to beryllium (Stange *et al.,* 1996). Participants received an initial BeLPT and follow-ups at one and three years. Based on histologic evidence of pulmonary granulomas and a positive BAL-BeLPT, Stange *et al.* published a study of 4,397 BHSP participants tested from June 1991 to March 1995, including current employees (42.8 percent) and former employees (57.2 percent). Twenty-nine cases of CBD and 76 cases of sensitization were identified. The sensitization rate for the population was 2.43 percent. Available exposure data included fixed airhead (FAH) exposure samples collected between 1970 and 1988 (mean concentration 0.016 μg/m^3) and personal samples collected between 1984 and 1987 (mean concentration 1.04 μg/m^3). Cases of CBD and sensitization were noted in individuals in all jobs classifications, including those believed to involve minimal exposure to beryllium. The authors recommended ongoing surveillance for workers in all jobs with potential for beryllium exposure.

Stange *et al.* (2001) extended the previous study, evaluating 5,173 participants in the Rocky Flats BHSP who were tested between June 1991 and December 1997. Three-year serial testing was offered to employees who had not been tested for three years or more and did not show beryllium sensitization during the previous study. This resulted in 2,891 employees being tested. Of the 5,173 workers participating in the study, 172 were found to have abnormal BeLPT. Ninety-eight (3.33 percent) of the workers were found to be sensitized (confirmed abnormal BeLPT results) in the initial screening, conducted in 1991. Of these workers 74 were diagnosed with CBD (history of beryllium exposure, evidence of non-caseating granulomas or mononuclear cell infiltrates on lung biopsy, and a positive BeLPT or BAL-BeLPT). A follow-up survey of 2,891 workers three years later identified an additional 56 sensitized workers and an additional seven cases of CBD. Sensitization and CBD rates were analyzed with respect to gender, building work locations, and length of employment. Historical employee data included hire date, termination date, leave of absences, and job title changes. Exposure to beryllium was determined by job categories and building or work area codes. Personal beryllium air monitoring results were used, when available, from employees with the same job title or similar job. However, no quantitative information was presented in the study. The authors conclude that for some individuals, exposure to beryllium at levels less that the OSHA PEL could cause sensitization and CBD.

Viet *et al.* (2001) conducted a case-control study of the Rocky Flats worker population studied by Stange *et al.* (1996 and 2001) to examine the relationship between estimated beryllium exposure level and risk of sensitization or CBD. The worker population included 74 beryllium-sensitized workers and 50 workers diagnosed with CBD. Beryllium exposure levels were estimated based on FAH airhead samples from one building, the beryllium machine shop. These were collected away from the BZ of the machine operator and likely underestimated exposure. To estimate levels in other locations, these air sample concentrations were used to construct a job exposure matrix that included the determination of the Building 444 exposure estimates for a 30-year period; each subject's work history by job location, task, and time period; and assignment of exposure estimates to each combination of job location, task, and time period as compared to Building 444 machinists. The authors adjusted the levels observed in the machine shop by factors based on interviews with former workers. Workers' estimated mean exposure concentrations ranged from 0.083 μg/m³ to 0.622 μg/m³. Estimated maximum air concentrations ranged from 0.54 μg/m³ to 36.8 μg/m³. Cases were matched to controls of the same age, race, gender, and smoking status (Viet *et al.,* 2001).

Estimated mean and cumulative exposure levels and duration of employment were found to be significantly higher for CBD cases than for controls. Estimated mean exposure levels were significantly higher for sensitization cases than for controls. No significant difference was observed for estimated cumulative exposure or duration of exposure. Similar results were found using logistic regression analysis, which identified statistically significant relationships between CBD and both cumulative and mean estimated exposure, but did not find significant relationships between estimated exposure levels and sensitization without CBD. Comparing CBD with sensitization cases, Viet *et al.* found that workers with CBD had significantly higher estimated cumulative and mean beryllium exposure levels than workers who were sensitized, but did not have CBD.

Johnson *et al.* (2001) conducted a review of personal sampling records and medical surveillance reports at an atomic weapons establishment in Cardiff, United Kingdom. The study evaluated airborne samples collected over the 36-year period of operation for the plant. Data included 367,757 area samples and 217,681 personal lapel samples from 194 workers over the time period from 1981–1997. Data was available prior to this time period but was not analyzed since this data was not available electronically. The authors estimated that over the 17 years of measurement data analyzed, airborne beryllium concentrations did exceed 2.0 μg/m³, however, due to the limitations with regard to collection times it is difficult to assess the full reliability of this estimate. The authors noted that in the entire plant's history, only one case of CBD had been diagnosed. It was also noted that BeLPT has not been routinely conducted among any of the workers at this facility.

Armojandi *et al.* (2010) conducted a cross-sectional study of workers at a nuclear weapons research and development (R&D) facility to determine the risk of developing CBD in sensitized workers at facilities with exposures much lower than production plants. Of the 1875 current or former workers at the R&D facility, 59 were determined to be sensitized based on at least two positive BeLPTs (*i.e.,* samples drawn on two separate occasions or on split samples tested in two separate DOE-approved laboratories) for a sensitization rate of 3.1 percent. Workers found to have positive BeLPTs were further evaluated in an Occupational Medicine Clinic between 1999 through 2005. Armojandi *et al.* (2010) evaluated 50 of the sensitized workers who also had medical and occupational histories, physical examination, chest imaging with high-resolution computed tomography (HRCT) (N = 49), and pulmonary function testing (nine of the 59 workers refused physical examinations so were not included in this study). Forty of the 50 workers chosen for this study underwent bronchoscopy for bronchoalveolar lavage and transbronchial biopsies in additional to the other testing. Five of the 49 workers had CBD at the time of evaluation (based on histology or high-resolution computed tomography); three others had evidence of probable CBD; however, none of these cases were classified as severe at the time of evaluation. The rate of CBD at the time of study among sensitized individuals was 12.5 percent (5/40) for those using pathologic review of lung tissue, and 10.2 percent (5/49) for those using HRCT as a criteria for diagnosis. The rate of CBD among the entire population (5/1875) was 0.3 percent.

The mean duration of employment at the facility was 18 years, and the mean latency period (from first possible exposure) to time of evaluation and diagnosis was 32 years. There was no available exposure monitoring in the breathing zone of workers at the facility but the beryllium levels were believed to be relatively low (possibly less than 0.1 μg/m³ for most jobs). There was not an apparent exposure-response relationship for sensitization or CBD. The sensitization prevalence was similar and the CBD prevalence higher among workers with the lower-exposure jobs. The authors concluded that these sensitized workers, who were subjected to an extended duration of low potential beryllium exposures over a long latency period, had a low prevalence of CBD (Armojandi *et al.,* 2010).

i. Aluminum Smelting

Bauxite ore, the primary source of aluminum, contains naturally occurring beryllium. Worker exposure to beryllium can occur at aluminum smelting facilities where aluminum extraction occurs via electrolytic reduction of aluminum oxide into aluminum metal. Characterization of beryllium exposures and sensitization prevalence rates were examined by Taiwo *et al.* (2010) in a study of nine aluminum smelting facilities from four different companies in the U.S., Canada, Italy and Norway.

Of the 3,185 workers determined to be potentially exposed to beryllium, 1,932 agreed to participate in a medical surveillance program between 2000 and 2006 (60 percent participation rate). The medical surveillance program included serum BeLPT analysis, confirmation of an abnormal BeLPT with a second BeLPT, and follow-up of all confirmed positive responses by a pulmonary physician to evaluate for progression to CBD.

Eight-hour TWAs were assessed utilizing 1,345 personal samples collected from the 9 smelters. The personal beryllium samples obtained showed a range of 0.01–13.00 μg/m³ time-weighted average with an arithmetic mean of 0.25 μg/m³ and geometric mean of 0.06 μg/m³. Exposure levels to beryllium observed in aluminum smelters are similar to those seen in other industries that utilize beryllium. Of the 1,932 workers surveyed by BeLPT, nine workers were diagnosed with sensitization (prevalence rate of 0.47 percent, 95% confidence interval = 0.21–0.88 percent) with 2 of these workers diagnosed with probable CBD after additional medical evaluations.

The authors concluded that compared with beryllium-exposed workers in other industries, the rate of sensitization among aluminum smelter workers appears lower. The authors speculated that this lower observed rate could be related to a more soluble form of beryllium found in the aluminum smelting work environment as well as the consistent use of respiratory protection. However, the authors also speculated that the 60 percent participation rate may have underestimated the sensitization rate in this worker population.

A study by Nilsen *et al.* (2010) also found a low rate of sensitization among aluminum workers in Norway. Three-hundred sixty-two workers and thirty-one control individuals were tested for beryllium sensitization based on the BeLPT. The results found that one (0.28%) of the smelter workers had been sensitized. No borderline results were reported. The exposure estimated in this plant was 0.1 μg/m³ to 0.31 μg/m³ (Nilsen *et al.*, 2010).

6. Animal Models of CBD

This section reviews the relevant animal studies supporting the mechanisms outlined above. Researchers have attempted to identify animal models with which to further investigate the mechanisms underlying the development of CBD. A suitable animal model should exhibit major characteristics of CBD, including the demonstration of a beryllium-specific immune response, the formation of immune granulomas following inhalation exposure to beryllium, and mimicking the progressive nature of the human disease. While exposure to beryllium has been shown to cause chronic granulomatous inflammation of the lung in animal studies using a variety of species, most of the granulomatous lesions were formed by foreign-body reactions, which result from persistent irritation and consist predominantly of macrophages and monocytes, and small numbers of lymphocytes. Foreign-body granulomas are distinct from the immune granulomas of CBD, which are caused by antigenic stimulation of the immune system and contain large numbers of lymphocytes. Animal studies have been useful in providing biological plausibility for the role of immunological alterations and lung inflammation and in clarifying certain specific mechanistic aspects of beryllium disease. However, the lack of a dependable animal model that mimics all facets of the human response combined with study limitations in terms of single dose experiments, few animals, or abbreviated observation periods have limited the utility of the data. Currently, no single model has completely mimicked the disease process as it progresses in humans. The following is a discussion of the most relevant animal studies regarding the mechanisms of sensitization and CBD development in humans. Table A.2 in the Appendix summarizes species, route, chemical form of beryllium, dose levels, and pathological findings of the key studies.

Harmsen *et al.* performed a study to assess whether the beagle dog could provide an adequate model for the study of beryllium-induced lung diseases (Harmsen *et al.,* 1986). One group of dogs served as a control group (air inhalation only) and four other groups received high (approximately 50 μg/kg) and low (approximately 20 μg/kg) doses of beryllium oxide calcined at 500 °C or 1,000° C, administered as aerosols in a single exposure. As discussed above, calcining temperature controls the solubility and SSA of beryllium particles. Those particles calcined at higher temperatures (*e.g.,* 1,000° C) are less soluble and have lower SSA than particles calcined at lower temperatures (*e.g.,* 500 °C). Solubility and SSA are factors in determining the toxic potential of beryllium compounds or materials.

Cells were collected from the dogs by BAL at 30, 60, 90, 180, and 210 days after exposure, and the percentages of neutrophils and lymphocytes were determined. In addition, the mitogenic responses of blood lymphocytes and lavage cells collected at 210 days were determined with either phytohemagglutinin or beryllium sulfate as mitogen. The percentage of neutrophils in the lavage fluid was significantly elevated only at 30 days with exposure to either dose of 500 °C beryllium oxide. The percentage of lymphocytes in the fluid was significantly elevated in samples across all times with exposure to the high dose of this beryllium oxide form. Beryllium oxide calcined at 1,000° C elevated lavage lymphocytes only in high dose at 30 days. No significant effect of 1,000° C beryllium oxide exposure on mitogenic response of any lymphocytes was seen. In contrast, peripheral blood lymphocytes from the 500 °C beryllium oxide exposed groups were significantly stimulated by beryllium sulfate compared with the phytohemagglutinin exposed cells. The investigators in this study were able to replicate some of the same findings as those observed in human studies—specifically, that beryllium in soluble and insoluble forms can be mitogenic to immune cells, an important finding for progression of sensitization and proliferation of immune cells to developing full-blown CBD.

In another beagle study Haley *et al.* also found that the beagle dog appears to model some aspects of human CBD (Haley *et al.,* 1989). The authors monitored lung pathologic effects, particle clearance, and immune sensitization of peripheral blood leukocytes following a single exposure to beryllium oxide aerosol generated from beryllium oxide calcined at 500 °C or 1,000° C. The aerosol was administered to the dogs perinasally to attain initial lung burdens of 6 or 18 μg beryllium/kg body weight. Granulomatous lesions and lung lymphocyte responses consistent with those observed in humans with CBD were observed, including perivascular and peribronchiolar infiltrates of lymphocytes and macrophages, progressing to microgranulomas with areas of granulomatous pneumonia and interstitial fibrosis. Beryllium specificity of the immune response was demonstrated by positive results in the BeLPT, although there was considerable inter-animal variation. The lesions declined in severity after 64 days post-exposure. Thus, while this model was able to mimic the formation of Be-specific immune granulomas, it was not able to mimic the progressive nature of disease.

This study also provided an opportunity to compare the effects of beryllium oxide calcination temperature on granulomatous disease in the beagle respiratory system. Haley *et al.* found an increase in the percentage and numbers of lymphocytes in BAL fluid at 3 months post-exposure in dogs exposed to either dose of beryllium oxide calcined at 500 °C, but not in dogs exposed to the material calcined at the higher temperature. Although there was considerable inter-animal variation, lesions were generally more severe in the dogs exposed to material calcined at 500 °C. Positive BeLPT results were observed with BAL lymphocytes only in the group with a high initial lung burden of the material calcined at 500 °C, but positive results with peripheral blood lymphocytes were observed at both doses with material calcined at both temperatures.

The histologic and immunologic responses of canine lungs to aerosolized beryllium oxide were investigated in another Haley *et al.* (1989) study. Beagle-dogs were exposed in a single exposure to high dose (50 μg/kg of body weight) or low dose (l7 μg/kg) levels of beryllium oxide calcined at either 500° or 1000° C. One group of dogs was examined up to 365 days after exposure for lung histology and biochemical assay to determine the fate of inhaled beryllium oxide. A second group underwent BAL for lung lymphocyte analysis for up to 22 months after exposure. Histopathologic examination revealed peribronchiolar and perivascular lymphocytic histiocytic inflammation, peaking at 64 days after beryllium oxide exposure. Lymphocytes were initially well differentiated, but progressed to lymphoblastic cells and aggregated in lymphofollicular nodules or microgranulomas over time. Alveolar macrophages were large, and filled with intracytoplasmic material. Cortical and paracortical lymphoid hyperplasia of the tracheobronchial nodes was found. Lung lymphocyte concentrations were increased at 3 months and returned to normal in both dose groups given 500 °C treated beryllium chloride. No significant elevations in lymphocyte concentrations were found in dogs given 1,000° C treated beryllium oxide. Lung retention was higher in the 500 °C treated beryllium oxide group. The lesions found in dog lungs closely resembled those found in humans with CBD: severe granulomas, lymphoblast transformation, increased pulmonary lymphocyte concentrations and variation in beryllium sensitivity. It was concluded that the canine model for berylliosis may provide insight into this disease.

In a follow-up experiment, control dogs and those exposed to beryllium oxide calcined at 500 °C were allowed to rest for 2.5 years, and then re-exposed to filtered air (controls) or beryllium oxide calcined at 500 °C for an initial lung burden (ILB) target of 50 µg beryllium oxide/kg body weight (Haley *et al.,* 1992). Immune responses of blood and BAL lymphocytes, and lung lesions in dogs sacrificed 210 days post-exposure, were compared with results following the initial exposure. The severity of lung lesions was comparable under both conditions, suggesting that a 2.5-year interval was sufficient to prevent cumulative pathologic effects. Conradi *et al.* (1971) found no exposure-related histological alterations in the lungs of six beagle dogs exposed to a range of 3,300–4,380 µg Be/m^3 as beryllium oxide calcined at 1,400° C for 30 min, once per month for 3 months. Because the dogs were sacrificed 2 years post-exposure, the long time period between exposure and response may have allowed for the reversal of any beryllium-induced changes (EPA, 1998).

A 1994 study by Haley *et al.* showed that intra-bronchiolar instillation of beryllium induced immune granulomas and sensitization in monkeys. Haley *et al.* (1994) exposed male cynomolgus monkeys to either beryllium metal or beryllium oxide calcined at 500 °C by intrabronchiolar instillation as a saline suspension. Lymphocyte counts in BAL fluid were observed, and were found to be significantly increased in monkeys exposed to beryllium metal on post-exposure days 14 to 90, and on post-exposure day 60 in monkeys exposed to beryllium oxide. The lungs of monkeys exposed to beryllium metal had lesions characterized by interstitial fibrosis, Type II cell hyperplasia, and lymphocyte infiltration. Some monkeys also exhibited immune granulomas. Similar lesions were observed in monkeys exposed to beryllium oxide, but the incidence and severity were much less. BAL lymphocytes from monkeys exposed to beryllium metal, but not from monkeys exposed to beryllium oxide, proliferated in response to beryllium sulfate in the BeLPT (EPA, 1998).

In an experiment similar to the one conducted with dogs, Conradi *et al.* (1971) found no effect in monkeys (Macaca irus) exposed via whole-body inhalation for three 30-minute monthly exposures to a range of 3,300–4,380 µg Be/m^3 as beryllium oxide calcined at 1,400° C. The lack of effect may have been related to the long period (2 years) between exposure and sacrifice, or to low toxicity of beryllium oxide calcined at such a high temperature.

As discussed earlier in this Health Effects section, at the cellular level, beryllium dissolution must occur for either a dendritic cell or a macrophage to present beryllium as an antigen to induce the cell-mediated CBD immune reactions (Stefaniak *et al.,* 2006). Several studies have shown that low-fired beryllium oxide, which is predominantly made up of poorly crystallized small particles, is more immunologically reactive than beryllium oxide calcined at higher firing temperatures that result in less reactivity due to increasing crystal size. As discussed previously, Haley *et al.* (1989a) found more severe lung lesions and a stronger immune response in beagle dogs receiving a single inhalation exposure to beryllium oxide calcined at 500 °C than in dogs receiving an equivalent initial lung burden of beryllium oxide calcined at 1,000° C. Haley *et al.* found that beryllium oxide calcined at 1,000° C elicited little local pulmonary immune response, whereas the much more soluble beryllium oxide calcined at 500 °C produced a beryllium-specific, cell-mediated immune response in dogs (Haley *et al.,* 1991).

In a later study, beryllium metal appeared to induce a greater toxic response than beryllium oxide following intrabronchiolar instillation in cynomolgus monkeys, as evidenced by more severe lung lesions, a larger effect on BAL lymphocyte counts, and a positive response in the BeLPT with BAL lymphocytes only after exposure to beryllium metal (Haley *et al.,* 1994). Because an oxide layer may form on beryllium-metal surfaces after exposure to air (Mueller and Adolphson, 1979; Harmsen *et al.,* 1986) dissolution of small amounts of poorly soluble beryllium compounds in the lungs might be sufficient to allow persistent low-level beryllium presentation to the immune system (NAS, 2008).

Genetic studies in humans led to the creation of an animal model containing different human HLA–DP alleles inserted into FVB/N mice for mechanistic studies of CBD. Three strains of genetically engineered mice (transgenic mice) were created that conferred different risks for developing CBD based on human studies (Weston *et al.,* 2005; Snyder *et al.,* 2008): (1) the HLDPB1*401 transgenic strain, where the transgene codes for lysine residue at the 69th position of the B-chain conferred low risk of CBD; (2) the HLA–DPB1*201 mice, where the transgene codes for glutamic acid residue at the 69th position of the B-chain and glycine residues at positions 84 and 85 conferred medium risk of CBD; and (3) the HLA–DPB1*1701 mice, where the transgene codes for glutamic acid at the 69th position of the B-chain and aspartic acid and glutamic acid residues at positions 84 and 85, respectively, conferred high risk of CBD (Tarantino-Hutchinson *et al.,* 2009).

In order to validate the transgenic model, Tarantino-Hutchison *et al.* challenged the transgenic mice along with seven different inbred mouse strains to determine the susceptibility and sensitivity to beryllium exposure. Mice were dermally exposed with either saline or beryllium, then challenged with either saline or beryllium (as beryllium sulfate) using the MEST protocol (mouse ear-swelling test). The authors determined that the high risk HLA–DPB1*1701 transgenic strain responded 4 times greater (as measured via ear swelling) than control mice and at least 2 times greater than other strains of mice. The findings correspond to epidemiological study results reporting an enhanced CBD odds ratio for the HLA–DPB1*1701 in humans (Weston *et al.,* 2005; Snyder *et al.,* 2008). Transgenic mice with the genes corresponding to the low and medium odds ratio study did not respond significantly over the control group. The authors concluded that while HLA–DPB1*1701 is important to beryllium sensitization and progression to CBD, other genetic and environmental factors contribute to the disease process as well.

7. Preliminary Beryllium Sensitization and CBD Conclusions

It is well-established that skin and inhalation exposure to beryllium may lead to sensitization and that inhalation exposure, or skin exposure coupled with inhalation exposure, may lead to the onset and progression of CBD. This is supported by extensive human studies. While all facets of the biological mechanism for this complex disease have yet to be fully elucidated, many of the key events in the disease sequence have been identified and described in the previous sections. Sensitization is a necessary first step to the onset of CBD (NAS, 2008). Sensitization is the process by which the immune system recognizes beryllium as a foreign substance and responds in a manner that may lead to development of CBD. It has been documented that a substantial proportion of sensitized workers exposed to airborne beryllium progress to CBD (Rosenman *et al.,* 2005; NAS, 2008; Mroz *et al.,* 2009). Animal studies, particularly in dogs and monkeys, have provided supporting evidence for T-cell lymphocyte proliferation in the development of granulomatous lung lesions after exposure to beryllium (Harmsen *et al.,* 1986; Haley *et al.,* 1989, 1992, 1994). The animal studies have also provided important insights into the roles of chemical form, genetic susceptibility, and residual lung burden in the development of beryllium lung disease (Harmsen *et al.,* 1986; Haley *et al.,* 1992; Tarantino-Hutchison *et al.,* 2009). OSHA has made a preliminary determination to consider sensitization and CBD to be adverse events along the pathological continuum in the disease process, with sensitization being the necessary first step in the progression to CBD.

The epidemiological evidence presented in this section demonstrates that sensitization and CBD are continuing to occur from present-day exposures below OSHA's PEL (Rosenman, 2005 with erratum published 2006). The available literature discussed above shows that disease prevalence can be reduced by reducing inhalation exposure (Thomas *et al.,* 2009). However, the available epidemiological studies also indicate that it may be necessary to minimize skin exposure to further reduce the incidence of sensitization (Bailey *et al.,* 2010). The preliminary risk assessment further discusses the effectiveness of interventions to reduce beryllium exposures and the risk of sensitization and CBD (see section VI, Preliminary Risk Assessment).

Studies have demonstrated there remains a prevalence of sensitization and CBD in facilities with exposure levels below the current OSHA PEL (Rosenman *et al.,* 2005; Thomas *et al.,* 2009), that risk of sensitization and CBD appears to vary across industries and processes (Deubner *et al.,* 2001; Kreiss *et al.,* 1997; Newman *et al.,* 2001; Henneberger *et al.,* 2001; Schuler *et al.,* 2005; Stange *et al.,* 2001; Taiwo *et al.,* 2010), and that efforts to reduce exposure have succeeded in reducing the frequency of beryllium sensitization and CBD (Bailey *et al.,* 2010) (See Table A–1 in the Appendix).

Of workers who were found to be sensitized and underwent clinical evaluation, 20–49 percent were diagnosed with CBD (Kreiss *et al.,* 1993; Newman, 1996, 2005 and 2007; Stange *et al.,* 2001). Overall prevalence of CBD in cross-sectional screenings ranges from 0.6 to 8 percent (Kreiss *et al.,* 2007). A study by Newman (2005) estimated from ongoing surveillance of sensitized individuals, with an average follow-up time of 6 years, that 31 percent of beryllium-exposed employees progressed to CBD (Newman, 2005). However, Newman (2005) went on to suggest that if follow-up times were increased the rate of progression from sensitization to CBD could be much higher. A study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that only about 20 percent of sensitized individuals employed less than five years eventually were diagnosed with CBD, while 40 percent of sensitized employees employed ten years or more developed CBD (Stange *et al.,* 2001) indicating length of exposure may play a role in further development of the disease. In addition, Mroz *et al.* (2009) conducted a longitudinal study of individuals clinically evaluated at National Jewish Health (between 1982 and 2002) who were identified as having sensitization and CBD through workforce medical surveillance. The authors identified 171 cases of CBD and 229 cases of sensitization; all individuals were identified through workplace screening using the BeLPT (Mroz *et al.,* 2009). Over the 20-year study period, 8.8 percent (*i.e.,* 22 cases out 251 sensitized) of individuals with sensitization went on to develop CBD. The findings from this study indicated that on the average span of time from initial beryllium exposure to CBD diagnosis was 24 years (Mroz *et al.,* 2009).

E. Beryllium Lung Cancer Section

Beryllium exposure has been associated with a variety of adverse health effects including lung cancer. The potential for beryllium and its compounds to cause cancer has been previously assessed by various other agencies (EPA, ATSDR, NAS, NIEHS, and NIOSH) with each agency identifying beryllium as a potential carcinogen. In addition, the International Agency for Research on Cancer (IARC) did an extensive evaluation in 1993 and reevaluation in April 2009 (IARC, 2012). In brief, IARC determined beryllium and its compounds to be carcinogenic to humans (Group 1 category), while EPA considers beryllium to be a probable human carcinogen (EPA, 1998), and the National Toxicology Program (NTP) has determined beryllium and its compounds to be known carcinogens (NTP, 2014). OSHA has conducted an independent evaluation of the carcinogenic potential of beryllium and these compounds as well. The following is a summary of the studies used to support the Agency findings that beryllium and its compounds are human carcinogens.

1. Genotoxicity Studies

Genotoxicity can be an important indicator for screening the potential of a material to induce cancer and an important mechanism leading to tumor formation and carcinogenesis. In a review conducted by the National Academy of Science, beryllium and its compounds have tested positively in nearly 50 percent of the genotoxicity studies conducted without exogenous metabolic activity. However, they were found to be non-genotoxic in most bacterial assays (NAS, 2008).

Gene mutations have been observed in mammalian cells cultured with beryllium chloride in a limited number of studies (EPA, 1998; ATSDR, 2002; Gordon and Bowser, 2003). Culturing mammalian cells with beryllium chloride, beryllium sulfate, or beryllium nitrate has resulted in clastogenic alterations. However, most studies have found that beryllium chloride, beryllium nitrate, beryllium sulfate, and beryllium oxide did not induce gene mutations in bacterial assays with or without metabolic activation. In the case of beryllium sulfate, all mutagenicity studies (Ames (Simmon, 1979; Dunkel *et al.,* 1984; Arlauskas *et al.,* 1985; Ashby *et al.,* 1990); E. coli *pol A* (Rosenkranz and Poirer, 1979); E. coli WP2 *uvr A* (Dunkel *et al.,* 1984) and *Saccharomyces cerevisiae* (Simmon, 1979)) were negative with the exception of results reported for Bacillus *subtilis rec* assay (Kada *et al.,* 1980; Kanematsu *et al.,* 1980; EPA, 1998). Beryllium sulfate did not induce unscheduled

DNA synthesis in primary rat hepatocytes and was not mutagenic when injected intraperitoneally in adult mice in a host-mediated assay using *Salmonella typhimurium* (Williams *et al.,* 1982).

Beryllium nitrate was negative in the Ames assay (Tso and Fung, 1981; Kuroda *et al.,* 1991) but positive in a Bacillus *subtilis rec* assay (Kuroda *et al.,* 1991). Beryllium chloride was negative in a variety of studies (Ames (Ogawa *et al.,* 1987; Kuroda *et al.,* 1991); E. coli WP2 uvr A (Rossman and Molina, 1984); and Bacillus *subtilis rec* assay (Nishioka, 1975)). In addition, beryllium chloride failed to induce SOS DNA repair in E. coli (Rossman *et al.,* 1984). However, positive results were reported for Bacillus *subtilis rec* assay using spores (Kuroda *et al.,* 1991), E. coli KMBL 3835; *lacI* gene (Zakour and Glickman, 1984), and *hprt* locus in Chinese hamster lung V79 cells (Miyaki *et al.,* 1979). Beryllium oxide was negative in the Ames assay and Bacillus *subtilis rec* assays (Kuroda *et al.,* 1991; EPA, 1998).

Gene mutations have been observed in mammalian cells (V79 and CHO) cultured with beryllium chloride (Miyaki *et al.,* 1979; Hsie *et al.,* 1979a, b), and culturing of mammalian cells with beryllium chloride (Vegni-Talluri and Guiggiani, 1967), and beryllium sulfate (Brooks *et al.,* 1989; Larramendy *et al.,* 1981) has resulted in clastogenic alterations—producing breakage or disrupting chromosomes (EPA, 1998). Beryllium chloride evaluated in a mouse model indicated increased DNA strand breaks and the formation of micronuclei in bone marrow (Attia *et al.,* 2013).

Data on the *in vivo* genotoxicity of beryllium are limited to a single study that found beryllium sulfate (1.4 and 2.3 g/kg, 50 percent and 80 percent of median lethal dose) administered by gavage did not induce micronuclei in the bone marrow of CBA mice. However, a marked depression of erythropoiesis (red blood cell production) was suggestive of bone marrow toxicity which was evident 24 hours after dosing. No mutations were seen in *p53* or *c-raf-1* and only weak mutations were detected in *K-ras* in lung carcinomas from F344/N rats given a single nose-only exposure to beryllium metal (Nickell-Brady *et al.,* 1994). The authors concluded that the mechanisms for the development of lung carcinomas from inhaled beryllium in the rat do not involve gene dysfunctions commonly associated with human non-small-cell lung cancer (EPA, 1998).

2. Human Epidemiological Studies

This section reviews in greater detail the studies used to support the mechanistic findings for beryllium-induced cancer. Table A.3 in the Appendix summarizes the important features and characteristics of each study.

a. Beryllium Case Registry (BCR).

Two studies evaluated participants in the BCR (Infante *et al.,* 1980; Steenland and Ward, 1991). Infante *et al.* (1980) evaluated the mortality patterns of white male participants in the BCR diagnosed with non-neoplastic respiratory symptoms of beryllium disease. Of the 421 cases evaluated, 7 of the participants had died of lung cancer. Six of the deaths occurred more than 15 years after initial beryllium exposure. The duration of exposure for 5 of the 7 participants with lung cancer was less than 1 year, with the time since initial exposure ranging from 12 to 29 years. One of the participants was exposed for 4 years with a 26-year interval since the initial exposure. Exposure duration for one participant diagnosed with pulmonary fibrosis could not be determined; however, it had been 32 years since the initial exposure. Based on BCR records, the participants were classified as being in the acute respiratory group (*i.e.,* those diagnosed with acute respiratory illness at the time of entry in the registry) or the chronic respiratory group (*i.e.,* those diagnosed with pulmonary fibrosis or some other chronic lung condition at the time of entry into the BCR). The 7 participants with lung cancer were in the BCR because of diagnoses of acute respiratory illness. For only one of those individuals was initial beryllium exposure less than 15 years prior. Only 1 of the 6 (with greater than 15 years since initial exposure to beryllium) had been diagnosed with chronic respiratory disease. The study did not report exposure concentrations or smoking habits. The authors concluded that the results of this cohort agreed with previous animal studies and with epidemiological studies demonstrating an increased risk of lung cancer in workers exposed to beryllium.

Steenland and Ward (1991) extended the work of Infante *et al.* (1980) to include females and to include 13 additional years of follow-up. At the time of entry in the BCR, 93 percent of the women in the study, but only 50 percent of the men, had been diagnosed with CBD. In addition, 61 percent of the women had worked in the fluorescent tube industry and 50 percent of the men had worked in the basic manufacturing industry. A total of 22 males and 6 females died of lung cancer. Of the 28 total deaths from lung cancer, 17 had been exposed to beryllium for less than 4 years and 11 had been exposed for greater than 4 years. The study did not report exposure concentrations. Survey data collected in 1965 provided information on smoking habits for 223 cohort members (32 percent), on the basis of which the authors suggested that the rate of smoking among workers in the cohort may have been lower than U.S. rates. The authors concluded that there was evidence of increased risk of lung cancer in workers exposed to beryllium and diagnosed with beryllium disease.

b. Beryllium Manufacturing and/or Processing Plants (Extraction, Fabrication, and Processing)

Several epidemiological cohort studies have reported excess lung cancer mortality among workers employed in U.S. beryllium production and processing plants during the 1930s to 1960s. The largest and most comprehensive study investigated the mortality experience of 9,225 workers employed in seven different beryllium processing plants over a 30-year period (Ward *et al.,* 1992). The workers at the two oldest facilities (*i.e.,* Lorain, OH, and Reading, PA) were found to have significant excess lung cancer mortality relative to the U.S. population. Of the seven plants in the study, these two plants were believed to have the highest exposure levels to beryllium. A different analysis of the lung cancer mortality in this cohort using various local reference populations and alternate adjustments for smoking generally found smaller, non-significant rates of excess mortality among the beryllium employees (Levy *et al.,* 2002). Both cohort studies are limited by a lack of job history and air monitoring data that would allow investigation of mortality trends with beryllium exposure. The majority of employees at the Lorain, OH, and Reading, PA, facilities were employed for a relatively short period of less than one year.

Bayliss *et al.* (1971) performed a nested cohort study of more than 7,000 former workers from the beryllium processing industry employed from 1942–1967. Information for the workers was collected from the personnel files of participating companies. Of the more than 7,000 employees, a cause of death was known for 753 male workers. The number of observed lung cancer deaths was 36 compared to 34.06 expected for a standardized mortality ratio (SMR) of 1.06. When evaluated by the number of years of employment, 24 of the 36 men were employed for less than 1 year in the industry (SMR = 1.24), 8 were employed for 1 to 5 years (SMR 1.40), and 4 were employed for more than 5 years (SMR = 0.54). Half of the workers who died from lung cancer began employment in the beryllium production industry prior to 1947. When grouped by job classification, over two thirds of the workers with lung cancer were in production-related jobs while the rest were classified as office workers. The authors concluded that while the lung cancer mortality rates were the highest of all other mortality rates, the SMR for lung cancer was still within range of the expected based on death rates in the United States. The limitations of this study included the lack of information regarding exposure concentrations, smoking habits, and the age and race of the participants.

Mancuso (1970, 1979, 1980) and Mancuso and El-Attar (1969) performed a series of occupational cohort studies on a group of over 3,685 workers (primarily white males) employed in the beryllium manufacturing industry during 1937–1948.[3] The beryllium production facilities were located in Ohio and Pennsylvania and the records for the employees, including periods of employment, were obtained from the Social Security Administration. These studies did not include analyses of mortality by job title or exposure category. In addition, there were no exposure concentrations estimated or adjustments for smoking. The estimated duration of employment ranged from less than 1 year to greater than 5 years. In the most recent study (Mancuso, 1980), employees from the viscose rayon industry served as a comparison population. There was a significant excess of lung cancer deaths based on the total number of 80 observed lung cancer mortalities at the end of 1976 compared to an expected number of 57.06 based on the comparison population resulting in an SMR of 1.40 ($p < 0.01$) (Mancuso, 1980). There was a statistically significant excess in lung cancer deaths for the shortest duration of employment (< 12 months, $p < 0.05$) and the longest duration of employment (≤ 49 months, $p < 0.01$). Based on the results of this study, the author concluded that the ability of beryllium to induce cancer in workers does not require continuous exposure and that it is reasonable to assume that the amount of exposure required to produce lung cancer can occur within a few months of exposure regardless of the length of employment.

Wagoner *et al.* (1980) expanded the work of Mancuso (1970; 1979; 1980) using a cohort of 3,055 white males from the beryllium extraction, processing, and fabrication facility located in Reading, Pennsylvania. The men included in the study worked at the facility sometime between 1942 and 1968, and were followed through 1976. The study accounted for length of employment. Other factors accounted for included age, smoking history, and regional lung cancer mortality. Forty-seven members of the cohort died of lung cancer compared to an expected 34.29 based on U.S. white male lung cancer mortality rates ($p < .05$). The results of this cohort showed an excess risk of lung cancer in beryllium-exposed workers at each duration of employment (< 5 years and ≥ 5 years), with a statistically significant excess noted at < 5 years durations of employment and a ≥ 25-year interval since the beginning of employment ($p < 0.05$). The study was criticized by several epidemiologists (MacMahon, 1978, 1979; Roth, 1983), by a CDC Review Committee appointed to evaluate the study, and by one of the study's coauthors (Bayliss, 1980) for inadequate discussion of possible alternative explanations of excess lung cancer in the cohort. The specific issues identified include the use of 1965–1967 U.S. white male lung cancer mortality rates to generate expected numbers of lung cancers in the period 1968–1975 and inadequate adjustment for smoking.

Ward *et al.* (1992) performed a retrospective mortality cohort study of 9,225 male workers employed at seven beryllium processing facilities, including the Ohio and Pennsylvania facilities studied by Mancuso and El-Attar (1969), Mancuso (1970; 1979; 1980), and Wagoner *et al.* (1980). The men were employed for no less than 2 days between January 1940 and December 1988. At the end of the study 61.1 percent of the cohort was known to be living and 35.1 percent was known to be deceased. The duration of employment ranged from 1 year or less to greater than 10 years with the largest percentage of the cohort (49.7 percent) employed for less than one year, followed by 1 to 5 years of employment (23.4 percent), greater than 10 years (19.1 percent), and 5 to 10 years (7.9 percent). Of the 3,240 deaths, 280 observed deaths were caused by lung cancer compared to 221.5 expected deaths, yielding a statistically significant SMR of 1.26 ($p < 0.01$). Information on the smoking habits of 15.9 percent of the cohort members, obtained from a 1968 Public Health Service survey conducted at four of the plants, was used to calculate a smoking-adjusted SMR of 1.12, which was not statistically significant. The number of deaths from lung cancer was also examined by decade of hire. The authors reported a relationship between earlier decades of hire and increased lung cancer risk.

The EPA Integrated Risk Information System (IRIS), IARC, and California EPA Office of Environmental Health Hazard Assessment (OEHHA) have all based their cancer assessment on the Ward *et al.* 1992 study, with supporting data concerning exposure concentrations from Eisenbud and Lisson (1983) and NIOSH (1972), who estimated that the lower-bound estimate of the median exposure concentration exceeded 100 $\mu g/m^3$ and found that concentrations in excess of 1,000 $\mu g/m^3$ were common. The IRIS cancer risk assessment recalculated expected lung cancers based on U.S. white male lung cancer rates (including the period 1968–1975) and used an alternative adjustment for smoking. In addition, one individual with lung cancer, who had not worked at the plant, was removed from the cohort. After these adjustments were made, an elevated rate of lung cancer was still observed in the overall cohort (46 cases vs. 41.9 expected cases). However, based on duration of employment or interval since beginning of employment, neither the total cohort nor any of the subgroups had a statistically significant excess in lung cancer (EPA, 1987). Based on their evaluation of this and other epidemiological studies, the EPA characterized the human carcinogenicity data then available as ''limited'' but ''suggestive of a causal relationship between beryllium exposure and an increased risk of lung cancer'' (IRIS database). This report includes quantitative estimates of risk that were derived using the information presented in Wagoner *et al.* (1980), the expected lung cancers recalculated by the EPA, and bounds on presumed exposure levels.

Levy *et al.* (2002) questioned the results of Ward *et al.* (1992) and performed a reanalysis of the Ward *et al.* data. The Levy *et al.* reanalysis differed from the Ward *et al.* analysis in the following significant ways. First, Levy *et al.* (2002) examined two alternative adjustments for smoking, which were based on (1) a different analysis of the American Cancer Society (ACS) data used by Ward *et al.* (1992) for their smoking adjustment, or (2) results from a smoking/lung cancer study of veterans (Levy and Marimont, 1998). Second, Levy *et al.* (2002) also examined the

[3] The third study (Mancuso *et al.*, 1979) restricted the cohort to workers employed between 1942 and 1948.

impact of computing different reference rates derived from information about the lung cancer rates in the cities in which most of the workers at two of the plants lived. Finally, Levy *et al.* (2002) considered a meta-analytical approach to combining the results across beryllium facilities. For all of the alternatives Levy *et al.* (2002) considered, except the meta-analysis, the facility-specific and combined SMRs derived were lower than those reported by Ward *et al.* (1992). Only the SMR for the Lorain, OH, facility remained statistically significantly elevated in some reanalyses. The SMR obtained when combining over the plants was not statistically significant in eight of the nine approaches they examined, leading Levy *et al.* (2002) to conclude that there was little evidence of statistically significant elevated SMRs in those plants.

One occupational nested case-control study evaluated lung cancer mortality in a cohort of 3,569 male workers employed at a beryllium alloy production plant in Reading, PA, from 1940 to 1969 and followed through 1992 (Sanderson *et al.,* 2001). There were a total of 142 known lung cancer cases and 710 controls. For each lung cancer death, 5 age- and race-matched controls were selected by incidence density sampling. Confounding effects of smoking were evaluated. Job history and historical air measurements at the plant were used to estimate job-specific beryllium exposures from the 1930s to 1990s. Calendar-time-specific beryllium exposure estimates were made for every job and used to estimate workers' cumulative, average, and maximum exposure. Because of the long period of time required for the onset of lung cancer, an ''exposure lag'' was employed to discount recent exposures less likely to contribute to the disease.

The cumulative, average, and maximum beryllium exposure concentration estimates for the 142 known lung cancer cases were 46.06 ± 9.3μg/m^3-days, 22.8 ± 3.4 μg/m^3, and 32.4 ± 13.8 μg/m^3, respectively. The lung cancer mortality rate was 1.22 (95 percent CI = 1.03 − 1.43). Exposure estimates were lagged by 10 and 20 years in order to account for exposures that did not contribute to lung cancer because they occurred after the induction of cancer. In the 10- and 20-year lagged exposures the geometric mean tenures and cumulative exposures of the lung cancer mortality cases were higher than the controls. In addition, the geometric mean and maximum exposures of the workers were significantly higher than controls when the exposure estimates were lagged 10 and 20 years ($p < 0.01$).

Results of a conditional logistic regression analysis indicated that there was an increased risk of lung cancer in workers with higher exposures when dose estimates were lagged by 10 and 20 years. There was also a lack of evidence that confounding factors such as smoking affected the results of the regression analysis. The authors noted that there was considerable uncertainty in the estimation of exposure in the 1940's and 1950's and the shape of the dose-response curve for lung cancer. Another analysis of the study data using a different statistical method did not find a significantly greater relative risk of lung cancer with increasing beryllium exposures (Levy *et al.,* 2007). The average beryllium air levels for the lung cancer cases were estimated to be an order of magnitude above the current 8-hour OSHA TWA PEL (2 μg/m^3) and roughly two orders of magnitude higher than the typical air levels in workplaces where beryllium sensitization and pathological evidence of CBD have been observed. IARC evaluated this reanalysis in 2012 and found the study introduced a downward bias into risk estimates (IARC, 2012).

Schubauer-Berigan *et al.* reanalyzed data from the nested case-control study of 142 lung cancer cases in the Reading, PA, beryllium processing plant (Schubauer-Berigan *et al.,* 2008). This dataset was reanalyzed using conditional (stratified by case age) logistic regression. Independent adjustments were made for potential confounders of birth year and hire age. Average and cumulative exposures were analyzed using the values reported in the original study. The objective of the reanalysis was to correct for the known differences in smoking rates by birth year. In addition, the authors evaluated the effects of age at hire to determine differences observed by Sanderson *et al.* in 2001. The effect of birth cohort adjustment on lung cancer rates in beryllium-exposed workers was evaluated by adjusting in a multivariable model for indicator variables for the birth cohort quartiles.

Unadjusted analyses showed little evidence of lung cancer risk associated with beryllium occupational exposure using cumulative exposure until a 20-year lag was used. Adjusting for either birth cohort or hire age attenuated the risk for lung cancer associated with cumulative exposure. Using a 10- or 20-year lag in workers born after 1900 also showed little evidence of lung cancer risk, while those born prior to 1900 did show a slight elevation in risk. Unlagged and lagged analysis for average exposure showed an increase in lung cancer risk associated with occupational exposure to beryllium. The finding was consistent for either workers adjusted or unadjusted for birth cohort or hire age. Using a 10-year lag for average exposure showed a significant effect by birth cohort.

The authors stated that the reanalysis indicated that differences in the hire ages among cases and controls, first noted by Deubner *et al.* (2001) and Levy *et al.* (2007), were primarily due to the fact that birth years were earlier among controls than among cases, resulting from much lower baseline risk of lung cancer for men born prior to 1900 (Schubauer-Berigan *et al.,* 2008). The authors went on to state that the reanalysis of the previous NIOSH case-control study suggested the relationship observed previously between cumulative beryllium exposure and lung cancer was greatly attenuated by birth cohort adjustment.

Hollins *et al.* (2009) re-examined the weight of evidence of beryllium as a lung carcinogen in a recent publication (Hollins *et al.,* 2009). Citing more than 50 relevant papers, the authors noted the methodological shortcomings examined above, including lack of well-characterized historical occupational exposures and inadequacy of the availability of smoking history for workers. They concluded that the increase in potential risk of lung cancer was observed among those exposed to very high levels of beryllium and that beryllium's carcinogenic potential in humans at these very high exposure levels were not relevant to today's industrial settings. IARC performed a similar re-evaluation in 2009 (IARC, 2012) and found that the weight of evidence for beryllium lung carcinogenicity, including the animal studies described below, still warranted a Group I classification, and that beryllium should be considered carcinogenic to humans.

Schubauer-Berigan *et al.* (2010) extended their analysis from a previous study estimating associations between mortality risk and beryllium exposure to include workers at 7 beryllium processing plants. The study (Schubauer-Berigan *et al.,* 2010) followed the mortality incidences of 9,199 workers from 1940 through 2005 at the 7 beryllium plants. JEMs were developed for three plants in the cohort: The Reading plant, the Hazleton plant, and the Elmore plant. The last is described in Couch *et al.* 2010. Including these JEMs substantially improved the evidence base for evaluating the carcinogenicity of beryllium and, and this change represents more than an update of the beryllium cohort. Standardized mortality ratios (SMRs) were estimated based on US population comparisons for lung, nervous system and urinary tract cancers, chronic obstructive pulmonary disease (COPD), chronic kidney disease, and categories containing chronic beryllium disease (CBD) and cor pulmonale. Associations with maximum and cumulative exposure were calculated for a subset of the workers.

Overall mortality in the cohort compared with the US population was elevated for lung cancer (SMR 1.17; 95% CI 1.08 to 1.28), COPD (SMR 1.23; 95% CI 1.13 to 1.32), and the categories containing CBD (SMR 7.80; 95% CI 6.26 to 9.60) and cor pulmonale (SMR 1.17; 95% CI 1.08 to 1.26). Mortality rates for most diseases of interest increased with time-since-hire. For the category including CBD, rates were substantially elevated compared to the US population across all exposure groups. Workers whose maximum beryllium exposure was ≥ 10 μg/m³ had higher rates of lung cancer, urinary tract cancer, COPD and the category containing cor pulmonale than workers with lower exposure. These studies showed strong associations for cumulative exposure (when short-term workers were excluded), maximum exposure or both. Significant positive trends with cumulative exposure were observed for nervous system cancers ($p = 0.0006$) and, when short-term workers were excluded, lung cancer ($p = 0.01$), urinary tract cancer ($p = 0.003$) and COPD ($p < 0.0001$).

The authors concluded the findings from this reanalysis reaffirmed that lung cancer and CBD are related to beryllium exposure. The authors went on to suggest that beryllium exposures may be associated with nervous system and urinary tract cancers and that cigarette smoking and other lung carcinogens were unlikely to explain the increased incidences in these cancers. The study corrected an error that was discovered in the indirect smoking adjustment initially conducted by Ward *et al.,* concluding that cigarette smoking rates did not differ between the cohort and the general U.S. population. No association was found between cigarette smoking and either cumulative or maximum beryllium exposure, making it very unlikely that smoking was a substantial confounder in this study (Schubauer-Berigan *et al.,* 2010).

3. Animal Cancer Studies

This section reviews the animal literature used to support the findings for beryllium-induced lung cancer. Lung tumors have been induced via inhalation and intratracheal administration of beryllium to rats and monkeys, and osteosarcomas have been induced via intravenous and intramedullary (inside the bone) injection of beryllium in rabbits and possibly in mice. The chronic oral studies did not report increased incidences of tumors in rodents, but these were conducted at doses below the maximum tolerated dose (MTD) (EPA, 1998).

Early animal studies revealed that some beryllium compounds are carcinogenic when inhaled (ATSDR, 2002). Animal experiments have shown consistent increases in lung cancers in rats, mice and rabbits chronically exposed to beryllium and beryllium compounds by inhalation or intratracheal instillation. In addition to lung cancer, osteosarcomas have been produced in mice and rabbits exposed to various beryllium salts by intravenous injection or implantation into the bone (NTP, 1999).

In an inhalation study assessing the potential tumorigenicity of beryllium, Schepers *et al.* (1957) exposed 115 albino Sherman and Wistar rats (male and female) via inhalation to 0.0357 mg beryllium/m³ (1 γ beryllium/ft³) [4] as an aqueous aerosol of beryllium sulfate for 44 hours/week for 6 months, and observed the rats for 18 months after exposure. Three to four control rats were killed every two months for comparison purposes. Seventy-six lung neoplasms, [5] including adenomas, squamous-cell carcinomas, acinous adenocarcinomas, papillary adenocarcinomas, and alveolar-cell adenocarcinomas, were observed in 52 rats exposed to beryllium sulfate aerosol. Adenocarcinomata were the most numerous. Pulmonary metastases tended to localize in areas with foam cell clustering and granulomatosis. No neoplasia was observed in any of the control rats. The incidence of lung tumors in exposed rats is presented in the following Table 2:

TABLE 2—NEOPLASM ANALYSIS

Neoplasm	Number	Metastases
Adenoma	18	
Squamous carcinoma	5	1
Acinous adenocarcinoma	24	2
Papillary adenocarcinoma	11	1
Alveolar-cell adenocarcinoma	7	
Mucigenous tumor	7	1
Endothelioma	1	
Retesarcoma	3	3
Total	76	8

[4] Schepers *et al.* (1957) reported concentrations in γ Be/ft³; however, γ/ft³ is no longer a common unit. Therefore, the concentration was converted to mg/m³.

[5] While a total of 89 tumors were observed or palpated at the time of autopsy in the $BeSO_4$-exposed animals, only 76 tumors are listed as histologically neoplastic. Only the new growths identified in single midcoronal sections of both lungs were recorded.

Schepers (1962) reviewed 38 existing beryllium studies that evaluated seven beryllium compounds and seven mammalian species. Beryllium sulfate, beryllium fluoride, beryllium phosphate, beryllium alloy ($BeZnMnSiO_4$), and beryllium oxide were proven to be carcinogenic and have remarkable pleomorphic neoplasiogenic proclivities. Ten varieties of tumors were observed, with adenocarcinoma being the most common variety.

In another study, Vorwald and Reeves (1959) exposed Sherman albino rats via the inhalation route to aerosols of 0.006 mg beryllium/m³ as beryllium oxide and 0.0547 mg beryllium/m³ as beryllium sulfate for 6 hours/day, 5 days/week for an unspecified duration. Lung tumors (single or multifocal) were observed in the animals sacrificed following 9 months of daily inhalation exposure. The histologic pattern of the cancer was primarily adenomatous; however, epidermoid and squamous cell cancers were also observed. Infiltrative, vascular, and lymphogenous extensions often developed with secondary metastatic growth in the tracheobronchial lymph nodes, the mediastinal connective tissue, the parietal pleura, and the diaphragm.

In the first of two articles, Reeves *et al.* (1967a) investigated the carcinogenic process in lungs resulting from chronic (up to 72 weeks) beryllium sulfate inhalation. One hundred fifty male and female Sprague Dawley C.D. strain rats were exposed to beryllium sulfate aerosol at a mean atmospheric concentration of 34.25 μg beryllium/m³ (with an average particle diameter of 0.12 μm). Prior to initial exposure and again during the 67–68 and 75–76 weeks of life, the animals received prophylactic treatments of tetracycline-HCl to combat recurrent pulmonary infections.

The animals entered the exposure chamber at 6 weeks of age and were exposed 7 hours per day/5 days per week for up to 2,400 hours of total exposure time. An equal number of unexposed controls were held in a separate chamber. Three male and three female rats were sacrificed monthly during the 72-week exposure period. Mortality due to respiratory or other infections did not appear until 55 weeks of age, and 87 percent of all animals survived until their scheduled sacrifices.

Average lung weight towards the end of exposure was 4.25 times normal with progressively increasing differences between control and exposed animals. The increase in lung weight was accompanied by notable changes in tissue texture with two distinct pathological processes—inflammatory and proliferative. The inflammatory response was characterized by marked accumulation of histiocytic elements forming clusters of macrophages in the alveolar spaces. The proliferative response progressed from early epithelial hyperplasia of the alveolar surfaces, through metaplasia (after 20–22 weeks of exposure), anaplasia (cellular dedifferentiation) (after 32–40 weeks of exposure), and finally to lung tumors.

Although the initial proliferative response occurred early in the exposure period, tumor development required considerable time. Tumors were first identified after nine months of beryllium sulfate exposure, with rapidly increasing rates of incidence until tumors were observed in 100 percent of exposed animals by 13 months. The 9-to-13-month interval is consistent with earlier studies. The tumors showed a high degree of local invasiveness. No tumors were observed in control rats. All 56 tumors studied appeared to be alveolar adenocarcinomas and 3 ''fast-growing'' tumors that reached a very large size comparatively early. About one-third of the tumors showed small foci where the histologic pattern differed. Most of the early tumor foci appeared to be alveolar rather than bronchiolar, which is consistent with the expected pathogenesis, since permanent deposition of beryllium was more likely on the alveolar epithelium rather than on the bronchiolar epithelium. Female rats appeared to have an increased susceptibility to beryllium exposure. Not only did they have a higher mortality (control males [n = 8], exposed males [n = 9] versus control females [n = 4], exposed females [n = 17]) and body weight loss than male rats, but the three ''fast-growing'' tumors only occurred in females.

In the second article, Reeves *et al.* (1967b) described the rate of accumulation and clearance of beryllium sulfate aerosol from the same experiment (Reeves *et al.,* 1967a). At the time of the monthly sacrifice, beryllium assays were performed on the lungs, tracheobronchial lymph nodes, and blood of the exposed rats. The pulmonary beryllium levels of rats showed a rate of accumulation which decreased during continuing exposure and reached a plateau (defined as equilibrium between deposition and clearance) of about 13.5 μg beryllium for males and 9 μg beryllium for females in whole lungs after approximately 36 weeks. Females were notably less efficient than males in utilizing the lymphatic route as a method of clearance, resulting in slower removal of pulmonary beryllium deposits, lower accumulation of the inhaled material in the tracheobronchial lymph nodes, and higher morbidity and mortality.

There was no apparent correlation between the extent and severity of pulmonary pathology and total lung load. However, when the beryllium content of the excised tumors was compared with that of surrounding nonmalignant pulmonary tissues, the former showed a notable decrease (0.50 ± 0.35 μg beryllium/gram versus 1.50 ± 0.55 μg beryllium/gram). This was believed to be largely a result of the dilution factor operating in the rapidly growing tumor tissue. However, other factors, such as lack of continued local deposition due to impaired respiratory function and enhanced clearance due to high vascularity of the tumor, may also have played a role. The portion of inhaled beryllium retained in the lungs for a longer duration, which is in the range of one-half of the original pulmonary load, may have significance for pulmonary carcinogenesis. This pulmonary beryllium burden becomes localized in the cell nuclei and may be an important factor in eliciting the carcinogenic response associated with beryllium inhalation.

Groth *et al.* (1980) conducted a series of experiments to assess the carcinogenic effects of beryllium, beryllium hydroxide, and various beryllium alloys. For the beryllium metal/alloys experiment, 12 groups of 3-month-old female Wistar rats (35 rats/group) were used. All rats in each group received a single intratracheal injection of either 2.5 or 0.5 mg of one of the beryllium metals or beryllium alloys as described in Table 3 below. These materials were suspended in 0.4 cc of isotonic saline followed by 0.2 cc of saline. Forty control rats were injected with 0.6 cc of saline. The geometric mean particle sizes varied from 1 to 2 μm. Rats were sacrificed and autopsied at various intervals ranging from 1 to 18 months post-injection.

TABLE 3—SUMMARY OF BERYLLIUM DOSE FROM GROTH ET AL. (1980)

Form of Be	Percent Be	Percent other compounds	Total No. rats autopsied	Compound dose (mg)	Be dose (mg)
Be metal	100	None	16	2.5	2.5
			21	0.5	0.5
Passivated Be metal	99	0.26% Chromium	26	2.5	2.5
			20	0.5	0.5
BeAl alloy	62	38% Aluminum	24	2.5	1.55
			21	0.5	0.3
BeCu alloy	4	96% Copper	28	2.5	0.1
			24	0.5	0.02
BeCuCo alloy	2.4	0.4% Cobalt	33	2.5	0.06
		96% Copper	30	0.5	0.012
BeNi alloy	2.2	97.8% Nickel	28	2.5	0.056
			27	0.5	0.011

Lung tumors were observed only in rats exposed to beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. Passivation refers to the process of removing iron contamination from the surface of beryllium metal. As discussed, metal alloys may have a different toxicity than beryllium alone. Rats exposed to 100 percent beryllium exhibited relatively high mortality rates, especially in the groups where lung tumors were observed. Nodules varying from 1 to 10 mm in diameter were also observed in the lungs of rats exposed to beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. These nodules were suspected of being malignant.

To test this hypothesis, transplantation experiments involving the suspicious nodules were conducted in nine rats. Seven of the nine suspected tumors grew upon transplantation. All transplanted tumor types metastasized to the lungs of their hosts. Lung tumors were observed in rats injected with both the high and low doses of beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. No lung tumors were observed in rats injected with the other compounds. From a total of 32 lung tumors detected, most were adenocarcinomas and adenomas; however, two epidermoid carcinomas and at least one poorly differentiated carcinoma were observed. Bronchiolar alveolar cell tumors were frequently observed in rats injected with beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. All stages of cuboidal, columnar, and squamous cell metaplasia were observed on the alveolar walls in the lungs of rats injected with beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. These lesions were generally reduced in size and number or absent from the lungs of animals injected with the other alloys (BeCu, BeCuCo, BeNi).

The extent of alveolar metaplasia could be correlated with the incidence of lung cancer. The incidences of lung tumors in the rats that received 2.5 mg of beryllium metal, and 2.5 and 0.5 mg of passivated beryllium metal, were significantly different ($p \leq 0.008$) from controls. When autopsies were performed at the 16-to-19-month interval, the incidence (2/6) of lung tumors in rats exposed to 2.5 mg of beryllium-aluminum alloy was statistically significant ($p = 0.004$) when compared to the lung tumor incidence (0/84) in rats exposed to BeCu, BeNi, and BeCuCo alloys, which contained much lower concentrations of Be (Groth *et al.,* 1980).

Finch *et al.* (1998b) investigated the carcinogenic effects of inhaled beryllium on heterozygous TSG-p53 knockout mice (*p53*$^{+/-}$) and wild-type (*p53*+/+) mice. Knockout mice can be valuable tools in determining the role of specific genes on the toxicity of a material of interest, in this case, beryllium. Equal numbers of approximately 10-week-old male and female mice were used for this study. Two exposure groups were used to provide dose-response information on lung carcinogenicity. The maximum initial lung burden (ILB) target of 60 μg beryllium was based on previous acute inhalation exposure studies in mice. The lower exposure target level of 15 μg was selected to provide a lung burden significantly less than the high-level group, but high enough to yield carcinogenic responses. Mice were exposed in groups to beryllium metal or to filtered air (controls) via nose-only inhalation. The specific exposure parameters are presented in Table 4 below. Mice were sacrificed 7 days post exposure for ILB analysis, and either at 6 months post exposure (n = 4–5 mice per group per gender) or when 10 percent or less of the original population remained (19 months post exposure for *p53*$^{+/-}$ knockout and 22.5 months post exposure for *p53*+/+ wild-type mice). The sacrifice time was extended in the study because a significant number of lung tumors were not observed at 6 months post exposure.

TABLE 4—SUMMARY OF ANIMAL DATA FROM FINCH ET AL., 1998 b

Mouse strain	Mean exposure concentration (μg Be/L)	Target be lung burden (μg)	Number of mice	Mean daily exposure duration (minutes)	Mean ILB (μg)	Number of mice with 1 or more lung tumors/total number examined
Knockout (*p53*$^{+/-}$)	34	15	30	112 (single)	NA	0/29
	36	60	30	139‡	NA	4/28
Wild-type (*p53*+/+)	34	15	6*	112 (single)	12 ± 4	NA
	36	60	36†	139‡	54 ± 6	0/28
Knockout (*p53*$^{+/-}$)	NA (air)	Control	30	60–180 (single)	NA	0/30

ILB = initial lung burden; NA = not applicable
Median aerodynamic diameter of Be aerosol = 1.4 μm (σ_g = 1.8)
* Wild-type mice in the low exposure group were not evaluated for carcinogenic effects; however ILB was analyzed in six wild-type mice.
† Thirty wild-type mice were analyzed for carcinogenic effects; six wild-type mice were analyzed for ILB.
‡ Mice were exposed for 2.3 hours/day for three consecutive days.

Lung burdens of beryllium measured in wild-type mice at 7 days post exposure were approximately 70–90 percent of target levels. No exposure-related effects on body weight were observed in mice; however, lung weights and lung-to-body-weight ratios were somewhat elevated in 60 μg target ILB *p53*$^{+/-}$ knockout mice compared to controls ($0.05 < p < 0.10$). In general, *p53*+/+ wild-type mice survived longer than *p53*$^{+/-}$ knockout mice and beryllium exposure tended to decrease survival time in both groups. The incidence of beryllium-induced lung tumors was marginally higher in the 60 μg target ILB *p53*$^{+/-}$ knockout mice compared to 60 μg target ILB *p53*+/+ wild-type mice ($p = 0.056$). The incidence of lung tumors in the 60 μg target ILB *p53*$^{+/-}$ knockout mice was also significantly higher than controls ($p = 0.048$). No tumors developed in the control mice, 15 μg target ILB *p53*$^{+/-}$ knockout mice, or 60 μg target ILB *p53*+/+ wild-type mice throughout the length of the study. Most lung tumors in beryllium-exposed mice were squamous cell carcinomas, three of four of which were poorly circumscribed and all were associated with at least some degree of granulomatous pneumonia. The study results suggest that having an inactivated *p53* allele is associated with lung tumor progression in *p53*$^{+/-}$ knockout mice. This is based on the significant difference seen in the incidence of beryllium-induced lung neoplasms for the *p53*$^{+/-}$knockout mice compared with the *p53*+/+ wild-type mice. The authors conclude that since there was a relatively late onset of tumors in the beryllium-exposed *p53*$^{+/-}$ knockout mice, a 6-month bioassay in this mouse strain might not be an appropriate model for lung carcinogenesis (Finch *et al.,* 1998b).

Nickell-Brady *et al.* (1994) investigated the development of lung tumors in 12-week-old F344/N rats after a single nose-only inhalation exposure to beryllium aerosol, and evaluated whether beryllium lung tumor induction involves alterations in the K-*ras, p53,* and c-*raf*−1 genes. Four groups of rats (30 males and 30 females per group) were exposed to different mass concentrations of beryllium (Group 1: 500 mg/m^3 for 8 min; Group 2: 410 mg/m^3 for 30 min; Group 3: 830 mg/m^3 for 48 min; Group 4: 980 mg/m^3 for 39 min). The beryllium mass median aerodynamic diameter was 1.4 μm (σ_g = 1.9). The mean beryllium lung burdens for each exposure group were 40, 110, 360, and 430 μg, respectively.

To examine genetic alterations, DNA isolation and sequencing techniques (PCR amplification and direct DNA sequence analysis) were performed on wild-type rat lung tissue (*i.e.,* control samples) along with two mouse lung tumor cell lines containing known K-*ras* mutations, 12 carcinomas induced by beryllium (*i.e.,* experimental samples), and 12 other formalin-fixed specimens. Tumors appeared in beryllium-exposed rats by 14 months, and 64 percent of exposed rats developed lung tumors during their lifetime. Lungs frequently contained multiple tumor sites, with some of the tumors greater than 1 cm. A total of 24 tumors were observed. Most of the tumors (n = 22) were adenocarcinomas exhibiting a papillary pattern characterized by cuboidal or columnar cells, although a few had a tubular or solid pattern. Fewer than 10 percent of the tumors were adenosquamous (n = 1) or squamous cell (n = 1) carcinomas.

No transforming mutations of the K-*ras* gene (codons 12, 13, or 61) were detected by direct sequence analysis in any of the lung tumors induced by beryllium. However, using a more sensitive sequencing technique (PCR enrichment restriction fragment length polymorphism (RFLP) analysis) resulted in the detection of K-*ras* codon 12 GGT to GTT transversions in 2 of 12 beryllium-induced adenocarcinomas. No *p53* and c-*raf*-1 alterations were observed in any of the tumors induced by beryllium exposure (*i.e.,* no differences observed between beryllium-exposed and control rat tissues). The authors note that the results suggest that activation of the K-*ras* proto-oncogene is both a rare and late event, possibly caused by genomic instability during the progression of beryllium-induced rat pulmonary adenocarcinomas. It is unlikely that the K-*ras* gene plays a role in the carcinogenicity of beryllium. The results also indicate that *p53* mutation is unlikely to play a role in tumor development in rats exposed to beryllium.

Belinsky *et al.* (1997) reviewed the findings by Nickell-Brady *et al.* (1994) to further examine the role of the K-*ras* and *p53* genes in lung tumors induced in the F344 rat by non-mutagenic (non-genotoxic) exposures to beryllium. Their findings are discussed along with the results of other genomic studies that look at carcinogenic agents that are either similarly non-mutagenic or, in other cases, mutagenic. The authors conclude that the identification of non-*ras* transforming genes in rat lung tumors induced by non-mutagenic exposures, such as beryllium, as well as mutagenic exposures will help define some of the mechanisms underlying cancer induction by different types of DNA damage.

The inactivation of the *p16^{INK4a}* (*p16*) gene is a contributing factor in disrupting control of the normal cell cycle and may be an important mechanism of action in beryllium-induced lung tumors. Swafford *et al.* (1997) investigated the aberrant methylation and subsequent inactivation of the *p16* gene in primary lung tumors induced in F344/N rats exposed to known carcinogens via inhalation. The research involved a total of 18 primary lung tumors that developed after exposing rats to five agents, one of which was beryllium. In this study, only one of the 18 lung tumors was induced by beryllium exposure; the majority of the other tumors were induced by radiation (x-rays or plutonium-239 oxide). The authors hypothesized that if *p16* inactivation plays a central role in development of non-small-cell lung cancer, then the frequency of gene inactivation in primary tumors should parallel that observed in the corresponding cell lines. To test the hypothesis, a rat model for lung cancer was used to determine the frequency and mechanism for inactivation of *p16* in matched primary lung tumors and derived cell lines. The methylation-specific PCR (MSP) method was used to detect methylation of *p16* alleles. The results showed that the presence of aberrant *p16* methylation in cell lines was strongly correlated with absent or low expression of the gene. The findings also demonstrated that aberrant *p16* CpG island methylation, an important mechanism in gene silencing leading to the loss of *p16* expression, originates in primary tumors.

Building on the rat model for lung cancer and associated findings from Swafford *et al.* (1997), Belinsky *et al.* (2002) conducted experiments in 12-week-old F344/N rats (male and female) to determine whether beryllium-induced lung tumors involve inactivation of the *p16* gene and estrogen receptor α (ER) gene. Rats received a single nose-only inhalation exposure to beryllium aerosol at four different exposure levels. The mean lung burdens measured in each exposure group were 40, 110, 360, and 430 μg. The methylation status of the *p16* and ER genes was determined by MSP. A total of 20 tumors detected in beryllium-exposed rats were available for analysis of gene-specific promoter methylation. Three tumors were classified as squamous cell carcinomas and the others were determined to be adenocarcinomas. Methylated *p16* was present in 80 percent (16/20), and methylated ER was present in one-half (10/20), of the lung tumors induced by exposure to beryllium. Additionally, both genes were methylated in 40 percent of the tumors. The authors noted that four tumors from beryllium-exposed rats appeared to be partially methylated at the *p16* locus. Bisulfite sequencing of exon 1 of the ER gene was conducted on normal lung DNA and DNA from three methylated, beryllium-induced tumors to determine the density of methylation within amplified regions of exon 1 (referred to as CpG sites). Two of the three methylated, beryllium-induced lung tumors showed extensive methylation, with more than 80 percent of all CpG sites methylated.

The overall findings of this study suggest that inactivation of the *p16* and ER genes by promoter hypermethylation are likely to contribute to the development of lung tumors in beryllium-exposed rats. The results showed a correlation between changes in *p16* methylation and loss of gene transcription. The authors hypothesize that the mechanism of action for beryllium-induced *p16* gene inactivation in lung tumors may be inflammatory mediators that result in oxidative stress. The oxidative stress damages DNA directly through free radicals or indirectly through the formation of 8-hydroxyguanosine DNA adducts, resulting primarily in a single-strand DNA break.

Wagner *et al.* (1969) studied the development of pulmonary tumors after intermittent daily chronic inhalation exposure to beryllium ores in three groups of male squirrel monkeys. One group was exposed to bertrandite ore, a second to beryl ore, and the third served as unexposed controls. Each of these three exposure groups contained 12 monkeys. Monkeys from each group were sacrificed after 6, 12, or 23 months of exposure. The 12-month sacrificed monkeys (n = 4 for bertrandite and control groups; n = 2 for beryl group) were replaced by a separate replacement group to maintain a total animal population approximating the original numbers and to provide a source of confirming data for biologic responses that might arise following the ore exposures. Animals were exposed to bertrandite and beryl ore concentrations of 15 mg/m³, corresponding to 210 µg beryllium/m³ and 620 µg beryllium/m³ in each exposure chamber, respectively. The parent ores were reduced to particles with geometric mean diameters of 0.27 µm (± 2.4) for bertrandite and 0.64 µm (± 2.5) for beryl. Animals were exposed for approximately 6 hours/day, 5 days/week. The histological changes in the lungs of monkeys exposed to bertrandite and beryl ore exhibited a similar pattern. The changes generally consisted of aggregates of dust-laden macrophages, lymphocytes, and plasma cells near respiratory bronchioles and small blood vessels. There were, however, no consistent or significant pulmonary lesions or tumors observed in monkeys exposed to either of the beryllium ores. This is in contrast to the findings in rats exposed to beryl ore and to a lesser extent bertrandite, where atypical cell proliferation and tumors were frequently observed in the lungs. The authors hypothesized that the rats' greater susceptibility may be attributed to the spontaneous lung disease characteristic of rats, which might have interfered with lung clearance.

As previously described, Conradi *et al.* (1971) investigated changes in the lungs of monkeys and dogs two years after intermittent inhalation exposure to beryllium oxide calcined at 1,400 °C. Five adult male and female monkeys (*Macaca irus*) weighing between 3 and 5.75 kg were used in the study. The study included two control monkeys. Beryllium concentrations in the atmosphere of whole-body exposed monkeys varied between 3.30 and 4.38 mg/m³. Thirty-minute exposures occurred once a month for three months, with beryllium oxide concentrations increasing at each exposure interval. Lung tissue was investigated using electron microscopy and morphometric methods. Beryllium content in portions of the lungs of five monkeys was measured two years following exposure by emission spectrography. The reported concentrations in monkeys (82.5, 143.0, and 112.7 µg beryllium per 100 gm of wet tissue in the upper lobe, lower lobe, and combined lobes, respectively) were higher than those in dogs. No neoplastic or granulomatous lesions were observed in the lungs of any exposed animals and there was no evidence of chronic proliferative lung changes after two years.

4. In vitro Studies

The exact mechanism by which beryllium induces pulmonary neoplasms in animals remains unknown (NAS 2008). Keshava *et al.* (2001) performed studies to determine the carcinogenic potential of beryllium sulfate in cultured mammalian cells. Joseph *et al.* (2001) investigated differential gene expression to understand the possible mechanisms of beryllium-induced cell transformation and tumorigenesis. Both investigations used cell transformation assays to study the cellular/molecular mechanisms of beryllium carcinogenesis and assess carcinogenicity. Cell lines were derived from tumors developed in nude mice injected subcutaneously with non-transformed BALB/c-3T3 cells that were morphologically transformed *in vitro* with 50–200 µg beryllium sulfate/ml for 72 hours. The non-transformed cells were used as controls.

Keshava *et al.* (2001) found that beryllium sulfate is capable of inducing morphological cell transformation in mammalian cells and that transformed cells are potentially tumorigenic. A dose-dependent increase (9–41 fold) in transformation frequency was noted. Using differential polymerase chain reaction (PCR), gene amplification was investigated in six proto-oncogenes (K-*ras,* c-*myc,* c-fos, c-*jun,* c-*sis, erb-B2*) and one tumor suppressor gene (*p53*). Gene amplification was found in c-*jun* and K-*ras.* None of the other genes tested showed amplification. Additionally, Western blot analysis showed no change in gene expression or protein level in any of the genes examined. Genomic instability in both the non-transformed and transformed cell lines was evaluated using random amplified polymorphic DNA fingerprinting (RAPD analysis). Using different primers, 5 of the 10 transformed cell lines showed genomic instability when compared to the non-transformed BALB/c-3T3 cells. The results indicate that beryllium sulfate-induced cell transformation might, in part, involve gene amplification of K-*ras* and c-*jun* and that some transformed cells possess neoplastic potential resulting from genomic instability.

Using the Atlas mouse 1.2 cDNA expression microarrays, Joseph *et al.* (2001) studied the expression profiles of 1,176 genes belonging to several different functional categories. Compared to the control cells, expression of 18 genes belonging to two functional groups (nine cancer-related genes and nine DNA synthesis, repair, and recombination genes) was found to be consistently and reproducibly different (at least 2-fold) in the tumor cells. Differential gene expression profile was confirmed using reverse transcription-PCR with primers specific to the differentially expressed genes. Two of the differentially expressed genes (c-*fos* and c-*jun*) were used as model genes to demonstrate that the beryllium-induced transcriptional activation of these genes was dependent on pathways of protein kinase C and mitogen-activated protein kinase and independent of reactive oxygen species in the control cells. These results indicate that beryllium-induced cell transformation and tumorigenesis are associated with up-regulated expression of the cancer-related genes (such as c-*fos,* c-*jun,* c-*myc,* and R-*ras*) and down-regulated expression of genes involved in DNA synthesis, repair, and recombination (such as *MCM4, MCM5, PMS2, Rad23,* and DNA *ligase I*).

5. Preliminary Lung Cancer Conclusions

OSHA has preliminarily determined that the weight of evidence indicates that beryllium compounds should be regarded as potential occupational lung carcinogens. Other scientific organizations, including the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists (ACGIH) have reached similar conclusions with respect to the carcinogenicity of beryllium.

While some evidence exists for direct-acting genotoxicity as a possible mechanism for beryllium carcinogenesis, the weight of evidence suggests a possible indirect mechanism may be responsible for most tumorigenic activity of beryllium in animal models and possibly humans (EPA, 1998). Inflammation has been postulated to be a key contributor to many different forms of cancer (Jackson *et al.,* 2006; Pikarsky *et al.,* 2004; Greten *et al.,* 2004; Leek, 2002). In fact, chronic inflammation may be a primary factor in the development of up to one-third of all cancers (Ames *et al.,* 1990; NCI, 2010).

In addition to a T-cell mediated response beryllium has been demonstrated to produce an inflammatory response in animal models similar to other particles (Reeves *et al.,* 1967; Swafford *et al.,* 1997; Wagner *et al.,* 1969) possibly contributing to its carcinogenic potential. Animal studies, as summarized above, have demonstrated a consistent scenario of beryllium exposure resulting in chronic pulmonary inflammation. Studies conducted in rats have demonstrated that chronic inhalation of materials similar in solubility to beryllium result in increased pulmonary inflammation, fibrosis, epithelial hyperplasia, and, in some cases, pulmonary adenomas and carcinomas (Heinrich *et al.,* 1995; Nikula *et al.,* 1995; NTP, 1993; Lee *et al.,* 1985; Warheit *et al.,* 1996). This response is generally referred to as an ''overload'' response or threshold effect. Substantial data indicate that tumor formation in the rat after exposure to some sparingly soluble particles at doses causing marked, chronic inflammation is due to a secondary mechanism unrelated to the genotoxicity (or lack thereof) of the particle itself.

It has been hypothesized that the recruitment of neutrophils during the inflammatory response and subsequent release of oxidants from these cells have been demonstrated to play an important role in the pathogenesis of rat lung tumors (Borm *et al.,* 2004; Carter and Driscoll, 2001; Carter *et al.,* 2006; Johnston *et al.,* 2000; Knaapen *et al.,* 2004; Mossman, 2000). Inflammatory mediators, as characterized in many of the studies summarized above, have been shown to play a significant role in the recruitment of cells responsible for the release of reactive oxygen and hydrogen species. These species have been determined to be highly mutagenic themselves as well as mitogenic, inducing a proliferative response (Feriola and Nettesheim, 1994; Jetten *et al.,* 1990; Moss *et al.,* 1994; Coussens and Werb, 2002). The resultant effect is an environment rich for neoplastic transformations and the progression of fibrosis and tumor formation. This finding does not imply no risk at levels below an inflammatory response; rather, the overall weight of evidence is suggestive of a mechanism of an indirect carcinogen at levels where inflammation is seen. While tumorigenesis secondary to inflammation is one reasonable mode of action, other plausible modes of action independent of inflammation (*e.g.,* epigenetic, mitogenic, reactive oxygen mediated, indirect genotoxicity, etc.) may also contribute to the lung cancer associated with beryllium exposure.

Epidemiological studies indicate excess risk of lung cancer mortality from occupational beryllium exposure levels at or below the current OSHA PEL (Schubauer-Berigan *et al.,* 2010; Table 4).

F. Other Health Effects

Past studies on other health effects have been thoroughly reviewed by several scientific organizations (NTP, 1999; EPA, 1998; ATSDR, 2002; WHO, 2001; HSDB, 2010). These studies include summaries of animal studies, *in vitro* studies, and human epidemiological studies associated with cardiovascular, hematological, hepatic, renal, endocrine, reproductive, ocular and mucosal, and developmental effects. High-dose exposures to beryllium have been shown to have an adverse effect upon a variety of organs and tissues in the body, particularly the liver. The adverse systemic effects from human exposures mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1972 (OSHA, 1971; ACGIH, 1971; ANSI, 1970) and 1974 (EPA, 1974) and therefore are less relevant today than in the past. The available data is fairly limited. The hepatic, cardiovascular, renal, and ocular and mucosal effects are briefly summarized below. Health effects in other organ systems listed above were only observed in animal studies at very high exposure levels and are, therefore, not discussed here.

1. Hepatic Effects

Beryllium has been shown to accumulate in the liver and a correlation has been demonstrated between beryllium content and hepatic damage. Different compounds have been shown to distribute differently within the hepatic tissues. For example, beryllium phosphate had accumulated almost exclusively within sinusoidal (Kupffer) cells of the liver, while the beryllium derived from beryllium sulfate was found mainly in parenchymal cells. Conversely, beryllium sulphosalicylic acid complexes were rapidly excreted (Skillteter and Paine, 1979).

According to a few autopsies, beryllium-laden liver had central necrosis, mild focal necrosis as well as congestion, and occasionally beryllium granuloma.

Residents near a beryllium plant may have been exposed by inhaling trace amounts of beryllium powder, and different beryllium compounds may have induced different toxicant reactions (Yian and Yin, 1982).

2. Cardiovascular Effects

There is very limited evidence of cardiovascular effects of beryllium and its compounds in humans. Severe cases of chronic beryllium disease can result in cor pulmonale, which is hypertrophy of the right heart ventricle. In a case history study of 17 individuals exposed to beryllium in a plant that manufactured fluorescent lamps, autopsies revealed right atrial and ventricular hypertrophy (Hardy and Tabershaw, 1946). It is not likely that these cardiac effects were due to direct toxicity to the heart, but rather were a response to impaired lung function. However, an increase in deaths due to heart disease or ischemic heart disease was found in workers at a beryllium manufacturing facility (Ward *et al.,* 1992).

Animal studies performed in monkeys indicate heart enlargement after acute inhalation exposure to 13 mg beryllium/m^3 as beryllium hydrogen phosphate, 0.184 mg beryllium/m^3 as beryllium fluoride, or 0.198 mg beryllium/m^3 as beryllium sulfate (Schepers 1964). Decreased arterial oxygen tension was observed in dogs exposed to 30 mg beryllium/m^3 as beryllium oxide for 15 days (HSDB, 2010), 3.6 mg beryllium/m^3 as beryllium oxide for 40 days (Hall *et al.,* 1950), or 0.04 mg beryllium/m^3 as beryllium sulfate for 100 days (Stokinger *et al.,* 1950). These are expected to be indirect effects on the heart due to pulmonary fibrosis and toxicity which can increase arterial pressure and restrict blood flow.

3. Renal Effects

Renal calculi (stones) were unusually prevalent in severe cases that resulted from high levels of beryllium exposure. Renal stones containing beryllium occurred in about 10 percent of patients affected by high exposures (Barnett, *et al.,* 1961). Kidney stones were observed in 10 percent of the CBD cases collected by the BCR up to 1959 (Hall *et al.,* 1959). In addition, an excess of calcium in the blood and urine has been seen frequently in patients with chronic beryllium disease (ATSDR, 2002).

4. Ocular and Mucosal Effects

Both the soluble, sparingly soluble, and insoluble beryllium compounds have been shown to cause ocular irritation in humans (Van Orstrand *et al.,* 1945; De Nardi *et al.,* 1953; Nishimura, 1966; Epstein, 1990; NIOSH, 1994). In addition, beryllium compounds (soluble, sparingly soluble, or insoluble) have been demonstrated to induce acute conjunctivitis with corneal maculae and diffuse erythema (HSDB, 2010).

The mucosa (mucosal membrane) is the moist lining of certain tissues/organs including the eyes, nose, mouth, lungs, and the urinary and digestive tracts. Soluble beryllium salts have been shown to be directly irritating to mucous membranes (HSDB, 2010).

G. Summary of Preliminary Conclusions Regarding Health Effects

Through careful analysis of the current best available scientific information outlined in this Health Effects Section V, OSHA has preliminarily determined that beryllium and beryllium-containing compounds are able to cause sensitization, chronic beryllium disease (CBD) and lung cancer below the current OSHA PEL of 2 μg/m³. The Agency has preliminarily determined through the studies outlined in section V.A.2 of this health effects section that skin and inhalation exposure to beryllium can lead to sensitization; and inhalation exposure, or skin exposure coupled with inhalation, can cause onset and progression of CBD. In addition, the Agency has preliminarily determined through studies outlined in section V.E. of this health effects section that inhalation exposure to beryllium and beryllium containing materials causes lung cancer.

1. Beryllium Causes Sensitization Below the Current PEL and Sensitization is a Precursor to CBD

Through the biological and immunological processes outlined in section V.B. of the Health Effects, the Agency believes that the scientific evidence supports the following mechanism for the development of sensitization and CBD.

- Inhaled beryllium and beryllium-containing materials able to be retained and solubilized in the lungs initiate sensitization and facilitate CBD development (Section V.B.5).
- Beryllium compounds that dissolve in biological fluids, such as sweat, can penetrate intact skin and initiate sensitization (section V.A.2; V.B). Phagosomal fluid and lung fluid have been demonstrated to dissolve beryllium compounds in the lung (section V.A.2a).
- Sensitization occurs through a CD4+ T-cell mediated process with both soluble and insoluble beryllium and beryllium-containing compounds through direct antigen presentation or through further antigen processing (section V.D.1) in the skin or lung. T-cell mediated responses, such as sensitization, are generally regarded as long-lasting (*e.g.*, not transient or readily reversible) immune conditions.
- Beryllium sensitization and CBD are adverse events along a pathological continuum in the disease process with sensitization being the necessary first step in the progression to CBD (section V.D).
  - Animal studies have provided supporting evidence for T-cell proliferation in the development of granulomatous lung lesions after beryllium exposure (section V.D.2; V.D.6).
  - Since the pathogenesis of CBD involves a beryllium-specific, cell-mediated immune response, CBD cannot occur in the absence of beryllium sensitization (V.D.1). While no clinical symptoms are associated with sensitization, a sensitized worker is at risk of developing CBD upon subsequent inhalation exposure to beryllium.
  - Epidemiological evidence that covers a wide variety of different beryllium compounds and industrial processes demonstrates that sensitization and CBD are continuing to occur at present-day exposures below OSHA's PEL (section V.D.4; V.D.5).
- OSHA considers CBD to be a progressive illness with a continuous spectrum of symptoms ranging from its earliest asymptomatic stage following sensitization through to full-blown CBD and death (section V.D.7).
- Genetic variabilities may enhance risk for developing sensitization and CBD in some groups (section V.D.3).

In addition, epidemiological studies outlined in section V.D.5 have demonstrated that efforts to reduce exposures have succeeded in reducing the frequency of sensitization and CBD.

2. Evidence Indicates Beryllium is a Human Carcinogen

OSHA has conducted an evaluation of the current available scientific information of the carcinogenic potential of beryllium and beryllium-containing compounds (section V.E). Based on weight of evidence and plausible mechanistic information obtained from *in vitro* and *in vivo* animal studies as well as clinical and epidemiological investigations, the Agency has preliminarily determined that beryllium and beryllium-containing materials should be regarded as human carcinogens. This information is in accordance with findings from IARC, NTP, EPA, NIOSH, and ACGIH (section V.E).

- Lung cancer is an irreversible and frequently fatal disease with an extremely poor 5-year survival rate (NCI, 2009).
- Epidemiological cohort studies have reported statistically significant excess lung cancer mortality among workers employed in U.S. beryllium production and processing plants during the 1930s to 1970s (Section V.E.2).
- Significant positive associations were found between lung cancer mortality and both average and cumulative beryllium exposures when appropriately adjusted for birth cohort and short-term work status (Section V.E.2).
- Studies in which large amounts of different beryllium compounds were inhaled or instilled in the respiratory tracts of experimental animals resulted in an increased incidence of lung tumors (Section V.E.3).
- Authoritative scientific organizations, such as the IARC, NTP, and EPA, have classified beryllium as a known or probable human carcinogen.

While OSHA has preliminarily determined there is sufficient evidence of beryllium carcinogenicity, the exact tumorigenic mechanism for beryllium is unclear and a number of mechanisms are plausibly involved, including chronic inflammation, genotoxicity, mitogenicity oxidative stress, and epigenetic changes (section V.E.3).

- Studies of beryllium exposed animals have consistently demonstrated chronic pulmonary inflammation after exposure (section V.E.3).
  - Substantial data indicate that tumor formation in certain animal models after inhalation exposure to sparingly soluble particles at doses causing marked, chronic inflammation is due to a secondary mechanism unrelated to the genotoxicty of the particle (section V.E.5).
- A review conducted by the NAS (2008) found that beryllium and beryllium-containing compounds tested positive for genotoxicity in nearly 50 percent of studies without exogenous metabolic activity, suggesting a possible direct-acting mechanism may exist (section V.E.1) as well as the potential for epigenetic changes (section V.E.4).

Other health effects have been summarized in sections F of the Health Effects Section and include hepatic, cardiovascular, renal, ocular, and mucosal effects. The adverse systemic effects from human exposures mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1972 (OSHA, 1971; ACGIH, 1971; ANSI, 1970) and 1974 (EPA, 1974) and therefore are less relevant today than in the past.

APPENDIX

TABLE A.1—SUMMARY OF BERYLLIUM SENSITIZATION AND CHRONIC BERYLLIUM DISEASE EPIDEMIOLOGICAL STUDIES

Reference	Study type	(%) Prevalence		Range of exposure measurements	Exposure-response relationship	Study limitations	Additional comments
		Sensitization	CBD				
Studies Conducted Prior to BeLPT							
Hardy and Tabershaw, 1946.	Case-series	N/A	N/A	N/A	N/A	Selection bias	Small sample size.
Hardy, 1980	Case-series	N/A	N/A	N/A	N/A	Selection bias	Small sample size.
Machle *et al.,* 1948	Case-series	N/A	N/A	Semi-quantitative	Yes	Selection bias	Small sample size; unreliable exposure data.
Eisenbud *et al.,* 1949.	Case-series	N/A	N/A	*Average concentration: 350–750 ft from plant*—0.05–0.15 μg/m³;. *<350 ft from plant*—2.1 μg/m³.			Non-occupational; ambient air sampling.
Lieben and Metzner, 1959.		N/A		N/A		No quantitative exposure data.	Family member contact with contaminated clothes.
Hardy *et al.,* 1967	Case Registry Review.	N/A	N/A	N/A	N/A	Incomplete exposure concentration data.	
Hasan and Kazemi, 1974.		N/A					
Eisenbud and Lisson, 1983.		N/A	1–10				
Stoeckle *et al.*, 1969	Case-series (60 cases).	N/A			No	Selection bias	Provided information regarding progression and identifying sarcoidosis from CBD.
Studies Conducted Following the Development of the BeLPT							
Beryllium Mining and Extraction							
Deubner *et al.,* 2001b.	Cross-sectional (75 workers).	4.0 (3 cases).	1.3 (1 case).	*Mining, milling*—range 0.05–0.8 μg/m³; *Annual maximum* 0.04–165.7 μg/m³.	No	Small sample size	Personal sampling.
Beryllium Metal Processing and Alloy Production							
Kreiss *et al.,* 1997	Cross-sectional study of 627 workers.	6.9 (43 cases).	4.6 (29 cases).	Median—1.4 μg/m³	No	Inconsistent BeLPT results between labs.	Short-term Breathing Zone sampling.
Rosenman *et al.,* 2005.	Cross-sectional study of 577 workers.	14.5 (83 cases).	5.5 (32 cases).	Mean average range—7.1–8.7 μg/m³;. Mean peak range—53–87 μg/m³; Mean cumulative range—100–209 μg/m³.	No		Daily weighted average: High exposures compared to other studies.
Beryllium Machining Operations							
Newman *et al.*, 2001.	Longitudinal study of 235 workers.	9.4 (22 cases).	8.5 (20 cases).		No		Engineering and administrative controls primarily used to control exposures.

TABLE A.1—SUMMARY OF BERYLLIUM SENSITIZATION AND CHRONIC BERYLLIUM DISEASE EPIDEMIOLOGICAL STUDIES—Continued

Reference	Study type	(%) Prevalence		Range of exposure measurements	Exposure-response relationship	Study limitations	Additional comments
		Sensitization	CBD				
Kelleher *et al.,* 2001	Case-control study of 20 cases and 206 controls.	11.5 (machinists). 2.9 (non-machinists).	11.5 (machinists). 2.9 (non-machinists).	0.08–0.6 μg/m³—lifetime weighted exposures.	Yes	....	Identified 20 workers with Sensitization or CBD.
Madl *et al.,* 2007	Longitudinal study of 27 cases.	....	....	*Machining* .... *1980–1995* median − 0.33 μg/m³; *1996–1999* median—0.16 μg/m³; *2000–2005* median—0.09 μg/m³;. *Non-machining 1980–1995* median—0.12 μg/m³; *1996–1999* median—0.08 μg/m³; *2000–2005* median—0.06 μg/m³.	Yes	....	Personal sampling: Required evidence of granulomas for CBD diagnosis.
Beryllium Oxide Ceramics							
Kreiss *et al.,* 1993b	Cross-sectional survey of 505 workers.	3.6 (18 cases).	1.8 (9 cases).	....	No		
Kreiss *et al.,* 1996	Cross-sectional survey of 136 workers.	5.9 (8 cases).	4.4 (6 cases).	*Machining* median—0.6 μg/m³;. *Other Areas* median—<0.3 μg/m³;	No	Small study population.	Breathing Zone Sampling.
Henneberger *et al.,* 2001.	Cross-sectional survey of 151 workers.	9.9 (15 cases).	5.3 (8 cases).	6.4% samples >2 μg/m³; 2.4% samples >5 μg/m³;. 0.3% samples >25 μg/m³.	Yes	Small study population.	Breathing zone sampling.
Cummings *et al.,* 2007.	Longitudinal study of 93 workers.	0.7–5.6 (4 cases).	0.1—7.9 (3 cases).	*Production* .... *1994–1999* median—0.1μg/m³; *2000–2003* median—0.04μg/m³; *Administrative 1994–1999* median <0.2 μg/m³; *2000–2003* median—0.02 μg/m³	Yes	Small sample size	Personal sampling was effective in reducing rates of new cases of sensitization.
Copper-Beryllium Alloy Processing and Distribution							
Schuler *et al.,* 2005	Cross-sectional survey of 153 workers.	7.0 (10 cases).	4.0 (6 cases).	*Rod and Wire Production* median—0.12 μg/m³; *Strip Metal Production* median—0.02 μg/m³; *Production Support* median—0.02 μg/m³; *Administration* median—0.02 μg/m³.	....	Small study population.	Personal sampling.

TABLE A.1—SUMMARY OF BERYLLIUM SENSITIZATION AND CHRONIC BERYLLIUM DISEASE EPIDEMIOLOGICAL STUDIES—Continued

Reference	Study type	(%) Prevalence		Range of exposure measurements	Exposure-response relationship	Study limitations	Additional comments
		Sensitization	CBD				
Thomas *et al.,* 2009	Cross-sectional study of 82 workers.	3.8 (3 cases).	1.9 (1 case).	Used exposure profile from Schuler study.	....	Authors noted workers may have been sensitized prior to available screening, underestimating sensitization rate in legacy workers.	Instituted PPE to reduce dermal exposures.
Stanton *et al.,* 2006	Cross-sectional study of 88 workers.	1.1 (1 case).	1.1 (1 case).	*Bulk Products Production* median 0.04 μg/m³; *Strip Metal Production* median—0.03 μg/m³; *Production support*. median—0.01 μg/m³; *Administration* median 0.01 μg/m³.	....	Study did not report use of PPE or respirators.	Personal sampling.
Bailey *et al.,* 2010 ...	Cross-sectional study of 660 total workers (258 partial program, 290 full program).	11.0	14.5 total	....	....	Study reported prevalence rates for pre enhanced control-program, partial enhanced control program, and full enhanced control program.	
Nuclear Weapons Production Facilities and Cleanup of Former Facilities							
Kreiss *et al.,* 1989 ..	Cross-sectional survey of 51 workers.	11.8 (6 cases).	7.8 (4 cases).	....	No	Small study population	
Kreiss *et al.,* 1993a	Cross-sectional survey of 895 workers.	1.9 (18 cases).	1.7 (15 cases).	....	No	Study population includes some workers with no reported Be exposure.	
Stange *et al.,* 1996	Longitudinal Study of 4,397 BHSP participants.	2.4 (76 cases).	0.7 (29 cases).	*Annual mean concentration*. *1970–1988* 0.016 μg/m³; *1984–1987* 1.04 μg/m³.	No	....	Personal sampling.
Stange *et al.,* 2001	Longitudinal study of 5,173 workers.	4.5 (154 cases).	1.6 (81 cases).	No quantitative information presented in study.	No	....	Personal sampling.
Viet *et al.,* 2000	Case-control	74 workers sensitized.	50 workers CBD.	Mean exposure range: 0.083–0.622 μg/m³. Maximum exposures: 0.54–36.8 μg/m.³	Yes	Likely underestimated exposures.	Fixed airhead sampling away from breathing zone: Matched controls for age, sex, smoking.

N/A = Information not available from study reports.

TABLE A.2—SUMMARY OF MECHANISTIC ANIMAL STUDIES FOR SENSITIZATION AND CBD

Reference	Species	Study length	Dose or exposure concentration	Type of beryllium	Study results	Other information
Intratracheal (intrabroncheal) or Nasal Instillation						
Barna *et al.,* 1981	Guinea pig.	3 month	10 mg-5μm particle size.	beryllium oxide	Granulomas, interstitial infiltrate with fibrosis with thickening of alveolar septae.	
Barna *et al.,* 1984	Guinea pig.	3 month	5 mg	beryllium oxide	Granulomatous lesions in strain 2 but not strain 13 indicating a genetic component.	
Benson *et al.,* 2000	Mouse	....	0, 12.5, 25, 100μg; 0, 2, 8 μg.	beryllium copper alloy; beryllium metal.	Acute pulmonary toxicity associated with beryllium/copper alloy but not beryllium metal.	
Haley *et al.,* 1994	Cynomolgus monkey.	14, 60, 90 days	0, 1, 50, 150 μg. 0, 2.5, 12.5, 37.5 μg.	Beryllium metal, beryllium oxide.	Beryllium oxide particles were less toxic than the beryllium metal.	
Huang *et al.,* 1992	Mouse	....	5 μg 1–5 μg	Beryllium sulfate immunization; beryllium metal challenge.	Granulomas produced in A/J strain but not BALB/c or C57BL/6.	
Votto *et al.,* 1987	Rat	3 month	2.4 mg 8 mg/ml	Beryllium sulfate immunization; beryllium sulfate challenge.	Granulomas, however, no correlation between T-cell subsets in lung and BAL fluid.	
Inhalation—Single Exposure						
Haley *et al.,* 1989a	Beagle dog.	Chronic—one dose	0, 6 μg/kg, 18 μg/kg.	500 °C; 1000 °C beryllium oxide.	Positive BeLPT results—developed granulomas; low-calcined beryllium oxide more toxic than high-calcined.	Granulomas resolved with time, no full-blown CBD.
Haley *et al.,* 1989b	Beagle dog.	Chronic—one dose/2 year recovery	0, 17 μg/kg, 50 μg/kg.	500 °C; 1000 °C beryllium oxide.	Granulomas, sensitization, low-fired more toxic than high fired.	Granulomas resolved over time.
Robinson *et al.,* 1968.	Dog	Chronic	0. 115mg/m^3.	Beryllium oxide, beryllium fluoride, beryllium chloride.	Foreign body reaction in lung.	
Sendelbach *et al.,* 1989.	Rat	2 week	0, 4.05 μg/L.	Beryllium as beryllium sulfate.	Interstial pneumonitis.	
Sendelbach and Witschi, 1987.	Rat	2 week	0, 3.3, 7 μg/L.	Beryllium as beryllium sulfate.	Enzyme changes in BAL fluid.	
Inhalation—Repeat Exposure						
Conradi *et al.,* 1971	Beagle dog.	Chronic—2 year	0. 3300 μg/m^3, 4380 μg/m^3 once/month for 3 months.	1400 °C beryllium oxide.	No changes detected.	May have been due to short exposure time followed by long recovery.

TABLE A.2—SUMMARY OF MECHANISTIC ANIMAL STUDIES FOR SENSITIZATION AND CBD—Continued

Reference	Species	Study length	Dose or exposure concentration	Type of beryllium	Study results	Other information
	Macaca irus Monkey.	Chronic—2 year	0. 3300 μg/m³, 4380 μg/m³ once/month for 3 months.	1400 °C beryllium oxide.	No changes detected.	May have been due to short exposure time followed by long recovery.
Haley *et al.,* 1992	Beagle dog.	Chronic—repeat dose (2.5 year intervals)	17, 50 μg/kg.	500 °C; 1000 °C beryllium oxide.	Granulomatous pneumonitis.	
Harmsen *et al.,* 1985.	Beagle dog. 5 dogs per group.	Chronic	0, 20 μg/kg, 50 μg/kg.	500°C; 1000 °C beryllium oxide.		
Dermal or Intradermal						
Kang *et al.,* 1977	Rabbit		10mg	Beryllium sulfate	Skin sensitization and skin granulomas.	
Tinkle *et al.,* 2003	Mouse	3 month	25 μL 70 μg	Beryllium sulfate Beryllium oxide	Microgranulomas with some resolution over time of study.	
Intramuscular						
Eskenasy, 1979	Rabbit	35 days (injections at 7 day intervals)	10mg.ml	Beryllium sulfate	Sensitization, evidence of CBD.	
Intraperitoneal Injection						
Marx and Burrell, 1973.	Guinea pig.	24 weeks (biweekly injections)	2.6 mg + 10 μg dermal injections.	Beryllium sulfate	Sensitization.	

TABLE A–3—SUMMARY OF BERYLLIUM LUNG CANCER EPIDEMIOLOGICAL STUDIES

Reference	Study type	Exposure range	Study number	Mortality ratio	Confounding factors	Study limitations	Additional comments
Beryllium Case Registry							
Infante *et al.,* 1980	Cohort	N/D	421 cases from the BCR.	SMR 2.12 7 lung cancer deaths.	Not reported	Exposure concentration data or smoking habits not reported.	
Steenland and Ward, 1991.	Cohort	N/D	689 cases from the BCR.	SMR 2.00 (95% CI 1.33–2.89). 28 lung cancer deaths.			Included women: 93% women diagnosed with CBD; 50% men diagnosed with CBD; SMR 157 for those with CBD and SMR 232 for those with ABD.
Beryllium Manufacturing and/or Processing Plants (Extraction, Fabrication, and Processing)							
Ward *et al.,* 1992	Retrospective Mortality Cohort.	N/D	9,225 males	SMR 1.26 (95% CI 1.12–1.42). 280 lung cancer deaths.		Lack of job history and air monitoring data.	Employment period 1940–1969.

TABLE A–3—SUMMARY OF BERYLLIUM LUNG CANCER EPIDEMIOLOGICAL STUDIES—Continued

Reference	Study type	Exposure range	Study number	Mortality ratio	Confounding factors	Study limitations	Additional comments
Levy *et al.,* 2002 ...	Cohort	N/D	9225 males	Statistically non-significant elevation in lung cancer deaths.	Adjusted for smoking.	Lack of job history and air monitoring data.	Majority of workers studied employed for less than one year
Bayliss *et al.,* 1971	Nested cohort	....	8,000 workers	SMR 1.06 .... 36 lung cancer deaths.	....	....	Employed prior to 1947 for almost half lung cancer deaths.
Mancuso, 1970	Cohort	411–43,300 μg/m³ annual exposure (reported from Zielinsky, 1961).	1,222 workers at OH plant; 2,044 workers at PA plant.	SMR 1.42 .... (95% CI 1.1–1.8) 80 lung cancer deaths.	Only partial smoking history.	Partial smoking history; No job analysis by title or exposure category.	Employment period from 1937–1948.
Mancuso, 1980	Cohort	N/D	Same OH and PA plant analysis.	SMR 1.40	No smoking adjustment.	No adjustment by job title or exposure.	Employment period from 1942–1948; Used workers at rayon plant for comparison.
Mancuso and El Attar, 1969.	Cohort	N/D	3,685 white males	SMR 1.49	Adjusted for age and local.	No job exposure data or smoking adjustment.	Employment history from 1937–1944.
Wagner *et al.,* 1980.	Cohort	N/D	3,055 white males PA plant.	SMR 1.25 .... (95% CI 0.9–1.7) 47 lung cancer deaths.	....	Inadequately adjusted for smoking; Used national lung-cancer risk for cancer not PA.	Reanalysis using PA lung-cancer rate revealed 19% underestimation of beryllium lung cancer deaths.
Sanderson *et al.,* 2001.	Nested case-control.	— Average exposure 22.8μg/m³. — Maximum exposure 32.4μg/m³.	3,569 males PA plant.	SMR 1.22 .... (95% CI 1.03–1.43). 142 lung cancer deaths.	Smoking was found not to be a confounding factor.	May not have adjusted properly for birth-year or age at hire.	Found association with 20 year latency.
Levy *et al.,* 2007 ...	Nested case-control.	Used log transformed exposure data.	Reanalysis of Sanderson *et al.,* 2001.	SMR 1.04 .... (95% CI 0.92–1.17).	Different methodology for smoking adjustment.	....	Found no association between beryllium exposure and increased risk of lung cancer.
Schubauer-Berigan *et al.,* 2008.	Nested case-control.	Used exposure data from Sanderson *et al.,* 2001, Chen 2001, and Couch *et al.,* 2010.	Reanalysis of Sanderson *et al.,* 2001.	Used Odds ratio: 1.91 (95% CI 1.06–3.44) unadjusted;. 1.29 (95% CI 0.61–2.71) birth-year adjusted;. 1.24 (95% CI 0.58–2.65) age-hire adjusted.	Adjusted for smoking, birth cohort, age.	....	— Controlled for birth-year and age at hire; — Found similar results to Sanderson *et al.,* 2001; — Found association with 10 year latency — "0" = used minuscule value at start to eliminate the use of 0 in a logarithmic analysis
Schubauer-Berigan *et al.,* 2010a.	Cohort	N/D	9199 workers from 7 processing plants.	SMR 1.17 (95%CI 1.08–1.28). 545 deaths	Adjusted for smoking.	....	Male workers employed at least 2 days between 1940 and 1970.
Schubauer-Berigan *et al.,* 2010b.	Cohort	Used exposure data from Sanderson *et al.,* 2001.	5436 workers OH and PA plants.	Evaluated using hazard ratios and excess absolute risk. 293 deaths	Adjusted for age, birth cohort, asbestos exposure, short-term work status.	....	— Exposure response was found between 0–10μg/m³ mean DWA; — Increased with statistical significance at 4μg/m³; — 1 in 1000 risk at 0.033μg/m³ mean DWA.

TABLE A–3—SUMMARY OF BERYLLIUM LUNG CANCER EPIDEMIOLOGICAL STUDIES—Continued

Reference	Study type	Exposure range	Study number	Mortality ratio	Confounding factors	Study limitations	Additional comments
Re-evaluation of Published Studies							
Hollins *et al.,* 2009	Review	Re-examination of weight-of-evidence from more than 50 publications.					Found lung cancer excess risk was associated with higher levels of exposure not relevant in today's industrial settings.
IARC, 2012	Multiple	Insufficient exposure concentration. Data		Sufficient evidence for carcinogenicity of beryllium.	IARC concluded beryllium lung cancer risk was not associated with smoking.		— Greater lung cancer risk in the BCR cohort — Correlation between highest lung cancer rates and highest amounts of ABD or other non-malignant lung diseases — Increased risk with longer latency — Greater excess lung cancers among those hired prior to 1950.

N/D = information not determined for most studies
DWA—daily weighted average

VI. Preliminary Beryllium Risk Assessment

The Occupational Safety and Health (OSH) Act and court cases arising under it have led OSHA to rely on risk assessment to support the risk determinations required to set a permissible exposure limit (PEL) for a toxic substance in standards under the OSH Act. Section 6(b)(5) of the OSH Act states that ''The Secretary [of Labor], in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life'' (29 U.S.C. 655(b)(5)).

In *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980) (*Benzene*), the United States Supreme Court ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made that there is a significant risk of material impairment of health at the existing PEL and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that ''before [the Secretary] can promulgate *any* permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices'' (*Id.* at 642). The Court also stated ''that the Act does limit the Secretary's power to requiring the elimination of significant risks'' (488 U.S. at 644 n.49), and that ''OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty'' (*Id.* at 656).

OSHA's approach for the risk assessment incorporates both a review of the recent literature on populations of workers exposed to beryllium below the current Permissible Exposure Limit (PEL) of 2 μg/m³ and a statistical exposure-response analysis. OSHA evaluated risk at several alternate PELs under consideration by the Agency: 2 μg/m³, 1 μg/m³, 0.5 μg/m³, 0.2 μg/m³, and 0.1 μg/m³. A number of recently published epidemiological studies evaluate the risk of sensitization and CBD for workers exposed at and below the current PEL and the effectiveness of exposure control programs in reducing risk. OSHA also conducted a statistical analysis of the exposure-response relationship for sensitization and CBD at the current PEL and alternate PELs the Agency is considering. For this analysis, OSHA used data provided by National Jewish Medical and Research Center (NJMRC) on a population of workers employed at a beryllium machining plant in Cullman, AL. The review of the epidemiological studies and OSHA's own analysis show substantial risk of sensitization and CBD among workers exposed at and below the current PEL of 2 μg/m³. They also show substantial reduction in risk where employers have implemented a combination of controls, including stringent control of airborne beryllium levels and additional measures such as respirators, dermal personal protective equipment (PPE), and strict housekeeping to protect workers against dermal and respiratory beryllium exposure. To evaluate lung cancer risk, OSHA relied primarily on a quantitative risk assessment published in 2011 by NIOSH. This risk assessment was based on an update of the Reading cohort analyzed by Sanderson *et al.,* as well as workers from two smaller plants (Schubauer-Berigan *et al.,* 2011) where workers were exposed to lower levels of beryllium and worked for longer periods than at the Reading plant. The authors found that lung cancer risk was strongly and significantly related to mean, cumulative, and maximum measures of workers' exposure; they predicted substantial risk of lung cancer at the current PEL, and substantial reductions in risk at the alternate PELs OSHA considered for the proposed rule (Schubauer-Berigan *et al.,* 2011).

A. Review of Epidemiological Literature on Sensitization and Chronic Beryllium Disease From Occupational Exposure

As discussed in the Health Effects section, studies of beryllium-exposed workers conducted using the beryllium lymphocyte proliferation test (BeLPT) have found high rates of beryllium sensitization and CBD among workers in many industries, including at some facilities where exposures were primarily below OSHA's PEL of 2 μg/m³ (Kreiss *et al.,* 1993; Henneberger *et* al., 2001; Schuler *et al.,* 2005; Schuler *et al.,* 2012). In the mid-1990s, some facilities using beryllium began to aggressively monitor and reduce workplace exposures. Four plants where several rounds of BeLPT screening were conducted before and after implementation of new exposure control methods provide the best currently available evidence on the effectiveness of various exposure control measures in reducing the risk of sensitization and CBD. The experiences of these plants—a copper-beryllium processing facility in Reading, PA, a beryllia ceramics facility in Tucson, AZ; a beryllium processing facility in Elmore, OH; and a machining facility in Cullman, AL—show that efforts to prevent sensitization and CBD by using engineering controls to reduce workers' beryllium exposures to median levels at or around 0.2 μg/m³ and did not emphasize PPE and stringent housekeeping methods, had only limited impact on risk. However, exposure control programs implemented more recently, which drastically reduced respiratory exposure to beryllium via a combination of engineering controls and respiratory protection, controlled dermal contact with beryllium using PPE, and employed stringent housekeeping methods to keep work areas clean and prevent transfer of beryllium between work areas, sharply curtailed new cases of sensitization among newly-hired workers. There is additional, but more limited, information available on the occurrence of sensitization and CBD among aluminum smelter workers with low-level beryllium exposures (Taiwo *et al.,* 2008; Taiwo *et al.,* 2010; Nilsen *et al.,* 2010). A discussion of the experiences at these plants follows.

The Health Effects section also discussed the role of particle characteristics and beryllium compound solubility in the development of sensitization and CBD among beryllium-exposed workers. Respirable particles small enough to reach the deep lung are responsible for CBD. However, larger inhalable particles that deposit in the upper respiratory tract may lead to sensitization. The weight of evidence indicates that both soluble and insoluble forms of beryllium are able to induce sensitization and CBD. Insoluble forms of beryllium that persist in the lung for longer periods may pose greater risk of CBD while soluble forms may more easily trigger immune sensitization. Although these factors potentially influence the toxicity of beryllium, the available data are too limited to reliably account for solubility and particle size in the Agency estimates of risk. The qualitative impact on conclusions and uncertainties with regard to risk are discussed in a later section.

1. Reading, PA, Plant

Schuler *et al.* conducted a study of workers at a copper-beryllium processing facility in Reading, PA, screening 152 workers with the BeLPT (Schuler *et al.,* 2005). Exposures at this plant were believed to be low throughout its history due to the low percentage of beryllium in the metal alloys used, and the relatively low exposures found in general area samples collected starting in 1969 (sample median ≤ 0.1 μg/m³, 97% < 0.5 μg/m³). The reported prevalences of sensitization (6.5 percent) and CBD (3.9 percent) showed substantial risk at this facility, even though airborne exposures were primarily below OSHA's current PEL of 2 μg/m³.

Personal lapel samples were collected in production and production support jobs between 1995 and May 2000. These samples showed primarily very low airborne beryllium levels, with a median of 0.073 μg/m³.[6] The wire annealing and pickling process had the highest personal lapel sample values, with a median of 0.149 μg/m³. Despite these low exposure levels, cases of sensitization continued to occur among workers whose first exposures to beryllium occurred in the 1990s. Five (11.5 percent) workers of 43 hired after 1992 who had no prior beryllium exposure became sensitized, including four in production work and one in production support (Thomas *et al.,* 2009; evaluation for CBD not reported). Two (13 percent) of these sensitized workers were among 15 workers in this group who had been hired less than a year before the screening.

After the BeLPT screening was conducted in 2000, the company began implementing new measures to further reduce workers' exposure to beryllium. Requirements designed to minimize dermal contact with beryllium, including long-sleeve facility uniforms and polymer gloves, were instituted in production areas in 2000. In 2001 the company installed local exhaust ventilation (LEV) in die grinding and polishing. Personal lapel samples collected between June 2000 and December 2001 show reduced exposures plant-wide. Of 2,211 exposure samples collected during this ''pre-enclosure program'' period, 98 percent were below 0.2 μg/m³ (Thomas *et al.,* 2009, p. 124). Median, arithmetic mean, and geometric mean values ≤ 0.03 μg/m³ were reported in this period for all processes except the wire annealing and pickling process. Samples for this process remained elevated, with a median of 0.1 μg/m³ (arithmetic mean of 0.127 μg/m³, geometric mean of 0.083 μg/m³). In January 2002, the plant enclosed the wire annealing and pickling process in a restricted access zone (RAZ), required respiratory PPE in the RAZ, and implemented stringent measures to minimize the potential for skin contact and beryllium transfer out of the zone. While exposure samples collected by the facility were sparse following the enclosure, they suggest exposure levels comparable to the 2000–01 samples in areas other than the RAZ. Within the RAZ, required use of powered air-purifying respirators (PAPRs) indicates that respiratory exposure was negligible. A 2009 publication on the facility reported that outside the RAZ, ''the vast majority of employees do not wear any form of respiratory protection due to very low airborne beryllium concentrations'' (Thomas *et al.,* 2009, p. 122).

To test the efficacy of the new measures in preventing sensitization and CBD, in June 2000 the facility began an intensive BeLPT screening program for all new workers. The company screened workers at the time of hire; at intervals of 3, 6, 12, 24, and 48 months; and at 3-year intervals thereafter. Among 82 workers hired after 1999, three cases of sensitization were found (3.7 percent). Two (5.4 percent) of 37 workers hired prior to enclosure of the wire annealing and pickling process were found to be sensitized within 3 and 6 months of beginning work at the plant. One (2.2 percent) of 45 workers hired after the enclosure was confirmed as sensitized. Among these early results, it appears that the greatest reduction in sensitization risk was achieved after median exposures in all areas of the plant were reduced to below 0.1 μg/m³

[6] In their publication, Schuler *et al.* presented median values for plant-wide and work-category-specific exposure levels; they did not present arithmetic or geometric mean values for personal samples.

and PPE to prevent dermal contact was instituted.

2. Tucson, AZ, Plant

Kreiss *et al.* conducted a study of workers at a beryllia ceramics plant, screening 136 workers with the BeLPT in 1992 (Kreiss *et al.,* 1996). Full-shift area samples collected between 1983 and 1992 showed primarily low airborne beryllium levels at this facility. Of 774 area samples, 76 percent were at or below 0.1 μg/m³ and less than 1 percent exceeded 2 μg/m³. A small set (75) of personal lapel samples collected at the plant beginning in 1991 had a median of 0.2 μg/m³ and ranged from 0.1 to 1.8 μg/m³ (arithmetic and geometric mean values not reported) (Kreiss *et al.,* 1996, p. 19). However, area samples and short-term breathing zone samples also showed occasional instances of very high beryllium exposure levels, with extreme values of several hundred μg/m³ and 3.6 percent of short-term breathing zone samples in excess of 5 μg/m³.

Kreiss *et al.* reported that eight (5.9 percent) of 136 workers tested were sensitized, six (4.4 percent) of whom were diagnosed with CBD. Seven of the eight sensitized employees had worked in machining, where general area samples collected between October 1985 and March 1988 had a median of 0.3 μg/m³, in contrast to a median value of less than 0.1 μg/m³ in other areas of the plant (Kreiss *et al.,* 1996, p. 20; mean values not reported). Short-term breathing zone measurements associated with machining had a median of 0.6 μg/m³, double the median of 0.3 μg/m³ for breathing zone measurements associated with other processes (*id.,* p. 20; mean values not reported). One sensitized worker was one of 13 administrative workers screened, and was among those diagnosed with CBD. Exposures of administrative workers were not well-characterized, but were believed to be among the lowest in the plant. Of three personal lapel samples reported for administrative staff during the 1990s, all were below the then detection limit of 0.2 μg/m³ (Cummings *et al.,* 2007, p.138).

Following the 1992 screening, the facility reduced exposures in machining areas by enclosing machines and installing HEPA filter exhaust systems. Personal samples collected between 1994 and 1999 had a median of 0.2 μg/m³ in production jobs and 0.1 μg/m³ in production support (geometric means 0.21 μg/m³ and 0.11 μg/m³, respectively; arithmetic means not reported. Cummings *et al.,* 2007, p. 138). In 1998, a second screening found that 9 percent of tested workers hired after the 1992 screening were sensitized, of whom one was diagnosed with CBD. All of the sensitized workers had been employed at the plant for less than two years (Henneberger *et al.,* 2001).

Following the 1998 screening, the company continued efforts to reduce exposures and risk of sensitization and CBD by implementing additional engineering and administrative controls and PPE. Respirator use was required in production areas beginning in 1999, and latex gloves were required beginning in 2000. The lapping area was enclosed in 2000, and enclosures were installed for all mechanical presses in 2001. Between 2000 and 2003, water-resistant or water-proof garments, shoe covers, and taped gloves were incorporated to keep beryllium-containing fluids from wet machining processes off the skin. The new engineering measures did not appear to substantially reduce airborne beryllium levels in the plant. Personal lapel samples collected in production processes between 2000 and 2003 had a median and geometric mean of 0.18 μg/m³, similar to the 1994–1999 samples (Cummings *et al.,* 2007, p. 138). However, respiratory protection requirements were instituted in 2000 to control workers' airborne beryllium exposures.

To test the efficacy of the new measures instituted after 1998, in January 2000 the company began screening new workers for sensitization at the time of hire and at 3, 6, 12, 24, and 48 months of employment (Cummings *et al.,* 2007). These more stringent measures appear to have substantially reduced the risk of sensitization among new employees. Of 97 workers hired between 2000 and 2004, one case of sensitization was identified (1 percent). This worker had experienced a rash after an incident of dermal exposure to lapping fluid through a gap between the glove and uniform sleeve, indicating that sensitization may have occurred via skin exposure.

3. Elmore, OH, Plant

Kreiss *et al.,* Schuler *et al.,* and Bailey *et al.* conducted studies of workers at a beryllium metal, alloy, and oxide production plant. Workers participated in BeLPT surveys in 1992 (Kreiss *et al.,* 1997) and in 1997 and 1999 (Schuler *et al.,* 2012). Exposure levels at the plant between 1984 and 1993 were characterized by a mixture of general area, short-term breathing zone, and personal lapel samples. Kreiss *et al.* reported that the median area samples for various work areas ranged from 0.1 to 0.7 μg/m³, with the highest values in the alloy arc furnace and alloy melting-casting areas (other measures of central tendency not reported). Personal lapel samples were available from 1990–1992, and showed high exposures overall (median value of 1.0 μg/m³) with very high exposures for some processes. The authors reported median sample values of 3.8 μg/m³ for beryllium oxide production, 1.75 μg/m³ for alloy melting and casting, and 1.75 μg/m³ for the arc furnace.

Kreiss *et al.* reported that 43 (6.9 percent) of 627 workers tested in 1992 were sensitized, six of whom were diagnosed with CBD (4.4 percent). Workers with less than one year tenure at the plant were not tested in this survey (Bailey *et al.,* 2010, p. 511). The work processes that appeared to carry the highest risk for sensitization and CBD (*e.g.,* ceramics) were not those with the highest reported exposure levels (*e.g.,* arc furnace and melting-casting). The authors noted several possible reasons for this, including factors such as solubility, particle size/number, and particle surface area that could not be accounted for in their analysis (Kreiss *et al.,* 1997).

In 1996–1999, the company took steps to reduce workers' beryllium exposures: some high-exposure processes were enclosed, special restricted-access zones were set up, HEPA filters were installed in air handlers, and some ventilation systems were updated. In 1997 workers in the pebble plant restricted access zone were required to wear half-face air-purifying respirators, and beginning in 1999 all new employees were required to wear loose-fitting powered air-purifying respirators (PAPR) in manufacturing buildings (Bailey *et al.,* 2010, p. 506). Skin protection became part of the protection program for new employees in 2000, and glove use was required in production areas and for handling work boots beginning in 2001. Also beginning in 2001, either half-mask respirators or PAPRs were required in the production facility (type determined by airborne beryllium levels), and respiratory protection was required for roof work and during removal of work boots (Bailey *et al.,* 2010, p. 506). Respirator use was reported to be used on about half or less of industrial hygiene sample records for most processes in 1990–1992 (Kreiss *et al.,* 1996).

Beginning in 2000, workers were offered periodic BeLPT testing to evaluate the effectiveness of a new exposure control program implemented by the company. Bailey *et al.* (2010) reported on the results of this surveillance for 290 workers hired between February 21, 2000 and December 18, 2006. They compared the occurrence of beryllium sensitization and disease among 258 employees who began work at the Elmore plant between January 15, 1993 and August 9, 1999 (the 'pre-program group') and among 290 employees who were hired between February 21, 2000 and December 18, 2006 and were tested at least once after hire (the 'program group'). They found that, as of 1999, 23 (8.9 percent) of the pre-program group were sensitized to beryllium. Six (2.1 percent) of the program group had confirmed abnormal results on their final round of BeLPTs, which occurred in different years for different employees. In addition, another five employees had confirmed abnormal BeLPT results at some point during the testing period, followed by at least one instance of a normal test result. One of these employees had a confirmed abnormal baseline BeLPT at hire, and had two subsequent normal BeLPT results at 6 and 12 months after hire. Four others had confirmed abnormal BeLPT results at 3 or 6 months after hire, later followed by a normal test. Including these four in the count of sensitized workers, there were a total of ten (3.5 percent) workers sensitized after hire in the program group. It is not clear whether the occurrence of a normal result following an abnormal result reflects an error in one of the test results, a change in the presence or level of memory T-cells circulating in the worker's blood, or other possibilities. Because most of the workers in the study had been employed at the facility for less than two years, Bailey *et al.* did not report the incidence of CBD among the sensitized workers (Bailey *et al.,* 2010, p. 511).

In addition, Bailey *et al.* divided the program group into the 'partial program subgroup' (206 employees hired between February 21, 2000 and December 31, 2003) and the 'full program subgroup' (84 employees hired between January 1, 2004 and December 18, 2006) to account for the greater effectiveness of the exposure control program after the first three years of implementation (Bailey *et al.,* pp 506–507). Four (1.9 percent) of the partial program group were found to be sensitized on their final BeLPT (excluding one with a confirmed abnormal BeLPT from their baseline test at hire). Two (2.4 percent) of the full program group were found to be sensitized on their final BeLPT (Bailey *et al.,* 2010, p. 509). An additional three employees in the partial program group and one in the full program group were confirmed sensitized at 3 or 6 months after hire, then later had a single normal BeLPT (Bailey *et al.,* 2010, p. 509).

Schuler *et al.* (2012) published a study examining beryllium sensitization and CBD among short-term workers at the Elmore, OH plant, using exposure estimates created by Virji *et al.* (2012). The study population included 264 workers employed in 1999 with up to six years tenure at the plant (91 percent of the 291 eligible workers). By including only short-term workers, Virji *et al.* were able to construct participants' exposures with more precision than was possible in studies involving workers exposed for longer durations and in time periods with less exposure sampling. Each participant completed a work history questionnaire and was tested for beryllium sensitization. The overall prevalence of sensitization was 9.8 percent (26/264). Sensitized workers were offered further evaluation for CBD. Twenty-two sensitized workers consented to clinical testing for CBD via transbronchial biopsy. Six of those sensitized were diagnosed with CBD (2.3 percent, 6/264).

Exposure estimates were constructed using two exposure surveys conducted in 1999: a survey of total mass exposures (4022 full-shift personal samples) and a survey of size-separated impactor samples (198 samples). The 1999 exposure surveys and work histories were used to estimate long-term lifetime weighted (LTW) average, cumulative, and highest-job-worked exposure for total, respirable, and submicron beryllium mass concentrations. *Schuler et al.* (2012) found no cases of sensitization among workers with total mass LTW average exposures below 0.09 μg/m³, among workers with total mass cumulative exposures below 0.08 μg/m³-yr, or among workers with total mass highest job worked exposures below 0.12 μg/m³. Twenty-four percent, 16 percent, and 25 percent of the study population were exposed below those levels, respectively. Both total and respirable beryllium mass concentration estimates were positively associated with sensitization (average and highest job), and CBD (cumulative) in logistic regression models.

4. Cullman, AL, Plant

Newman *et al.* conducted a series of BeLPT screenings of workers at a precision machining facility between 1995 and 1999 (Newman *et al.,* 2001). A small set of personal lapel samples collected in the early 1980s and in 1995 suggests that exposures in the plant varied widely during this time period. In some processes, such as engineering, lapping, and electrical discharge machining (EDM), exposures were apparently low (≤ 0.1 μg/m³). Madl *et al.* reported that personal lapel samples from all machining processes combined had a median of 0.33 μg/m³, with a much higher arithmetic mean of 1.63 μg/m³ (Madl *et al.,* 2007, Table IV, p. 457). The majority of these samples were collected in the high-exposure processes of grinding (median of 1.05 μg/m³, mean of 8.48 μg/m³), milling (median of 0.3 μg/m³, mean of 0.82 μg/m³), and lathing (median of 0.35 μg/m³, mean of 0.88 μg/m³) (Madl *et al.,* 2007, Table IV, p. 457). As discussed in greater detail in the background document,[7] the data set of machining exposure measurements included a few extremely high values (41–73 μg/m³) that a NIOSH researcher identified as probable errors, and that appear to be included in Madl *et al.*'s arithmetic mean calculations. Because high single-data point exposure errors influence the arithmetic mean far more than the median value of a data range, OSHA believes the median values reported by Madl *et al.* are more reliable than the arithmetic means they reported.

After a sentinel case of CBD was diagnosed at the plant in 1995, the company began BeLPT screenings to identify workers at increased risk of CBD and implemented engineering and administrative controls and PPE designed to reduce workers' beryllium exposures in machining operations. Newman *et al.* reported 22 (9.4 percent) sensitized workers among 235 tested, 13 of whom were diagnosed with CBD within the study period. Between 1995 and 1997, the company built enclosures and installed or updated local exhaust ventilation (LEV) for several machining departments, removed pressurized air hoses, and required the use of company uniforms. Madl *et al.* reported that historically, engineering and work process controls, rather than personal protective equipment, were used to limit workers' exposure to beryllium; respirators were used only in cases of high exposure, such as during sandblasting (Madl *et al.,* 2007, p. 450). In contrast to the Reading and Tucson plants, gloves were not required at this plant.

Personal lapel samples collected extensively between 1996 and 1999 in machining jobs have an overall median of 0.16 μg/m³, showing that the new controls achieved a marked reduction in machinists' exposures during this

[7] When used throughout this section, "background document" refers to a more comprehensive, companion risk-assessment document that can be found at *www.regulations.gov* in OSHA Docket No. ___.

period. Nearly half of the samples were collected in milling (median = 0.18 μg/m³). Exposures in other machining processes were also reduced, including grinding (median of 0.18 μg/m³) and lathing (median of 0.13 μg/m³). However, cases of sensitization and CBD continued to occur.

At the time that Newman *et al.* reviewed the results of BeLPT screenings conducted in 1995–1999, a subset of 60 workers had been employed at the plant for less than a year. Four (6.7 percent) of these workers were found to be sensitized, of whom two were diagnosed with CBD and one with probable CBD (Newman *et al.,* 2001). All four had been hired in 1996. Two (one CBD case, one sensitized only) had worked only in milling, and had worked for approximately 3–4 months (0.3–0.4 yrs) at the time of diagnosis. One of those diagnosed with CBD worked only in EDM, where lapel samples collected between 1996 and 1999 had a median of 0.03 μg/m³. This worker was diagnosed with CBD in the same year that he began work at the plant. The last CBD case worked as a shipper, where exposures in 1996–1999 were similarly low, with a median of 0.09 μg/m³.

Beginning in 2000, exposures in all jobs at the machining facility were reduced to extremely low levels. Personal lapel samples collected in machining processes between 2000 and 2005 had a median of 0.09 μg/m³, where more than a third of samples came from the milling process (n = 765, median of 0.09 μg/m³). A later publication on this plant by Madl *et al.* reported that only one worker hired after 1999 became sensitized. This worker had been employed for 2.7 years in chemical finishing, where exposures were roughly similar to other machining processes (n = 153, median of 0.12 μg/m³). Madl *et al.* did not report whether this worker was evaluated for CBD.

5. Aluminum Smelting Plants

Taiwo *et al.* (2008) studied a population of 734 employees at four aluminum smelters located in Canada (2), Italy (1), and the United States (1). In 2000, a beryllium exposure limit of 0.2 μg/m³ 8-hour TWA (action level 0.1 μg/m³) and a short-term exposure limit (STEL) of 1.0 μg/m³ (15-minute sample) were instituted at these plants. Sampling to determine compliance with the exposure limit began at all smelters in 2000. Table VI–1 below, adapted from Taiwo *et al.* (2008), shows summary information on samples collected from the start of sampling through 2005.

TABLE VI–1—EXPOSURE SAMPLING DATA BY PLANT—2000–2005

Smelter	Number of samples	Median (μg/m³)	Arithmetic mean (μg/m³)	Geometric mean (μg/m³)
Canadian smelter 1	246	0.03	0.09	0.03
Canadian smelter 2	329	0.11	0.29	0.08
Italian smelter	44	0.12	0.14	0.10
U.S. smelter	346	0.03	0.26	0.04

Adapted from Taiwo *et al.,* 2008, Table 1.

All employees potentially exposed to beryllium levels at or above the action level for at least 12 days per year, or exposed at or above the STEL 12 or more times per year, were offered medical surveillance including the BeLPT (Taiwo *et al.,* 2008, p. 158). Table VI–2 below, adapted from Taiwo *et al.* (2008), shows test results for each facility between 2001 and 2005.

TABLE VI–2—BeLPT RESULTS BY PLANT—2001–2005

Smelter	Employees tested	Normal	Abnormal BeLPT (unconfirmed)	Confirmed Sensitized
Canadian smelter 1	109	107	1	1
Canadian smelter 2	291	290	1	0
Italian smelter	64	63	0	1
U.S. smelter	270	268	2	0

Adapted from Taiwo *et al.,* 2008, Table 2.

The two workers with confirmed beryllium sensitization were offered further evaluation for CBD. Both were diagnosed with CBD, based on broncho-alveolar lavage (BAL) results in one case and pulmony function tests, respiratory symptoms, and radiographic evidence in the other.

In 2010, Taiwo *et al.* published a study of beryllium-exposed workers from smelters at four companies, including some of the workers from the 2008 publication. 3,185 workers were determined to be ''significantly exposed'' to beryllium and invited to participate in BeLPT screening. Each company used different criteria to determine ''significant'' exposure, which appeared to vary considerably (p. 570). About 60 percent of invited workers participated in the program between 2000 and 2006, of whom nine were determined to be sensitized (see Table VI–3 below). The authors state that all nine workers were referred to a respiratory physician for further evaluation for CBD. Two were diagnosed with CBD, as described above (Taiwo *et al.,* 2008). The authors do not report the details of other sensitized workers' evaluation for CBD.

TABLE VI–3—MEDICAL SURVEILLANCE FOR BeS IN ALUMINUM SMELTERS

Company	Number of smelters	At-risk employees	Employees tested	BeS
A	4	1278	734	4
B	3	423	328	0
C	1	1100	508	4
D	1	384	362	1
Total	9	3185	1932	9

Adapted from Taiwo *et al.,* 2011, Table 1.

In general, there appeared to be a low level of sensitization and CBD among employees at the aluminum smelters studied by Taiwo *et al.* This is striking in light of the fact that many of the employees tested had worked at the smelters long before the institution of exposure limits for beryllium at some smelters in 2000. However, the authors note that respiratory protection had long been used at these plants to protect workers from other hazards. The results are roughly consistent with the observed prevalence of sensitization following the institution of respiratory protection at the Tucson beryllium ceramics plant discussed previously. A study by Nilsen *et al.* (2010) also found a low rate of sensitization among aluminum workers in Norway. Three-hundred sixty-two workers and thirty-one control individuals received BeLPT testing for beryllium sensitization. The authors found one sensitized worker (0.28 percent). No borderline results were reported. The authors reported that current exposures in this plant ranged from 0.1 μg/m³ to 0.31 μg/m³ (Nilsen et al., 2010) and that respiratory protection was in use, as is the case in the smelters studied by Taiwo *et al.* (2008, 2010).

B. Preliminary Conclusions

The published literature on beryllium sensitization and CBD shows that risk of both can be substantial in workplaces in compliance with OSHA's current PEL (Kreiss *et al.,* 1993; Schuler *et al.,* 2005). The experiences of several facilities in developing effective industrial hygiene programs have shown that minimizing both airborne and dermal exposure, using a combination of engineering and administrative controls, respiratory protection, and dermal PPE, has substantially lowered workers' risk of beryllium sensitization. In contrast, risk-reduction programs that relied primarily on engineering controls to reduce workers' exposures to median levels in the range of 0.1–0.2 μg/m³, such as those implemented in Tucson following the 1992 survey and in Cullman during 1996–1999, had only limited impact on reducing workers' risk of sensitization. The prevalence of sensitization among workers hired after such controls were installed at the Cullman plant remained high (Newman *et al.* (6.7 percent) and Henneberger *et al.* (9 percent)). A similar prevalence of sensitization was found in the screening conducted in 2000 at the Reading plant, where the available sampling data show median exposure levels of less than 0.2 μg/m³ (6.5 percent). The risk of sensitization was found to be particularly high among newly-hired workers (≤1 year of beryllium exposure) in the Reading 2000 screening (13 percent) and the Tucson 1998 screening (16 percent).

Cases of CBD have also continued to develop among workers in facilities and jobs where exposures were below 0.2 μg/m³. One case of CBD was found in the Tucson 1998 screening among nine sensitized workers hired less than two years previously (Henneberger *et al.,* 2001). At the Cullman plant, at least two cases of CBD were found among four sensitized workers screened in 1995–1999 and hired less than a year previously (Newman *et al.,* 2001). These results suggest a substantial risk of progression from sensitization to CBD among workers exposed at levels well below the current PEL, especially considering the extremely short time of exposure and follow-up for these workers. Six of 10 sensitized workers identified at Reading in the 2000 screening were diagnosed with CBD. The four sensitized workers who did not have CBD at their last clinical evaluation had been hired between one and five years previously; therefore, the time may have been too short for CBD to develop.

In contrast, more recent exposure control programs that have used a combination of engineering controls, PPE, and stringent housekeeping measures to reduce workers' airborne and dermal exposures have substantially lowered risk of sensitization among newly-hired workers. Of 97 workers hired between 2000 and 2004 in Tucson, where respiratory and skin protection was instituted for all workers in production areas, only one (1 percent) worker became sensitized, and in that case the worker's dermal protection had failed during wet-machining work (Thomas *et al.,* 2009). In the aluminum smelters discussed by Taiwo *et al.,* where available exposure samples indicated median beryllium levels of about 0.1 μg/m³ or below (measured as an 8-hour TWA) and workers used respiratory and dermal protection, confirmed cases of sensitization were rare (zero or one case per location). Sensitization was also rare among workers at a Norwegian aluminum smelter (Nilsen *et al.,* 2010), where estimated exposures in the plant ranged from 0.1 μg/m³ to 0.3 μg/m³ and respiratory protection was regularly used. In Reading, where in 2000–2001 airborne exposures in all jobs were reduced to a median of 0.1 μg/m³ or below (measured as an 8-hour TWA) and dermal protection was required for production-area workers, two (5.4 percent) of 37 newly hired workers became sensitized (Thomas *et al.,* 2009). After the process with the highest exposures (median of 0.1 μg/m³) was enclosed in 2002 and workers in that process were required to use respiratory protection, the remaining jobs had very low exposures (medians ~ 0.03 μg/m³). Among 45 workers hired after the enclosure, one was found to be sensitized (2.2 percent). In Elmore, where all workers were required to wear respirators and skin PPE in production areas beginning in 2000–2001, the estimated prevalence of sensitization among workers hired after these measures were put in place was around 2–3 percent (Bailey *et al.,* 2010). In addition, *Schuler et al.* (2012) found no cases of sensitization among short-term Elmore workers employed in 1999 who had total mass LTW average exposures below 0.09 μg/m³, among workers with total mass cumulative exposures below 0.08 μg/m³-yr, or among workers with total mass highest job worked exposures below 0.12 μg/m³.

Madl *et al.* reported one case of sensitization among workers at the Cullman plant hired after 2000. The median personal exposures were about

0.1 μg/m³ or below for all jobs during this period. Several changes in the facility's exposure control methods were instituted in the late 1990s that were likely to have reduced dermal as well as respiratory exposure to beryllium. For example, the plant installed change/locker rooms for workers entering the production facility, instituted requirements for work uniforms and dedicated work shoes for production workers, implemented annual beryllium hazard awareness training that encouraged glove use, and purchased high efficiency particulate air (HEPA) filter vacuum cleaners for workplace cleanup and decontamination.

The results of the Reading, Tucson, and Elmore studies show that reducing airborne exposures to below 0.1 μg/m³ and protecting workers from dermal exposure, in combination, have achieved a substantial reduction in sensitization risk among newly-hired workers. Because respirator use, dermal protection, and engineering changes were often implemented concurrently at these plants, it is difficult to attribute the reduced risk to any single control measure. The reduction is particularly evident when comparing newly-hired workers in the most recent Reading screenings (2.2–5.4 percent), and the rate of sensitization found among workers hired within the year before the 2000 screening (13 percent). There is a similarly striking difference between the rate of prevalence found among newly-hired workers in the most recent Tucson study (1 percent) and the rate found among workers hired within the year before the 1998 screening at that plant (16 percent). These results are echoed in the Cullman facility, which combined engineering controls to reduce airborne exposures to below 0.1 μg/m³ with measures such as housekeeping improvements and worker training to reduce dermal exposure.

The studies on recent programs to reduce workers' risk of sensitization and CBD were conducted on populations with very short exposure and follow-up time. Therefore, they could not address the question of how frequently workers who become sensitized in environments with extremely low airborne exposures (median <0.1 μg/m³) develop CBD. Clinical evaluation for CBD was not reported for sensitized workers identified in the most recent Tucson, Reading, and Elmore studies. In Cullman, however, two of the workers with CBD had been employed for less than a year and worked in jobs with very low exposures (median 8-hour personal sample values of 0.03–0.09 μg/m³). The body of scientific literature on occupational beryllium disease also includes case reports of workers with CBD who are known or believed to have experienced minimal beryllium exposure, such as a worker employed only in shipping at a copper-beryllium distribution center (Stanton *et al.,* 2006), and workers employed only in administration at a beryllium ceramics facility (Kreiss *et al.,* 1996).

Arjomandi *et al.* published a study of 50 sensitized workers from a nuclear weapons research and development facility (Arjomandi *et al.,* 2010). Occupational and medical histories including physical examination and chest imaging were available for the great majority (49) of these individuals. Forty underwent testing for CBD via bronchoscopy and transbronchial biopsies. In contrast to the studies of low-exposure populations discussed previously, this group had much longer follow-up time (mean time since first exposure = 32 years) and length of employment at the facility (mean of 18 years). Quantitative exposure estimates for the workers were not presented; however, the authors characterized their probable exposures as ''low'' (13 workers), ''moderate'' (28 workers), or ''high'' (nine workers) based on the jobs they performed at the facility.

Five of the 50 sensitized workers (10 percent) were diagnosed with CBD based on histology or high-resolution computed tomography. An additional three (who had not undergone full clinical evaluation for CBD) were identified as probable CBD cases, bringing the total prevalence of CBD and probable CBD in this group to 16 percent. As discussed in the epidemiology section of the Health Effects chapter, the prevalence of CBD among worker populations regularly exposed at higher levels (*e.g.,* median > 0.1 μg/m³) is typically much greater, approaching 80–100% in several studies. The lower prevalence of CBD in this group of sensitized workers, who were believed to have primarily low exposure levels, suggests that controlling respiratory exposure to beryllium may reduce risk of CBD among sensitized workers as well as reducing risk of CBD via prevention of sensitization. However, it also demonstrates that some workers in low-exposure environments can become sensitized and go on to develop CBD. The next section discusses an additional source of information on low-level beryllium exposure and CBD: studies of community-acquired CBD in residential areas surrounding beryllium production facilities.

C. Review of Community-Acquired CBD Literature

The literature on community-acquired chronic beryllium disease (CA–CBD) documents cases of CBD among individuals exposed to airborne beryllium at concentrations below the proposed PEL. OSHA notes that these case studies do not provide information on how frequently individuals exposed to very low airborne levels develop CBD and that reconstructed exposure estimates for CA–CBD cases are less reliable than exposure estimates for working populations reviewed in the previous sections. In addition, the cumulative exposure that an occupationally exposed person would accrue at any given exposure concentration is far less than would typically accrue from long-term environmental exposure. The literature on CA–CBD thus has important limitations and is not used as a basis for quantitative risk assessment for CBD from low-level beryllium exposure. Nevertheless, these case reports and the broader CA–CBD literature indicate that individuals exposed to airborne beryllium below the proposed PEL can develop CBD.

Cases of CA–CBD were first reported among residents of Lorain, OH, and Reading, PA, who lived in the vicinity of beryllium plants. More recently, BeLPT screening has been used to identify additional cases of CA–CBD in Reading.

1. Lorain, OH

In 1948, the State of Ohio Department of Public Health conducted an X-ray program surveying more than 6,000 people who lived within 1.5 miles of a Lorain beryllium plant (Eisenbud, 1949; Eisenbud, 1982; Eisenbud, 1998). This survey, together with a later review of all reported cases of CBD in the area, found 13 cases of CBD. All of the residents who developed CBD lived within 0.75 miles of the plant, and none had occupational exposure or lived with beryllium-exposed workers. Among the population of 500 people living within 0.25 miles of the plant, seven residents (1.4 percent) were diagnosed with CBD. Five cases were diagnosed among residents living between 0.25 and 0.5 miles from the plant, one case was diagnosed among residents living between 0.5 and 0.75 miles from the plant, and no cases were found among those living farther than 0.75 miles from the plant (total populations not reported) (Eisenbud, 1998).

Beginning in January 1948, air sampling was conducted using a mobile sampling station to measure atmospheric beryllium downwind from the plant. An approximate concentration of 0.2 μg/m³ was measured at 0.25 miles from the plant's exhaust stack, and concentrations decreased with greater distance from the plant, to 0.003 μg/m³ at a distance of 5 miles (Eisenbud, 1982). A 10-week sampling program was conducted using three fixed monitoring stations within 700 feet of the plant and one station 7,000 feet from the plant. Interpolating the measurements collected at these locations, Eisenbud and colleagues estimated an average airborne beryllium concentration of between 0.004 and 0.02 μg/m³ at a distance of 0.75 miles from the plant. Accounting for the possibility that previous exposures may have been higher due to production level fluctuations and greater use of rooftop emissions, they concluded that the lowest airborne beryllium level associated with CA–CBD in this community was somewhere between 0.01 μg/m³ and 0.1 μg/m³ (Eisenbud, 1982).

2. Reading, PA

Thirty-two cases of CA–CBD were reported in a series of papers published in 1959–1969 concerning a beryllium refinery in Reading (Lieben and Metzner, 1959; Metzner and Lieben, 1961; Dattoli *et al.,* 1964; Lieben and Williams, 1969). The plant, which opened in 1935, manufactured beryllium oxide, alloys and metal, and beryllium tools and metal products (Maier *et al.,* 2008; Sanderson *et al.,* 2001b). In a follow-up study, Maier *et al.* presented eight additional cases of CA–CBD who had lived within 1.5 miles of the plant (Maier *et al.,* 2008). Individuals with a history of occupational beryllium exposure and those who had resided with occupationally exposed workers were not classified as having CA–CBD.

The Pennsylvania Department of Health conducted extensive environmental sampling in the area of the plant beginning in 1958. Based on samples collected in 1958, Maier *et al.* stated that most cases identified in their study would typically have been exposed to airborne beryllium at levels between 0.0155 and 0.028 μg/m³ on average, with the potential for some excursions over 0.35 μg/m³ (Maier *et al* 2008, p. 1015). To characterize exposures to cases identified in the earlier publications, Lieben and Williams cited a sampling program conducted by the Department of Health between January and July 1962, using nine sampling stations located between 0.2 and 4.8 miles from the plant. They reported that 72 percent of 24-hour samples collected were below 0.01 μg/m³. Of samples that exceeded 0.01 μg/m³, most were collected at close proximity to the plant (*e.g.,* 0.2 miles from the plant).

In the early series of publications, cases of CA–CBD were reported among people living both close to the plant (Maier *et al.,* 2008; Dutra, 1948) and up to several miles away. Of new cases identified in the 1968 update, all lived between 3 and 7.5 miles from the plant. Lieben and Williams suggested that some cases of CA–CBD found among more distant residents might have resulted from working or visiting a graveyard closer to the plant (Lieben and Williams, 1969). For example, a milkman who developed CA–CBD had a route in the neighborhood of the plant. Another resident with CA–CBD had worked as a cleaning woman in the area of the plant, and a third worked within a half-mile of the plant.

At the time of the final follow-up study (1968), 11 residents diagnosed with CA–CBD were alive and 21 were deceased. Among those who had died, berylliosis was listed as the cause of death for three, including a 10-year-old girl and two women in their sixties. Fibrosis, granuloma or granulomatosis, and chronic or fibrous pneumonitis were listed as the cause of death for eight more of those deceased. Histologic evidence of CBD was reported for nine of 12 deceased individuals who had been evaluated for it. In addition to showing radiologic abnormalities associated with CBD, all living cases were dyspneic.

Following the 1969 publication by Liebman and Williams, no additional CA–CBD cases were reported in the Reading area until 1999, when a new case was diagnosed. The individual was a 72-year-old woman who had had abnormal chest x-rays for the previous six years (Maier *et al.,* 2008). After the diagnosis of this case, Maier *et al.* reviewed medical records and/or performed medical evaluations, including BeLPT results for 16 community residents who were referred by family members or an attorney.

Among those referred, eight cases of definite or probable CBD were identified between 1999 and 2002. All eight were women who lived between 0.1 and 1.05 miles from the plant, beginning between 1943–1953 and ending between 1956–2001. Five of the women were considered definite cases of CA–CBD, based on an abnormal blood or lavage cell BeLPT and granulomatous inflammation on lung biopsy. Three probable cases of CA–CBD were identified. One had an abnormal BeLPT and radiography consistent with CBD, but granulomatous disease was not pathologically proven. Two met Beryllium Case Registry epidemiologic criteria for CBD based on radiography, pathology and a clinical course consistent with CBD, but both died before they could be tested for beryllium sensitization. One of the probable cases, who could not be definitively diagnosed with CBD because she died before she could be tested, was the mother of both a definite case and the probable case who had an abnormal BeLPT but did not show granulomatous disease.

The individuals with CA–CBD identified in this study suffered significant health impacts from the disease, including obstructive, restrictive, and gas exchange pulmonary defects in the majority of cases. All but two had abnormal pulmonary physiology. Those two were evaluated at early stages of disease following their mother's diagnosis. Six of the eight women required treatment with prednisone, a step typically reserved for severe cases due to the adverse side effects of steroid treatment. Despite treatment, three had died of respiratory impairment from CBD as of 2002 (Maier *et al.,* 2008). The authors concluded that ''low levels of exposures with significant disease latency can result in significant morbidity and mortality'' (*id.,* p. 1017).

OSHA notes that compared with the occupational studies discussed in the previous section, there is comparatively sparse information on exposure levels of Lorain and Reading residents. There remains the possibility that some individuals with CA–CBD may have had higher exposures than were known and reported in these studies, or have had unreported exposure to beryllium dust via contact with beryllium-exposed workers. Nevertheless, the studies conducted in Lorain and Reading demonstrate that long-term exposure to the apparent low levels of airborne beryllium, with sufficient disease latency, can lead to serious or fatal CBD. Genetic susceptibility may play a role in cases of CBD among individuals with very low or infrequent exposures to beryllium. The role of genetic susceptibility in the CBD disease process is discussed in detail in section V.D.3.

D. Exposure-Response Literature on Beryllium Sensitization and CBD

To further examine the relationship between exposure level and risk of both sensitization and disease, we next review exposure-response studies in the CBD literature. Many publications have reported that exposure levels correlate with risk, including a small number of exposure-response analyses. Most of these studies examined the association between job-specific beryllium air measurements and prevalence of sensitization and CBD. This section focuses on studies at three facilities that included a more rigorous historical reconstruction of individual worker exposures in their exposure-response analyses.

1. Rocky Flats, CO, Facility

In 2000, Viet *et al.* published a case-control study of participants in the Rocky Flats Beryllium Health Surveillance Program (BHSP), which was established in 1991 to screen workers at the Department of Energy's Rocky Flats, CO, nuclear weapons facility for beryllium sensitization and evaluate sensitized workers for CBD (Viet *et al.,* 2000). The program, which at the time of publication had tested over 5,000 current and former Rocky Flats employees, had identified a total of 127 sensitized individuals as of 1994 when Viet *et al.* initiated their study.

Workers were considered sensitized if two BeLPT results were positive, either from two blood draws or from a single blood draw analyzed by two different laboratories. All sensitized individuals were offered clinical evaluation, and 51 were diagnosed with CBD based on positive lung LPT and evidence of noncaseating granulomas upon lung biopsy. The number of sensitized individuals who declined clinical evaluation was not reported. Two cases, one with CBD and one who was sensitized but not diagnosed with CBD, were excluded from the case-control analysis due to reported or potential prior beryllium exposure at a ceramics plant. Another sensitized individual who had not been diagnosed with CBD was excluded because she could not be matched by the study's criteria to a non-sensitized control within the BHSP database. Viet *et al.* matched a total of 50 CBD cases to 50 controls who were negative on the BeLPT and had the same age (± 3 years), gender, race and smoking status, and were otherwise randomly selected from the database. Using the same matching criteria, 74 sensitized workers who were not diagnosed with CBD were age-, gender-, race-, and smoking status-matched to 74 control individuals who tested negative by the BeLPT from the BHSP database.

Viet *et al.* developed exposure estimates for the cases and controls based on daily beryllium air samples collected in one of 36 buildings where beryllium was used at Rocky Flats, the Building 444 Beryllium Machine Shop. Over half of the approximately 500,000 industrial hygiene samples collected at Rocky Flats were taken from this building. Air monitoring in other buildings was reported to be limited and inconsistent and, thus, not utilized in the exposure assessment. The sampling data used to develop worker exposure estimates were exclusively Building 444 fixed airhead (FAH) area samples collected at permanent fixtures placed around beryllium work areas and machinery.

Exposure estimates for jobs in Building 444 were constructed for the years 1960–1988 from this database. Viet *et al.* worked with Rocky Flats industrial hygienists and staff to assign a ''building area factor'' (BAF) to each of the other buildings, indicating the likely level of exposure in a building relative to exposures in Building 444. Industrial hygienists and staff similarly assigned a job factor (JF) to all jobs, representing the likely level of beryllium exposure relative to the levels experienced by beryllium machinists. A JF of 1 indicated the lowest exposures, and a JF of 10 indicated the highest exposures. For example, administrative work and vehicle operation were assigned a JF of 1, while machining, mill operation, and metallurgical operation were each assigned a JF of 10. Estimated FAH values for each combination of job, building and year in the study subjects' work histories were generated by multiplying together the job and building factors and the mean annual FAH exposure level. Using data collected by questionnaire from each BHSP participant, Viet *et al.* reconstructed work histories for each case and control, including job title and building location in each year of their employment at Rocky Flats. These work histories and the estimated FAH values were used to generate a cumulative exposure estimate (CEE) for each case and control in the study. A long-term mean exposure estimate (MEE) was generated by dividing each CEE by the individual's number of years employed at Rocky Flats.

Viet *et al.*'s statistical analysis of the resulting data set included conditional logistic regression analysis, modeling the relationship between risk of each health outcome and log-transformed CEE and MEE. They found highly statistically significant relationships between log-CEE and risk of CBD (coef = 0.837, p = 0.0006) and between log-MEE (coef = 0.855, p = 0.0012) and risk of CBD, indicating that risk of CBD increases with exposure level. These coefficients correspond to odds ratios of 6.9 and 7.2 per 10-fold increase in exposure, respectively. Risk of sensitization without CBD did not show a statistically significant relationship with log-CEE (coef = 0.111, p = 0.32), but showed a nearly-significant relationship with log-MEE (coef = 0.230, p = 0.097).

2. Cullman, AL, Facility

The Cullman, AL, precision machining facility discussed previously was the subject of a case-control study published by Kelleher *et al.* in 2001. After the diagnosis of an index case of CBD at the plant in 1995, NJMRC researchers worked with the plant to conduct a medical surveillance program using the BeLPT to screen workers biennially for beryllium sensitization and CBD. Of 235 employees screened between 1995 and 1999, 22 (9.4 percent) were found to be sensitized, including 13 diagnosed with CBD (Newman *et al.,* 2001). Concurrently, research was underway by Martyny *et al.* to characterize the particle size distribution of beryllium exposures generated by processes at this plant (Martyny *et al.,* 2000). The exposure research showed that the machining operations during this time period generated respirable particles (10 μm or less) at the worker breathing zone that made up greater than 50 percent of the beryllium mass. Kelleher *et al.* used the dataset of 100 personal lapel samples collected by Martyny *et al.* and other NJMRC researchers in 1996, 1997, and 1999 to characterize exposures for each job in the plant. Following a statistical analysis comparing the samples collected by NJMRC with earlier samples collected at the plant, Kelleher *et al.* concluded that the 1996–1999 data could be used to represent job-specific exposures from earlier periods.

Detailed work history information gathered from plant data and worker interviews was used in combination with job exposure estimates to characterize cumulative and LTW average beryllium exposures for workers in the surveillance program. In addition to cumulative and LTW exposure estimates based the total mass of beryllium reported in their exposure samples, Kelleher *et al.* calculated cumulative and LTW estimates based specifically on exposure to particles < 6 μm and particles < 1 μm in diameter.

To analyze the relationship between exposure level and risk of sensitization and CBD, Kelleher *et al.* performed a case-control analysis using measures of both total beryllium exposure and particle size-fractionated exposure. The analysis included sensitization cases identified in the 1995–1999 surveillance and 206 controls from the group of 215 non-sensitized workers. For nine workers, the researchers could not reconstruct complete job histories. Logistic regression models using categorical exposure variables showed positive associations between risk of sensitization and the six exposure measures tested: Total CEE, total MEE, and variations of CEE and MEE constructed based on particles < 6 μm and < 1 μm in diameter. None of the associations were statistically significant ($p < 0.05$); however, the authors noted that the dataset was relatively small, with limited power to detect a statistically significant exposure-response relationship.

Although the Viet *et al.* and Kelleher *et al.* exposure-response analyses provide valuable insight into exposure-response for beryllium sensitization and CBD, both studies have limitations that affect their suitability as a basis for quantitative risk assessment. Their limitations primarily involve the exposure data used to estimate workers' exposures. Viet *et al.*'s exposure reconstruction was based on area samples from a single building within a large, multi-building facility. Where possible, OSHA prefers to base risk estimates on exposure data collected in the breathing zone of workers rather than area samples, because data collected in the breathing zone more accurately represent workers' exposures. Kelleher's analysis, on the other hand, was based on personal lapel samples. However, the samples Kelleher *et al.* used were collected between 1996 and 1999, after the facility had initiated new exposure control measures in response to the diagnosis of a case of CBD in 1995. OSHA believes that industrial hygiene samples collected at the Cullman plant prior to 1996 better characterize exposures prior to the new exposure controls. In addition, since the publication of the Kelleher study, the population has continued to be screened for sensitization and CBD. Data collected on workers hired in 2000 and later, after most exposure controls had been completed, can be used to characterize risk at lower levels of exposure than have been examined in many previous studies.

To better characterize the relationship between exposure level and risk of sensitization and CBD, OSHA developed an independent exposure-response analysis based on a dataset maintained by NJMRC on workers at the Cullman, AL, machining plant. The dataset includes exposure samples collected between 1980 and 2005, and has updated work history and screening information for several hundred workers through 2003. OSHA's analysis of the NJMRC data set is presented in the next section, E. OSHA's Exposure-Response Analysis.

3. Elmore, OH, Facility

After OSHA completed its analysis of the NJMRC data set, Schuler *et al. (2012)* published a study examining beryllium sensitization and CBD among 264 short-term workers employed at the previously described Elmore, OH plant in 1999. The analysis used a high-quality exposure reconstruction by Virji *et al.* (2012) and presented a regression analysis of the relationship between beryllium exposure levels and beryllium sensitization and CBD in the short-term worker population. By including only short-term workers, *Virji et al.* were able to construct participants' exposures with more precision than was possible in studies involving workers exposed for longer durations and in time periods with less exposure sampling. In addition, the focus on short-term workers allowed more precise knowledge of when sensitization and CBD occurred than had been the case for previously published cross-sectional studies of long-term workers. Each participant completed a work history questionnaire and was tested for beryllium sensitization, and sensitized workers were offered further evaluation for CBD. The overall prevalence of sensitization was 9.8 percent (26/264). Twenty-two sensitized workers consented to clinical testing for CBD via transbronchial biopsy. Six of those sensitized were diagnosed with CBD (2.3 percent, 6/264).

Schuler *et al.* (2012) used logistic regression to explore the relationship between estimated beryllium exposure and sensitization and CBD, using estimates of total, respirable, and submicron mass concentrations. Exposure estimates were constructed using two exposure surveys conducted in 1999: a survey of total mass exposures (4,022 full-shift personal samples) and a survey of size-separated impactor samples (198 samples). The 1999 exposure surveys and work histories were used to estimate long-term lifetime weighted (LTW) average, cumulative, and highest-job-worked exposure for total, respirable, and submicron beryllium mass concentrations.

For beryllium sensitization, logistic models showed elevated odds ratios for average (OR 1.48) and highest job (OR 1.37) exposure for total mass exposure; the OR for cumulative exposure was smaller (OR 1.23) and borderline statistically significant (95 percent CI barely included unity). Relationships between sensitization and respirable exposure estimates were similarly elevated for average (OR 1.37) and highest job (OR 1.32). Among the submicron exposure estimates, only highest job (OR 1.24) had a 95 percent CI that just included unity for sensitization. For CBD, elevated odds ratios were observed only for the cumulative exposure estimates and were similar for total mass and respirable exposure (total mass OR 1.66, respirable (OR 1.68). Cumulative submicron exposure showed an elevated, borderline significant odds ratio (OR 1.58). The odds ratios for average exposure and highest-exposed job were not statistically significantly elevated. Schuler *et al.* concluded that both total and respirable mass concentrations of beryllium exposure were relevant predictors of risk for beryllium sensitization and CBD.

E. OSHA's Exposure-Response Analysis

OSHA evaluated exposure and health outcome data on a population of workers employed at the Cullman machining facility. NJMRC researchers, with consent and information provided by the facility, compiled a dataset containing employee work histories, medical diagnoses, and air sampling results and provided it to OSHA for analysis. OSHA's contractors from Eastern Research Group (ERG) gathered additional information from (1) two surveys of the Cullman plant conducted by OSHA's contractor (ERG, 2003 and ERG, 2004a), (2) published articles of investigations conducted at the plant by researchers from NJMRC (Kelleher *et al.,* 2001; Madl *et al.,* 2007; Martyny *et al.,* 2000; and Newman *et al.,* 2001), (3) a case file from a 1980 OSHA complaint inspection at the plant, (4) comments submitted to the OSHA docket office in 1976 and 1977 by representatives of the metal machining plant regarding their beryllium control program, and (5) personal communications with the plant's current industrial hygienist (ERG, 2009b) and an industrial hygiene researcher at NJMRC (ERG, 2009a).

1. Plant Operations

The Cullman plant is a leading fabricator of precision-machined and processed materials including beryllium and its alloys, titanium, aluminum, quartz, and glass (ERG, 2009b). The plant has approximately 210 machines, primarily mills and lathes, and processes large quantities of beryllium on an annual basis. The plant provides complete fabrication services including ultra-precision machining; ancillary processing (brazing, ion milling, photo etching, precision cleaning, heat treating, stress relief, thermal cycling, mechanical assembly, and chemical milling/etching); and coatings (plasma spray, anodizing, chromate conversion coating, nickel sulfamate plate, nickel plate, gold plate, black nickel plate, copper plate/strike, passivation, and painting). Most of the plant's beryllium operations involve machining beryllium metal and high beryllium content composite materials (beryllium metal/beryllium oxide metal composites called E-Metal or E-Material), with occasional machining of beryllium oxide/metal matrix (such as AlBeMet, aluminum beryllium matrix) and beryllium-containing alloys. E-Materials such as E–20 and E–60 are currently processed in the E-Cell department.

The 120,000 square-foot plant has two main work areas: a front office area and a large, open production shop. Operations in the production shop include inspection of materials, machining, polishing, and quality assurance. The front office is physically separated from the production shop. Office workers enter through the front of the facility and have access to the production shop through a change room where they must don laboratory coats and shoe covers to enter the production area. Production workers enter the shop area at the rear of the facility where a change/locker room is available to change into company uniforms and work shoes. Support operations are located in separate areas adjacent to the production shop and include management and administration, sales, engineering, shipping and receiving, and maintenance. Management and administrative personnel include two groups: those primarily working in the front offices (front office management) and those primarily working on the shop floor (shop management).

In 1974, the company moved its precision machining operations to the plant's current location in Cullman. Workplace exposure controls reportedly did not change much until the diagnosis of an index case of CBD in 1995. Prior to 1995, exposure controls for machining operations primarily included a low volume/high velocity (LVHV) central exhaust system with operator-adjusted exhaust pickups and wet machining methods. Protective clothing, gloves, and respiratory protection were not required. After the diagnosis, the facility established an in-house target exposure level of 0.2 μg/m^3, installed change/locker rooms for workers entering the production facility, eliminated pressurized air hoses, discouraged the use of dry sweeping, initiated biennial medical surveillance using the BeLPT, and implemented annual beryllium hazard awareness training.

In 1996, the company instituted requirements for work uniforms and dedicated work shoes for production workers, eliminated dry sweeping in all departments, and purchased high-efficiency particulate air (HEPA) filter vacuum cleaners for workplace cleanup and decontamination. Major engineering changes were also initiated in 1996, including the purchase of a new local exhaust ventilation (LEV) system to exhaust machining operations producing finer aerosols (*e.g.,* dust and fume versus metal chips). The facility also began installing mist eliminators for each machine. Departments affected by these changes included cutter grind (tool and die), E-cell, electrical discharge machining (EDM), flow lines, grind, lapping, and optics. Dry machining operations producing chips were exhausted using the existing LVHV exhaust system (ERG, 2004a). In the course of making the ventilation system changes, old ductwork and baghouses were dismantled and new ductwork and air cleaning devices were installed. The company also installed Plexiglas enclosures on machining operations in 1996–1997, including the lapping, deburring, grinding, EDM, and tool and die operations. In 1998, LEV was installed in EDM and modified in the lap, deburr, and grind departments.

Most exposure controls were reportedly in place by 2000 (ERG, 2009a). In 2004, the plant industrial hygienist reported that all machines had LEV and about 65 percent were also enclosed with either partial or full enclosures to control the escape of machining coolant (ERG, 2004b). Over time, the facility has built enclosures for operations that consistently produce exposures greater than 0.2 μg/m^3. The company has never required workers to use gloves or other PPE.

2. Air Sampling Database and Job Exposure Matrix (JEM)

The NJMRC dataset includes industrial hygiene sampling results collected by the plant (1980–1984 and 1995–2005) and NJMRC researchers (June 1996 to February 1997 and September 1999), including 4,370 breathing zone (personal lapel) samples and 712 area samples (ERG, 2004b). Limited air sampling data is available before 1980 and no exposure data appears to be available for the 10-year time period 1985 through 1994. A review of the NJMRC air sampling database from 1995 through 2005 shows a significant increase in the number of air samples collected beginning in 2000, which the plant industrial hygienist attributes to an increase in the number of air sampling pumps (from 5 to 23) and the purchase of an automated atomic absorption spectrophotometer.

ERG used the personal breathing zone sampling results contained in the sample database to quantify exposure levels for each year and for several-year periods. Separate exposure statistics were calculated for each job included in the job history database. For each job included in the job history database, ERG estimated the arithmetic mean, geometric mean, median, minimum, maximum, and 95th percentile value for the available exposure samples. Prior to generating these statistics ERG made several adjustments. After consultation with researchers at NJMRC, four particularly high exposures were identified as probably erroneous and excluded from calculations. In addition, a 1996 sample for the HS (Health and Safety) process was removed from the sample calculations after ERG determined it was for a non-employee researcher visiting the facility.

Most samples in the sample database for which sampling times were recorded were long-term samples: 2,503 of the 2,557 (97.9 percent) breathing zone samples with sampling time recorded had times greater than or equal to 400 minutes. No adjustments were made for sampling time, except in the case of four samples for the ''maintenance'' process for 1995. These results show relatively high values and exceptionally short sampling times consistent with the nature of much maintenance work, marked by short-term exposures and periods of no exposure. The four 1995 maintenance samples were adjusted for an eight-hour sampling time assuming that the maintenance workers received no further beryllium exposure over the rest of their work shift.

OSHA examined the database for trends in exposure by reviewing sample statistics for individual years and grouping years into four time periods that correspond to stages in the plant's approach to beryllium exposure control. These were: 1980–1995, a period of relatively minimal control prior to the 1995 discovery of a case of CBD among the plant's workers; 1996–1997, a period during which some major engineering controls were in the process of being installed on machining equipment; 1998–1999, a period during which most engineering controls on the machining equipment had been installed; and 2000–2003, a period when installation of all exposure controls on machining equipment was complete and exposures very low throughout the plant. Table VI–4 below summarized the available data for each time period. As the four probable sampling errors identified in the original data set are excluded here, arithmetic mean values are presented.

TABLE VI–4—EXPOSURE VALUES FOR MACHINING JOB TITLES, EXCLUDING PROBABLE SAMPLING ERRORS (µg/m³) IN NJMRC DATA SET

Job title	1980–1995		1996–1997		1998–1999		2000–2003	
	Samples	Mean	Samples	Mean	Samples	Mean	Samples	Mean
Deburring	27	1.17	19	1.29	0	NA	67	0.1
Electrical Discharge Machining	2	0.06	2	1.32	16	0.08	63	0.1
Grinding	12	3.07	6	0.49	15	0.24	68	0.1
Lapping	9	0.15	16	0.24	42	0.21	103	0.1
Lathe	18	0.88	8	1.13	40	0.17	200	0.1
Milling	43	0.64	15	0.23	95	0.17	434	0.1

Reviewing the revised statistics for individual years for different groupings, OSHA noted that exposures in the 1996–1997 period were for some machining jobs equivalent to, or even higher than, exposure levels recording during the 1980–1995 period. During 1996–1997, major engineering controls were being installed, but exposure levels were not yet consistently reduced.

Table VI–5 below summarizes exposures for the four time periods in jobs other than beryllium machining. These include jobs such as administrative work, health and safety, inspection, toolmaking ('Tool' and 'Cgrind'), and others. A description of jobs by title is available in the risk assessment background document.

TABLE VI–5—EXPOSURE VALUES FOR NON-MACHINING JOB TITLES (µg/m³) IN NJMRC DATA SET

Job title	1980–1995		1996–1997		1998–1999		2000–2003	
	Samples	mean	Samples	mean	Samples	mean	Samples	mean
Administration	0	NA	0	NA	39	0.052	74	0.061
Assembly	0	NA	0	NA	8	0.136	2	0.051
Cathode	0	NA	0	NA	0	NA	9	0.156
Cgrind	1	0.120	0	NA	14	0.105	76	0.112
Chem	0	NA	1	0.529	21	0.277	91	0.152
Ecell	0	NA	13	1.873	0	NA	26	0.239
Engineering	1	0.065	0	NA	49	0.069	125	0.062
Flow Lines	0	NA	0	NA	0	NA	113	0.083
Gas	0	NA	0	NA	0	NA	121	0.058
Glass	0	NA	0	NA	0	NA	38	0.068
Health and Safety[8]	0	NA	0	NA	0	NA	5	0.076
Inspection	0	NA	0	NA	32	0.101	150	0.066
Maintenance	4	1.257	1	0.160	16	0.200	70	0.126
Msupp	0	NA	0	NA	47	0.094	68	0.081
Optics	0	NA	0	NA	0	NA	41	0.090
PCIC	1	0.040	0	NA	13	0.071	42	0.083
Qroom	1	0.280	0	NA	0	NA	2	0.130
Shop	0	NA	0	NA	4	0.060	0	NA
Spec	3	0.247	0	NA	24	0.083	19	0.087
Tool	0	NA	0	NA	0	NA	1	0.070

FromTable VI–5, it is evident that exposure samples are not available for many non-machining jobs prior to 2000. Where samples are available before 2000, sample numbers are small, particularly prior to 1998. In jobs for which exposure values are available in 1998–1999 and 2000–2003, exposures appear either to decline from 1998–1999 to 2000–2003 (Assembly, Chem, Inspection, Maintenance) or to be roughly equivalent (Administration, Cgrind, Engineering, Msupp, PCIC, and Spec). Among the jobs with exposure samples prior to 1998, most had very few (1–5) samples, with the exception of Ecell (13 samples in 1996–1997). Based on this limited information, it appears that exposures declined from the period before the first dentification of a CBD case to the period in which exposure controls were introduced.

Because exposure results from 1996–1997 were not found to be consistently reduced in comparison to the 1985–1995 period in primary machining jobs, these two periods were grouped together in the JEM. Exposure monitoring for jobs other than the primary machining operations were represented by a single mean exposure value for 1980–2003. As respiratory protection was not routinely used at the plant, there was no adjustment for respiratory protection in workers' exposure estimates. The job exposure matrix is presented in full in the background document for the quantitative risk assessment.

3. Worker Exposure Reconstruction

The work history database contains job history records for 348 workers, including start years, duration of employment, and percentage of worktime spent in each job. One hundred ninety-eight of the workers had been employed at some point in primary machining jobs, including deburring,

[8] An exceptionally high result (0.845 µg/m³, not shown in Table 5) for a 1996 sample for the HS (Health and Safety) process was removed from the sample calculations. OSHA's contractor determined this sample to be associated with a non-employee researcher visiting the facility.

EDM, grinding, lapping, lathing, and milling. The remainder worked only in non-primary machining jobs, such as administration, engineering, quality control, and shop management. The total number of years worked at each job are presented as integers, leaving some uncertainty regarding the worker's exact start and end date at the job.

Based on these records and the JEM described previously, ERG calculated cumulative and average exposure estimates for each worker in the database. Cumulative exposure was calculated as, $\Sigma_i\, {}^{e}{}_{i}\, {}^{t}{}_{i}$, where e(i) is the exposure level for job (i), and t(i) is the time spent in job (i). Cumulative exposure was divided by total exposure time to estimate each worker's long-term average exposure. These exposures were computed in a time-dependent manner for the statistical modeling. For workers with beryllium sensitization or CBD, exposure estimates excluded exposures following diagnosis.

Workers who were employed for long time periods in jobs with low-level exposures tend to have low average and cumulative exposures due to the way these measures are constructed, incorporating the worker's entire work history. As discussed in the Health Effects chapter, higher-level exposures or short-term peak exposures such as those encountered in machining jobs may be highly relevant to risk of sensitization. Unfortunately, because it is not possible to continuously monitor individuals' beryllium exposure levels and sensitization status, it is not known exactly when workers became sensitized or what their ''true'' peak exposures leading up to sensitization were. Only a rough approximation of the upper levels of exposure a worker experienced is possible. ERG constructed a third type of exposure estimate reflecting the exposure level associated with the highest-exposure job (HEJ) and time period experienced by each worker. This exposure estimate (HEJ), the cumulative exposure estimate, and the average exposure were used in the quartile analysis and statistical analyses.

4. Prevalence of Sensitization and CBD

In the database provided to OSHA, seven workers were reported as sensitized only. Sixteen workers were listed as sensitized and diagnosed with CBD upon initial clinical evaluation. Three workers, first shown to be sensitized only, were later diagnosed with CBD. Tables VI–6, VI–7, and VI–8 below present the prevalence of sensitization and CBD cases across several categories of lifetime-weighted (LTW) average, cumulative, and highest-exposed job (HEJ) exposure. Exposure values were grouped by quartile. Note that all workers with CBD are also sensitized. Thus, the columns ''Total Sensitized'' and ''Total %'' refer to all sensitized workers in the dataset, including workers with and without a diagnosis of CBD.

TABLE VI–6—PREVALENCE OF SENSITIZATION AND CBD BY LTW AVERAGE EXPOSURE QUARTILE IN NJMRC DATA SET

Average exposure (μg/m³)	Group size	Sensitized only	CBD	Total sensitized	Total %	CBD %
0.0–0.080	91	1	1	2	2.2	1.0
0.081–0.18	73	2	4	6	8.2	5.5
0.19–0.51	77	0	6	6	7.8	7.8
0.51–2.15	78	4	8	12	15.4	10.3
Total	319	7	19	26	8.2	6.0

TABLE VI–7—PREVALENCE OF SENSITIZATION AND CBD BY CUMULATIVE EXPOSURE QUARTILE IN NJMRC DATA SET

Cumulative exposure (μg/m³-yrs)	Group size	Sensitized only	CBD	Total sensitized	Total %	CBD %
0.0–0.147	81	2	2	4	4.9	2.5
0.148–1.467	79	0	2	2	2.5	2.5
1.468–7.008	79	3	8	11	13.9	8.0
7.009–61.86	80	2	7	9	11.3	8.8
Total	319	7	19	26	8.2	6.0

TABLE VI–8—PREVALENCE OF SENSITIZATION AND CBD BY HIGHEST-EXPOSED JOB EXPOSURE QUARTILE IN NJMRC DATA SET

HEJ exposure (μg/m³)	Group size	Sensitized only	CBD	Total sensitized	Total %	CBD %
0.0–0.086	86	1	0	1	1.2	0.0
0.091–0.214	81	1	6	7	8.6	7.4
0.387–0.691	76	2	9	11	14.5	11.8
0.954–2.213	76	3	4	7	9.2	5.3
Total	319	7	19	26	8.2	6.0

Table VI–6 shows increasing prevalence of total sensitization and CBD with increasing LTW average exposure, measured both as average and cumulative exposure. The lowest prevalence of sensitization and CBD was observed among workers with average exposure levels less than or equal to 0.08 μg/m³, where two sensitized workers (2.2 percent) including one case of CBD (1.0 percent) were found. The sensitized worker in this category without CBD had worked at the facility as an inspector since 1972, one of the lowest-exposed jobs at the plant.

Because the job was believed to have very low exposures, it was not sampled prior to 1998. Thus, estimates of exposures in this job are based on data from 1998–2003 only. It is possible that exposures earlier in this worker's employment history were somewhat higher than reflected in his estimated average exposure. The worker diagnosed with CBD in this group had been hired in 1996 in production control, and had an estimated average exposure of 0.08 μg/m³. He was diagnosed with CBD in 1997.

The second quartile of LTW average exposure (0.081—0.18 μg/m³) shows a marked rise in overall prevalence of beryllium-related health effects, with six workers sensitized (8.2 percent), of whom four (5.5 percent) were diagnosed with CBD. Among six sensitized workers in the third quartile (0.19—0.50 μg/m³), all were diagnosed with CBD (7.8 percent). Another increase in prevalence is seen from the third to the fourth quartile, with 12 cases of sensitization (15.4 percent), including eight (10.3 percent) diagnosed with CBD.

The quartile analysis of cumulative exposure also shows generally increasing prevalence of sensitization and CBD with increasing exposure. As shown in Table VI–7, the lowest prevalences of CBD and sensitization are in the first two quartiles of cumulative exposure (0.0–0.147 μg/m³-yrs, 0.148–1.467 μg/m³-yrs). The upper bound on this cumulative exposure range, 1.467 μg/m³-yrs, is the cumulative exposure that a worker would have if exposed to beryllium at a level of 0.03 μg/m³ for a working lifetime of 45 years; 0.15 μg/m³ for ten years; or 0.3 μg/m³ for five years.

A sharp increase in prevalence of sensitization and CBD and total sensitization occurs in the third quartile (1.468–7.008 μg/m³-yrs), with roughly similar levels of both in the highest group (7.009–61.86 μg/m³-yrs). Cumulative exposures in the third quartile would be experienced by a worker exposed for 45 years to levels between 0.03 and 0.16 μg/m³, for 10 years to levels between 0.15 and 0.7 μg/m³, or for five years to levels between 0.3 and 1.4 μg/m³.

When workers' exposures from their highest-exposed job are considered, the exposure-response pattern is similar to that for LTW average exposure in the lower quartiles (Table VI–8). The lowest prevalence is observed in the first quartile (0.0–0.86 μg/m³), with sharply rising prevalence from first to second and second to third exposure quartiles. The prevalence of sensitization and CBD in the top quartile (0.954–2.213 μg/m³) decreases relative to the third, with levels similar to the overall prevalence in the dataset. Many workers in the highest exposure quartiles are long-time employees, who were hired during the early years of the shop when exposures were highest. One possible explanation for the drop in prevalence in the highest exposure quartiles is that highly-exposed workers from early periods may have developed CBD and left the plant before sensitization testing began in 1995.

It is of some value to compare the prevalence analysis of the Cullman (NJMRC) data set with the results of the Reading and Tucson studies discussed previously. An exact comparison is not possible, in part because the Reading and Tucson exposure values are associated with jobs and the NJMRC values are estimates of lifetime weighted average, cumulative, and highest-exposed job (HEJ) exposures for individuals in the data set. Nevertheless, OSHA believes it is possible to very roughly compare the results of the Reading and Tucson studies and the results of the NJMRC prevalence analysis presented above. As discussed in detail below, OSHA found a general consistency between the prevalence of sensitization and CBD in the quartiles of average exposure in the NJMRC data set and the prevalence of sensitization and CBD at the Reading and Tucson plants for similar exposure values.

Personal lapel samples collected at the Reading plant between 1995 and 2000 were relatively low overall (median of 0.073 μg/m³), with higher exposures (median of 0.149 μg/m³) concentrated in the wire annealing and pickling process (Schuler *et al.,* 2005). Exposures in the Reading plant in this time period were similar to the second-quartile average (Table VI–6–0.081–0.18 μg/m³). The prevalence of sensitization observed in the NJMRC second quartile was 8.2 percent and appears roughly consistent with the prevalence of sensitization among Reading workers in the mid-1990s (11.5 percent). The reported prevalence of CBD (3.9 percent) among the Reading workforce was also consistent with that observed in the second NJMRC quartile (5.5 percent), After 2000, exposure controls reduced exposures in most Reading jobs to median levels below 0.03 μg/m³, with a median value of 0.1 μg/m³ for the wire annealing and pickling process. The wire annealing and pickling process was enclosed and stringent respirator and skin protection requirements were applied for workers in that area after 2002, essentially eliminating airborne and dermal exposures for those workers. Thomas *et al.* (2009) reported that one of 45 workers (2.2 percent) hired after the enclosure in 2002 was confirmed as sensitized, a value in line with the sensitization prevalence observed in the lowest quartiles of average exposure (2.2 percent, 0.0–0.08 μg/m³).

As with Reading, the prevalence of sensitization observed at Tucson and in the NJMRC data set are not exactly comparable due to the different natures of the exposure estimates. Nevertheless, in a rough sense the results of the Tucson study and the NJMRC prevalence analysis appear similar. In Tucson, a 1998 BeLPT screening showed that 9.5 percent of workers hired after 1992 were sensitized (Henneberger *et al.,* 2001). Personal full-shift exposure samples collected in production jobs between 1994 and 1999 had a median of 0.2 μg/m³ (0.1 μg/m³ for non-production jobs). In the NJMRC data set, a sensitization prevalence of 8.2 percent was seen among workers with average exposures between 0.081 and 0.18 μg/m³. At the time of the 1998 screening, workers hired after 1992 had a median one year since first beryllium exposure and, therefore, CBD prevalence was only 1.4 percent. This prevalence is likely an underestimate since CBD often requires more than a year to develop. Longer-term workers at the Tucson plant with a median 14 years since first beryllium exposure had a 9.1 percent prevalence of CBD. There was a 5.5 percent prevalence of CBD among the entire workforce (Henneberger *et al.,* 2001). As with the Reading plant employees, this reported prevalence is reasonably consistent with the 5.5 percent CBD prevalence observed in the second NJMRC quartile.

Beginning in 1999, the Tucson facility instituted strict requirements for respiratory protection and other PPE, essentially eliminating airborne and dermal exposure for most workers. After these requirements were put in place, Cummings *et al.* (2007) reported only one case of sensitization (1 percent; associated with a PPE failure) among 97 workers hired between 2000 and 2004. This appears roughly in line with the sensitization prevalence of 2.2 percent observed in the lowest quartiles of average exposure (0.0–0.08 μg/m³) in the NJMRC data set.

While the literature analysis presented here shows a clear reduction in risk with well-controlled airborne exposures (≤ 0.1 μg/m³ on average) and protection from dermal exposure, the level of detail presented in the published studies limits the Agency's ability to characterize risk at all the alternate PELs OSHA is considering. To better understand these risks, OSHA used the NJMRC dataset to characterize risk of sensitization and CBD among workers exposed to each of the alternate PELs under consideration in the proposed beryllium rule.

F. OSHA's Statistical Modeling

OSHA's contractor performed a complementary log-log proportional hazards model using the NJMRC data set. The proportional hazards model is a generalization of logistic regression that allows for time-dependent exposures and differential time at risk. The proportional hazards model accounts for the fact that individuals in the dataset are followed for different amounts of time, and that their exposures change over time. The proportional hazards model provides hazards ratios, which estimate the relative risk of disease at a specified time for someone with exposure level 1 compared to exposure level 2. To perform this analysis, OSHA's contractor constructed exposure files with time-dependent cumulative and average exposures for each worker in the data set in each year that a case of sensitization or CBD was identified. Workers were included in only those years after they started working at the plant and continued to be followed. Sensitized cases were not included in analysis of sensitization after the year in which they were identified as being sensitized, and CBD cases were not included in analyses of CBD after the year in which they were diagnosed with CBD. Follow-up is censored after 2002 because work histories were deemed to be less reliable after that date.

The results of the discrete proportional hazards analyses are summarized in Tables VI–9–12 below. All coefficients used in the models are displayed, including the exposure coefficient, the model constant for diagnosis in 1995, and additional exposure-independent coefficients for each succeeding year (1996–1999 for sensitization and 1996–2002 for CBD) of diagnosis that are fit in the discrete time proportional hazards modeling procedure. Model equations and variables are explained more fully in the companion risk assessment background document.

Relative risk of sensitization increased with cumulative exposure ($p = 0.05$). A positive, but not statistically significant, association was observed with LTW average exposure ($p = 0.09$). The association was much weaker for exposure duration ($p = 0.31$), consistent with the expected biological action of an immune hypersensitivity response where onset is believed to be more dependent on the concentration of the sensitizing agent at the target site rather than the number of years of occupational exposure. The association was also much weaker for highest-exposed job (HEJ) exposure ($p = 0.3$).

TABLE VI–9—PROPORTIONAL HAZARDS MODEL—CUMULATIVE EXPOSURE AND SENSITIZATION

Variable	Coefficient	95% Confidence interval	P-value
Cumulative Exposure (μg/m³–yrs)	0.031	0.00 to 0.063	0.05
constant	−3.48	−4.27 to −2.69	<0.001
1996	−1.49	−3.04 to 0.06	0.06
1997	−0.29	−1.31 to 0.72	0.57
1998	−1.56	−3.11 to −0.01	0.05
1999	−1.57	−3.12 to −0.02	0.05

TABLE VI–10—PROPORTIONAL HAZARDS MODEL—LTW AVERAGE EXPOSURE AND SENSITIZATION

Variable	Coefficient	95% Confidence interval	P-value
Average Exposure (μg/m³)	0.54	−0.09 to 1.17	0.09
constant	−3.55	−4.42 to −2.69	<0.001
1996	−1.48	−3.03 to 0.07	0.06
1997	−0.29	−1.31 to 0.72	0.57
1998	−1.54	−3.09 to 0.01	0.05
1999	−1.53	−3.08 to 0.03	0.05

TABLE VI–11—PROPORTIONAL HAZARDS MODEL—EXPOSURE DURATION AND SENSITIZATION

Variable	Coefficient	95% Confidence interval	P-value
Exposure Duration (years)	0.03	−0.03 to 0.08	0.31
constant	−3.55	−4.57 to −2.53	<0.001
1996	−1.48	−3.03 to 0.70	0.06
1997	−0.30	−1.31 to 0.72	0.57
1998	−1.59	−3.14 to −0.04	0.05
1999	−1.62	−3.17 to −0.72	0.04

TABLE VI–12—PROPORTIONAL HAZARDS MODEL—HEJ EXPOSURE AND SENSITIZATION

Variable	Coefficient	95% Confidence interval	P-value
HEJ Exposure (μg/m³)	0.31	−0.27 to 0.88	0.30
constant	−3.42	−4.27 to −2.56	<0.001
1996	−1.49	−3.04 to 0.06	0.06
1997	−0.31	−1.33 to 0.70	0.55
1998	−1.59	−3.14 to −0.04	0.05
1999	−1.60	−3.15 to −0.05	0.04

The proportional hazards models for the CBD endpoint (Tables VI–13 through 16 below) showed positive relationships with cumulative exposure (p = 0.09) and duration of exposure (p = 0.10). However, the association with the cumulative exposure metric was not as strong as that for sensitization, probably due to the smaller number of CBD cases. LTW average exposure and HEJ exposure were not closely related to relative risk of CBD (p-values > 0.5).

TABLE VI–13—PROPORTIONAL HAZARDS MODEL—CUMULATIVE EXPOSURE AND CBD

Variable	Coefficient	95% Confidence interval	P-value
Cumulative Exposure (µg/m³–yrs)	0.03	.00 to 0.07	0.09
constant	−3.77	−4.67 to −2.86	<0.001
1997	−0.59	−1.86 to 0.68	0.36
1998	−2.01	−4.13 to 0.11	0.06
1999	−0.63	−1.90 to 0.64	0.33
2002	−2.13	−4.25 to −0.01	0.05

TABLE VI–14—PROPORTIONAL HAZARDS MODEL—LTW AVERAGE EXPOSURE AND CBD

Variable	Coefficient	95% Confidence interval	P-value
Average Exposure (µg/m³)	0.24	−0.59 to 1.06	0.58
constant	−3.62	−4.60 to −2.64	<0.001
1997	−0.61	−1.87 to 0.66	0.35
1998	−2.02	−4.14 to 0.10	0.06
1999	−0.64	−1.92 to 0.63	0.32
2002	−2.15	−4.28 to −0.02	0.05

TABLE VI–15—PROPORTIONAL HAZARDS MODEL—EXPOSURE DURATION AND CBD

Variable	Coefficient	95% Confidence interval	P-value
Exposure Duration (yrs)	0.05	−0.01 to 0.11	0.10
constant	−4.18	−5.40 to −2.96	<0.001
1997	−0.53	1.84 to 0.69	0.38
1998	−2.01	−4.13 to 0.11	0.06
1999	−0.67	−1.94 to 0.60	0.30
2002	−2.22	−4.34 to −0.10	0.04

TABLE VI–16—PROPORTIONAL HAZARDS MODEL—HEJ EXPOSURE AND CBD

Variable	Coefficient	95% Confidence interval	P-value
HEJ Exposure (µg/m³)	0.03	−0.70 to 0.77	0.93
constant	−3.49	−4.45 to −2.53	<0.001
1997	−0.62	−1.88 to 0.65	0.34
1998	−2.05	−4.16 to 0.07	0.06
1999	−0.68	−1.94 to 0.59	0.30
2002	−2.21	−4.33 to −0.09	0.04

In addition to the models reported above, comparable models were fit to the upper 95 percent confidence interval of the HEJ exposure; log-transformed cumulative exposure; log-transformed LTW average exposure; and log-transformed HEJ exposure. Each of these measures was positively but not significantly associated with sensitization.

OSHA used the proportional hazards models based on cumulative exposure, shown in Tables VI–9 and VI–13, to derive quantitative risk estimates. Of the metrics related to exposure level, the cumulative exposure metric showed the most consistent association with sensitization and CBD in these models. Table VI–17 summarizes these risk estimates for sensitization and the corresponding 95 percent confidence intervals separately for 1995 and 1999, the years with the highest and lowest baseline rates, respectively. The estimated risks for CBD are presented in VI–18. The expected number of cases is based on the estimated conditional probability of being a case in the given year. The models provide time-specific point estimates of risk for a worker with any given exposure level, and the corresponding interval is based on the uncertainty in the exposure coefficient (*i.e.,* the predicted values based on the 95 percent confidence limits for the exposure coefficient).

Each estimate represents the number of sensitized workers the model predicts in a group of 1000 workers at risk during the given year with an exposure history at the specified level and duration. For example, in the exposure scenario where 1000 workers are occupationally exposed to 2 µg/m³ for 10 years in 1995, the model predicts that about 56 (55.7) workers would be sensitized that year. The model for CBD predicts that about 42 (41.9) workers would be diagnosed with CBD that year.

TABLE VI–17a—PREDICTED CASES OF SENSITIZATION PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[1995 Baseline]

1995 Exposure level (µg/m³)	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m³-yrs)	cases/ 1000	µg/m³-yrs	cases/ 1000	µg/m³-yrs	cases/ 1000	µg/m³-yrs	cases/ 1000
2.0	10.0	41.1 30.3–56.2	20.0	55.7 30.3–102.9	40.0	101.0 30.3–318.1	90.0	394.4 30.3–999.9
1.0	5.0	35.3 30.3–41.3	10.0	41.1 30.3–56.2	20.0	55.7 30.3–102.9	45.0	116.9 30.3–408.2
0.5	2.5	32.7 30.3–35.4	5.0	35.3 30.3–41.3	10.0	41.1 30.3–56.2	22.5	60.0 30.3–119.4
0.2	1.0	31.3 30.3–32.3	2.0	32.2 30.3–34.3	4.0	34.3 30.3–38.9	9.0	39.9 30.3–52.9
0.1	0.5	30.8 30.3–31.3	1.0	31.3 30.3–32.3	2.0	32.2 30.3–34.3	4.5	34.8 30.3–40.1

TABLE VI–17b—PREDICTED CASES OF SENSITIZATION PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[1999 Baseline]

1999 Exposure level (µg/m³)	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m³-yrs)	cases/ 1000	µg/m³-yrs	cases/ 1000	µg/m³-yrs	cases/ 1000	µg/m³-yrs	cases/ 1000
2.0	10.0	8.4 6.2–11.6	20.0	11.5 6.2–21.7	40.0	21.3 6.2–74.4	90.0	96.3 6.2–835.4
1.0	5.0	7.2 6.2–8.5	10.0	8.4 6.2–11.6	20.0	11.5 6.2–21.7	45.0	24.8 6.2–100.5
0.5	2.5	6.7 6.2–7.3	5.0	7.2 6.2–8.5	10.0	8.4 6.2–11.6	22.5	12.4 6.2–25.3
0.2	1.0	6.4 6.2–6.6	2.0	6.6 6.2–7.0	4.0	7.0 6.2–8.0	9.0	8.2 6.2–10.9
0.1	0.5	6.3 6.2–6.4	1.0	6.4 6.2–6.6	2.0	6.6 6.2–7.0	4.5	7.1 6.2–8.2

TABLE VI–18a—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[1995 baseline]

1995 Exposure level (µg/m³)	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m³-yrs)	Estimated cases/1000 95% c.i.	µg/m³-yrs	Estimated cases/1000 95% c.i.	µg/m³-yrs	Estimated cases/1000 95% c.i.	µg/m³-yrs	Estimated cases/1000 95% c.i.
2.0	10.0	30.9 22.8–44.0	20.0	41.9 22.8–84.3	40.0	76.6 22.8–285.5	90.0	312.9 22.8–999.9
1.0	5.0	26.6 22.8–31.7	10.0	30.9 22.8–44.0	20.0	41.9 22.8–84.3	45.0	88.8 22.8–375.0
0.5	2.5	24.6 22.8–26.9	5.0	26.6 22.8–31.7	10.0	30.9 22.8–44.0	22.5	45.2 22.8–98.9
0.2	1.0	23.5 22.8–24.3	2.0	24.2 22.8–26.0	4.0	25.8 22.8–29.7	9.0	30.0 22.8–41.3
0.1	0.5	23.1 22.8–23.6	1.0	23.5 22.8–24.3	2.0	24.2 22.8–26.0	4.5	26.2 22.8–30.7

TABLE VI–18b—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[2002 baseline]

2002 Exposure level (μg/m³)	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (μg/m³-yrs)	Estimated cases/1000 95% c.i.	μg/m³-yrs	Estimated cases/1000 95% c.i.	μg/m³-yrs	Estimated cases/1000 95% c.i.	μg/m³-yrs	Estimated cases/1000 95% c.i.
2.0	10.0	3.7 2.7–5.3	20.0	5.1 2.7–10.4	40.0	9.4 2.7–39.2	90.0	43.6 2.7–679.8
1.0	5.0	3.2 2.7–3.8	10.0	3.7 2.7–5.3	20.0	5.1 2.7–10.4	45.0	11.0 2.7–54.3
0.5	2.5	3.0 2.7–3.2	5.0	3.2 2.7–3.8	10.0	3.7 2.7–5.3	22.5	5.5 2.7–12.3
0.2	1.0	2.8 2.7–2.9	2.0	2.9 2.7–3.1	4.0	3.1 2.7–3.6	9.0	3.6 2.7–5.0
0.1	0.5	2.8 2.7–2.8	1.0	2.8 2.7–2.9	2.0	2.9 2.7–3.1	4.5	3.1 2.7–3.7

The statistical modeling analysis predicts high risk of both sensitization (96–394 cases per 1000, or 9.6–39.4 percent) and CBD (44–313 cases per 1000, or 4.4–31.3 percent) at the current PEL of 2 μg/m³ for an exposure duration of 45 years (90 μg/m³-yr). The predicted risks of < 8.2–39.9 per 1000 (0.8–3.9 percent) cases of sensitization or 3.6 to 30.0 per 1000 (0.4–3 percent) cases of CBD are substantially less for a 45-year exposure at the proposed PEL, 0.2 μg/m³ (9 μg/m³-yr).

The model estimates are not directly comparable to prevalence values discussed in previous sections. They assume a group without turnover and are based on a comparison of unexposed and hypothetically exposed workers at specific points in time, whereas the prevalence analysis simply reports the percentage of workers at the Cullman plant with sensitization or CBD in each exposure category. Despite the difficulty of direct comparison, the level of risk seen in the prevalence analysis and predicted in the modeling analysis appear roughly similar at low exposures. In the second quartile of cumulative exposure (0.148–1.467 μg/m³-yr), prevalence of sensitization and CBD was 2.5 percent. This is roughly congruent with the model predictions for workers with cumulative exposures between 0.5 and 1 μg/m³-yr: 6.3–31.3 cases of sensitization per 1000 workers (0.6–3.1 percent) and 2.8 to 23.5 cases of CBD per 1000 workers (0.28–2.4 percent). As discussed in the background document for this analysis, most workers in the data set had low cumulative exposures (roughly half below 1.5 μg/m³-years). It is difficult to make any statement about the results at higher levels, because there were few workers with high exposure levels and the higher quartiles of cumulative exposure include an extremely wide range of exposures. For example, the highest quartile of cumulative exposure was 7.009–61.86 μg/m³-yr. This quartile, which showed an 11.3 percent prevalence of sensitization and 8.8 percent prevalence of CBD, includes the cumulative exposure that a worker exposed for 45 years at the proposed PEL would experience (9 μg/m³-yr) near its lower bound. Its upper bound approaches the cumulative exposure that a worker exposed for 45 years at the current PEL would experience (90 μg/m³-yr).

Due to limitations including the size of the dataset, relatively limited exposure data from the plant's early years, study size-related constraints on the statistical analysis of the dataset, and limited follow-up time on many workers, OSHA must interpret the model-based risk estimates presented in Tables VI–17 and VI–18 with caution. The Cullman study population is a relatively small group and can support only limited statistical analysis. For example, its size precludes inclusion of multiple covariates in the exposure-response models or a two-stage exposure-response analysis to model both sensitization and the subsequent development of CBD within the subpopulation of sensitized workers. The limited size of the Cullman dataset is characteristic of studies on beryllium-exposed workers in modern, low-exposure environments, which are typically small-scale processing plants (up to several hundred workers, up to 20–30 cases). However, these recent studies also have important strengths: They include workers hired after the institution of stringent exposure controls, and have extensive exposure sampling using full-shift personal lapel samples. In contrast, older studies of larger populations tend to have higher exposures, less exposure data, and exposure data collected in short-term samples or outside of workers' breathing zones.

Another limitation of the Cullman dataset, which is common to recent low-exposure studies, is the short follow-up time available for many of the workers. While in some cases CBD has been known to develop in short periods (< 2 years), it more typically develops over a longer time period. Sensitization occurs in a typically shorter time frame, but new cases of sensitization have been observed in workers exposed to beryllium for many years. Because the data set is limited to individuals then working at the plant, the Cullman data set cannot capture CBD occurring among workers who retire or leave the plant. OSHA expects that the dataset does not fully represent the risk of sensitization, and is likely to particularly under-represent CBD among workers exposed to beryllium at this facility. The Agency believes the short follow-up time to be a significant source of uncertainty in the statistical analysis, a factor likely to lead to underestimation of risk in this population.

A common source of uncertainty in quantitative risk assessment is the series of choices made in the course of statistical analysis, such as model type, inclusion or exclusion of additional explanatory variables, and the assumption of linearity in exposure-response. Sensitivity analyses and statistical checks were conducted to test the validity of the choices and assumptions in the exposure-response analysis and the impact of alternative choices on the end results. These analyses did not yield substantially different results, adding to OSHA's confidence in the conclusions of its preliminary risk assessment.

OSHA's contractor examined whether smoking and age were confounders in the exposure-response analysis by adding them as variables in the discrete proportional hazards model. Neither smoking status nor age was a statistically significant predictor of sensitization or CBD. The model coefficients, 95 percent confidence intervals, and p values can be found in the background document. A sensitivity analysis was done using the standard Cox model that treats survival time as continuous rather than discrete. The model coefficients with the standard Cox using cumulative exposure were 0.025 and very similar to the 0.03 reported in Tables VI–9 and VI–13 above. The interaction between exposure and follow-up time was not significant in these models, suggesting that the proportional hazard assumption should not be rejected. The proportional hazards model assumes a linear relationship between exposure level and relative risk. The linearity assumption was assessed using a fractional polynomial approach. For both sensitization and CBD, the best-fitting fractional polynomial model did not fit significantly better than the linear model. This result supports OSHA's use of the linear model to estimate risk. The details of these statistical analyses can be found in the background document.

The possibility that the number of times a worker has been tested for sensitization might influence the probability of a positive test was examined (surveillance bias). Surveillance bias could occur if workers were tested because they showed some sign of disease, and not tested otherwise. It is also possible that the original analysis included erroneous assumptions about the dates of testing for sensitization and CBD. OSHA's contractor performed a sensitivity analysis, modifying the original analysis to gauge the effect of different assumptions about testing dates. In the sensitivity analysis, the exposure coefficients increased for all four indices of exposure when the sensitization analysis was restricted to times when cohort members were assumed to be tested. The exposure coefficient was statistically significant for duration of exposure but not for cumulative, LTW average, or HEJ exposure. The increase in exposure coefficients suggests that the original models may have underestimated the exposure-response relationship for sensitization and CBD.

Errors in exposure measurement are a common source of uncertainty in quantitative risk assessments. Because errors in high exposures can heavily influence modeling results, OSHA's contractor performed sensitivity analyses excluding the highest 5 percent of cumulative exposures (those above 25.265 μg/m^3-yrs) and the highest 10 percent of cumulative exposures (those above 18.723 μg/m^3-yrs). As discussed in more detail in the background document, exposure coefficients were not statistically significant when these exposures were dropped. This is not surprising, given that the exclusion of high exposure values reduced the size of the data set. Prior to excluding high exposure values, the data set was already relatively small and many of the exposure coefficients were non-significant or weakly significant in the original analyses. As a result, the sensitivity analyses did not provide much information about uncertainty due to exposure measurement error and its effects on the modeling analysis.

Particle size, particle surface area, and beryllium compound solubility are believed to be important factors influencing the risk of sensitization and CBD among beryllium-exposed workers. The workers at the Cullman machining plant were primarily handling insoluble beryllium compounds, such as beryllium metal and beryllium metal/beryllium oxide composites. Particle size distributions from a limited number of airborne beryllium samples collected just after the 1996 installation of engineering controls indicate worker exposure to a substantial proportion of respirable particulates. There was no available particle size data for the 1980 to 1995 period prior to installation of engineering controls when total beryllium mass exposure levels were greatest. Particle size data was also lacking from 1998 to 2003 when additional control measures were in place and total beryllium mass exposures were lowest. For these reasons, OSHA was not able to quantitatively account for the influence of particle size and solubility in developing the risk estimates based on the Cullman data set. However, it is not unreasonable to expect the CBD experienced by this cohort to generally reflect the risk from exposure to beryllium that is relatively insoluble and enriched with respirable particles. As explained previously, the role of particle size and surface area on risk of sensitization is more difficult to predict.

Additional uncertainty is introduced when extrapolating the quantitative estimates presented above to operations that process beryllium compounds that have different solubility and particle characteristics than those encountered at the Cullman machining plant. OSHA does not have sufficient information to quantitatively assess the degree to which risks of beryllium sensitization and CBD based on the NJMRC data may be impacted in workplaces where such beryllium forms and processes are used. However, OSHA does not expect this uncertainty to alter its qualitative conclusions with regard to the risk at the current PEL and at alternate PELs as low as 0.1 μg/m^3. The existing studies provide clear evidence of sensitization and CBD risk among workers exposed to a number of beryllium forms as a result of different processes such as beryllium machining, beryllium-copper alloy production, and beryllium ceramics production. The Agency believes all of these forms of beryllium exposure contribute to the overall risk of sensitization and CBD among beryllium-exposed workers.

G. Lung Cancer

OSHA considers lung cancer to be an important health endpoint for beryllium-exposed workers. The International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), and American Conference of Governmental Industrial Hygienists (ACGIH) have all classified beryllium as a known human carcinogen. The National Academy of Sciences (NAS), Environmental Protection Agency, the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute of Occupational Safety and Health (NIOSH), and other reputable scientific organizations have reviewed the scientific evidence demonstrating that beryllium is associated with an increased incidence of cancer. OSHA also has performed an extensive review of the scientific literature regarding beryllium and cancer. This includes an evaluation of human epidemiological, animal cancer, and mechanistic studies described in the Health Effects section of this preamble. Based on the weight of evidence, the Agency has preliminarily determined beryllium to be an occupational carcinogen.

Although epidemiological and animal evidence supports a conclusion of beryllium carcinogenicity, there is considerable uncertainty surrounding the mechanism of carcinogenesis for beryllium. The evidence for direct genotoxicity of beryllium and its compounds has been limited and inconsistent (NAS, 2008; IARC, 1993; EPA, 1998; NTP, 2002; ATSDR, 2002). One plausible pathway for beryllium carcinogenicity described in the Health Effects section of this preamble includes a chronic, sustained neutrophilic inflammatory response that induces epigenetic alterations leading to the neoplastic changes necessary for carcinogenesis. The National Cancer Institute estimates that nearly one-third of all cancers are caused by chronic inflammation (NCI, 2009). This mechanism of action has also been hypothesized for crystalline silica and other agents that are known to be human carcinogens but have limited evidence of genotoxicity.

OSHA's review of epidemiological studies of lung cancer mortality among beryllium workers found that most did not characterize exposure levels sufficiently for exposure-response analysis. However, one NIOSH study evaluated the association between beryllium exposure and lung cancer mortality based on data from a beryllium processing plant in Reading, PA (Sanderson *et al.,* 2001a). As discussed in the Health Effects section of this preamble, this case-control study evaluated lung cancer incidence in a cohort of workers employed at the plant from 1940 to 1969 and followed through 1992. For each lung cancer victim, 5 age- and race-matched controls were selected by incidence density sampling, for a total of 142 lung cancer cases and 710 controls.

Between 1971 and 1992, the plant collected close to 7,000 high volume filter samples consisting of both general area and short-term, task-based breathing zone measurements for production jobs and exclusively area measurements for office, lunch, and laboratory areas (Sanderson *et al.,* 2001b). In addition, a few (< 200) impinger and high-volume filter samples were collected by other organizations between 1947 and 1961, and about 200 6-to-8-hour personal samples were collected in 1972 and 1975. Daily-weighted-average (DWA) exposure calculations based on the impinger and high-volume samples collected prior to the 1960s showed that exposures in this period were extremely high. For example, about half of production jobs had estimated DWAs ranging between 49 and 131 μg/m³ in the period 1935–1960, and many of the ''lower-exposed'' jobs had DWAs of approximately 20–30 μg/m³ (Table II, Sanderson *et al.,* 2001b). Exposures were reported to have decreased between 1959 and 1962 with the installation of ventilation controls and improved housekeeping and following the passage of the OSH Act in 1970. While no exposure measurements were available from the period 1961–1970, measurements from the period 1971–1980 showed a dramatic reduction in exposures plant-wide. Estimated DWAs for all jobs in this period ranged from 0.1 μg/m³ to 1.9 μg/m³. Calendar-time-specific beryllium exposure estimates were made for every job based on the DWA calculations and were used to estimate workers' cumulative, average, and maximum exposures. Exposure estimates were lagged by 10 and 20 years in order to account for exposures that did not contribute to lung cancer because they occurred after the induction of cancer.

Results of a conditional logistic regression analysis showed an increased risk of lung cancer in workers with higher exposures when dose estimates were lagged by 10 and 20 years (Sanderson *et al.,* 2001a). The authors noted that there was considerable uncertainty in the estimation of exposure in the 1940s and 1950s and the shape of the dose-response curve for lung cancer. NIOSH later reanalyzed the data, adjusting for potential confounders of hire age and birth year (Schubauer-Berigan *et al.,* 2008). The study reported a significant increasing trend ($p<0.05$) in the odds ratio when increasing quartiles of average (log transformed) exposure were lagged by 10 years. However, it did not find a significant trend when quartiles of cumulative (log transformed) exposure were lagged by 0, 10, or 20 years.

OSHA is interested in lung cancer risk estimates from a 45-year (*i.e.,* working lifetime) exposure to beryllium levels between 0.1 μg/m³ and 2 μg/m³. The majority of case and control workers in the Sanderson *et al.* case-control analysis were first hired during the 1940s when exposures were extremely high (estimated DWAs > 20 μg/m³ for most jobs). The cumulative, average, and maximum beryllium exposure concentration estimates for the 142 known lung cancer cases were: 46.06 ± 9.3μg/m³-days, 22.8 ± 3.4 μg/m³, and 32.4 ± 13.8 μg/m³, respectively. About two-thirds of cases and half of controls worked at the plant for less than a year. Thus, a risk assessment based on this exposure-response analysis would need to extrapolate from very high to very low exposures, based on a working population with extremely short tenure. While OSHA risk assessments must often make extrapolations to estimate risk within the range of exposures of interest, the Agency acknowledges that these issues of short tenure and extremely high exposures would create substantial uncertainty in a risk assessment based on this study population.

In addition, the relatively high exposures of even the least-exposed workers in the NIOSH study may create methodological issues for the lung cancer case-control study design. Mortality risk is expressed as an odds ratio that compares higher exposure quartiles to the lowest quartile. It is preferable that excess risks attributable to occupational beryllium be determined relative to an unexposed or minimally exposed reference population. However, in the NIOSH study workers in the lowest quartile were exposed well above the OSHA PEL (average exposure <11.2 μg/m³) and may have had a significant lung cancer risk. This issue would introduce further uncertainty in lung cancer risks estimated from this epidemiological study.

In 2010, researchers at NIOSH published a quantitative risk assessment based on an update of the Reading cohort analyzed by Sanderson *et al.,* as well as workers from two smaller plants (Schubauer-Berigan *et al.,* 2010b). This new risk assessment addresses several of OSHA's concerns regarding the Sanderson *et al.* analysis. The new cohort was exposed, on average, to lower levels of beryllium and had fewer short-term workers. Finally, the updated cohorts followed the populations through 2005, increasing the length of follow-up time overall by an additional 17 years of observation. For these reasons, OSHA considers the Schubauer-Berigan risk analysis more appropriate than the Sanderson *et al.* analysis for its preliminary risk assessment.

The cohort studied by Schubauer-Berigan *et al.* included 5,436 male workers who had worked for at least two days at the Reading facility and beryllium processing plants at Hazleton PA and Elmore OH prior to 1970. The authors developed job-exposure matrices (JEMs) for the three plants based on extensive historical exposure data, primarily short-term general area and personal breathing zone samples, collected on a quarterly basis from a wide variety of operations. These samples were used to create daily weighted average (DWA) estimates of workers' full-shift exposures, using records of the nature and duration of tasks performed by workers during a shift. Details on the JEM and DWA construction can be found in Sanderson *et al.* (2001a), Chen *et al.* (2001), and Couch *et al.* (2010).

Workers' cumulative exposures (μg/m³-days) were estimated by summing daily average exposures (assuming five workdays per week). To estimate mean exposure (μg/m³), cumulative exposure was divided by exposure time (in days). Maximum exposure (μg/m³) was estimated as the highest annual DWA on record for a worker prior to the study cutoff date of December 31, 2005 and accounting where appropriate for lag time. Exposure estimates were lagged by 5, 10, 15, and 20 years in order to account for exposures that may not have contributed to lung cancer because of the long latency required for manifestation of the disease. The authors also fit models with no lag time. As shown in Table VI–19 below, estimated exposure levels for workers from the Hazleton and Elmore plants were on average far lower than those for workers from the Reading plant. The median worker from Hazleton had a mean exposure across his tenure of less than 2 μg/m³, while the median worker from Elmore had a mean exposure of less than 1 μg/m³. The Elmore and Hazleton worker populations also had fewer short-term workers than the Reading population. This was particularly evident at Hazleton where the median value for cumulative exposure among cases was higher than at Reading despite the much lower mean and maximum exposure levels.

TABLE VI–19—COHORT DESCRIPTION AND DISTRIBUTION OF CASES BY EXPOSURE LEVEL

		All plants	Reading plant	Hazleton plant	Elmore plant
Number of cases		293	218	30	45
Number of non-cases		5143	3337	583	1223
Median value for mean exposure	*No lag*	15.42	25	1.443	0.885
(μg/m³) among cases	*10-year lag*	15.15	25	1.443	0.972
Median value for cumulative exposure.	*No lag*	2843	2895	3968	1654
(μg/m³-days) among cases	*10-year lag*	2583	2832	3648	1449
Median value for maximum exposure	*No lag*	25	25.1	3.15	2.17
(μg/m³) among cases	*10-year lag*	25	25	3.15	2.17
Number of cases with potential asbestos exposure.		100 (34%)	68 (31%)	16 (53%)	16 (36%)
Number of cases who were professional workers.		26 (9%)	21 (10%)	3 (10%)	2 (4%)

Table adapted from Schubauer-Berigan *et al.* 2011, Table 1.

Schubauer-Berigan *et al.* analyzed the data set using a variety of exposure-response modeling approaches, including categorical analyses and continuous-variable piecewise log-linear and power models, described in Schubauer-Berigan *et al.* (2011). All models adjusted for birth cohort and plant. As exposure values were log-transformed for the power model analyses, the authors added small values to exposures of 0 in lagged analyses (0.05 μg/m³ for mean and maximum exposure, 0.05 μg/m³-days for cumulative exposure). The authors used restricted cubic spline models to assess the shape of the exposure-response curve and suggest appropriate parametric model forms. The Akaike Information Criterion (AIC) value was used to evaluate the fit of different model forms and lag times.

Because smoking information was available for only about 25 percent of the cohort, smoking could not be controlled for directly in the models. The authors reported that within the subset with smoking information, there was little difference in smoking by cumulative or maximum exposure category (p. 6), suggesting that smoking was unlikely to act as a confounder in the cohort. In addition to models based on the full cohort, Schubauer-Berigan *et al.* also prepared risk estimates based on models excluding professional workers and workers believed to have asbestos exposure. These models were intended to mitigate the potential impact of smoking and asbestos as confounders. If professional workers had both lower beryllium exposures and lower smoking rates than production workers, smoking could be a confounder in the cohort comprising both production and professional workers. However, the authors reasoned that smoking was unlikely to be correlated with beryllium exposure among production workers, and would therefore probably not act as a confounder in a cohort excluding professional workers.

The authors found that lung cancer risk was strongly and significantly related to mean, cumulative, and maximum measures of workers' exposure (all models reported in Schubauer-Berigan *et al.,* 2011). They selected the best-fitting categorical, power, and monotonic piecewise log-linear (PWL) models with a 10-year lag to generate hazard ratios for male workers with a mean exposure of 0.5 μg/m³ (the current NIOSH Recommended Exposure Limit for beryllium).[9] To estimate excess lifetime risk of cancer, they multiplied this hazard ratio by the 2004–2006 background lifetime lung cancer rate among U.S. males who had survived, cancer-free, to age 30. In addition, they estimated the mean exposure that would be associated with an excess lifetime risk of one in 1000, a value often used as a benchmark for significant risk in OSHA regulations. At OSHA's request, they also estimated excess lifetime risks for workers with mean exposures at the current PEL of 2 μg/m³ each of the other alternate PELs under consideration: 1 μg/m³, 0.2 μg/m³, and 0.1 μg/m³ (Schubauer-Berigan, 4/22/11). The resulting risk estimates are presented in Table VI–20 below.

[9] Here, ''monotonic PWL model'' means a model producing a monotonic exposure-response curve in the 0–2 ug/m³ region.

TABLE VI–20—EXCESS LIFETIME RISK PER 1000 [95% CONFIDENCE INTERVAL] FOR MALE WORKERS AT ALTERNATE PELS

[NIOSH models]

Exposure-response model	Mean exposure				
	0.1 µg/m³	0.2 µg/m³	0.5 µg/m³	1 µg/m³	2 µg/m³
Best monotonic PWL—all workers	7.3[2.0–13]	15[3.3–29]	45[9–98]	120[20–340]	200[29–370]
Best monotonic PWL—excluding professional and asbestos workers	3.1[<0–11]	6.4[<0–23]	17[<0–74]	39[39–230]	61[<0–280]
Best categorical—all workers	4.4[1.3–8]	9[2.7–17]	25[6–48]	59[13–130]	170[29–530]
Best categorical—excluding professional and asbestos workers	1.4[<0–6.0]	2.7[<0–12]	7.1[<0–35]	15[<0–87]	33[<0–290]
Power model—all workers	12[6–19]	19[9.3–29]	30[15–48]	40[19–66]	52[23–88]
Power model—excluding professional and asbestos workers	19[8.6–31]	30[13–50]	49[21–87]	68[27–130]	90[34–180]

Schubauer-Berigan *et al.* discuss several strengths, weaknesses, and uncertainties of their analysis. Strengths include long (> 30 years) follow-up time for members of the cohort and the extensive exposure and work history data available for the development of exposure estimates for workers in the cohort. Among the weaknesses and uncertainties of the study are the limited information available on workers' smoking habits: smoking information was available only for workers employed in 1968, about 25 percent of the cohort. In addition, the JEMs used did not account for possible respirator use among workers in the cohort. The authors note that workers' exposures may therefore have been overestimated, and that overestimation may have been especially severe for workers with high estimated exposures. They suggest that overestimation of exposures for workers in highly exposed positions may have caused attenuation of the exposure-response curve in some models at higher exposures.

The NIOSH publication did not discuss the reasons for basing risk estimates on mean exposure rather than cumulative exposure that is more commonly used for lung cancer risk analysis. OSHA believes the decision may involve the nonmonotonic relationship NIOSH observed between cancer risk and cumulative exposure level. As discussed previously, workers from the Reading plant frequently had very short tenures and high exposures yielding lower cumulative exposures compared to cohort workers from other plants with longer employment. Despite the low estimated cumulative exposures among the short-term Reading workers, they may be at high risk of lung cancer due to the tendency of beryllium to persist in the lung for long periods. This exposure misclassification could lead to the appearance of a nonmonotonic relationship between cumulative exposure and lung cancer risk. It is possible that a dose-rate effect may exist for beryllium, such that the risk from a cumulative exposure gained by long-term, low-level exposure is not equivalent to the risk from a cumulative exposure gained by very short-term, high-level exposure. In this case, mean exposure level may better correlate with the risk of lung cancer than cumulative exposure level. For these reasons OSHA considers the NIOSH choice of mean exposure metric to be appropriate and scientifically defensible for this particular dataset.

H. Preliminary Conclusions

As described above, OSHA's risk assessment for beryllium sensitization and CBD relied on two approaches: (1) review of the literature and (2) analysis of a dataset provided by NJRMC. First, the Agency reviewed the scientific literature to ascertain whether there is substantial risk to workers exposed at and below the current PEL and to characterize the expected impact of more stringent controls on workers' risk of sensitization and CBD. This review focused on facilities where exposures were primarily below the current PEL, and where several rounds of BeLPT and CBD screening had been conducted to evaluate the effectiveness of various exposure control measures. Second, OSHA investigated the exposure-response relationship for beryllium sensitization and CBD by analyzing a dataset that NJMRC provided on workers at a prominent, long-established beryllium machining facility. Although exposure-response studies have been published on sensitization and CBD, OSHA believes the nature and quality of their exposure data significantly limits their value for the Agency's risk assessment. Therefore, OSHA developed an independent exposure-response analysis using the NJMRC dataset, which was recently updated, includes workers exposed at low levels, and includes extensive exposure data collected in workers' breathing zones, as is preferred by OSHA.

OSHA's review of the scientific literature found substantial risk of both sensitization and CBD in workplaces in compliance with OSHA's current PEL (*e.g.,* Kreiss *et al.,* 1992; Schuler *et al.,* 2000; Madl *et al.,* 2007). At these plants, including a copper-beryllium processing facility, a beryllia ceramics facility, and a beryllium machining facility, exposure reduction programs that primarily used engineering controls to reduce airborne exposures to median levels at or around 0.2 µg/m³ had only limited impact on workers' risk. Cases of sensitization continued to occur frequently among newly hired workers, and some of these workers developed CBD within the short follow-up time.

In contrast, industrial hygiene programs that minimized both airborne and dermal exposure substantially lowered workers' risk of sensitization in the first years of employment. Programs that drastically reduced respiratory exposure via a combination of engineering controls and respiratory protection, minimized the potential for skin exposure via dermal PPE, and employed stringent housekeeping methods to keep work areas clean and prevent transfer of beryllium between areas sharply curtailed new cases of sensitization among newly-hired workers. For example, studies conducted at copper-beryllium processing, beryllium production, and beryllia ceramics facilities show that reduction of exposures to below 0.1 µg/m³ and protection from dermal exposure, in combination, achieved a substantial reduction in sensitization risk among newly-hired workers. However, even these stringent measures did not protect all workers from sensitization.

The most recent epidemiological literature on programs that have been successful in reducing workers' risk of sensitization have had very short follow-up time; therefore, they cannot address the question of how frequently workers sensitized in very low-exposure environments develop CBD. Clinical evaluation for CBD was not reported for workers at the copper-beryllium processing, beryllium production, and ceramics facilities. However, cases of CBD among workers exposed at low levels at a machining plant and cases of CA–CBD demonstrate that individuals exposed to low levels of airborne beryllium can develop CBD, and over time, can progress to severe disease. This conclusion is also supported by case reports within the literature of workers with CBD who may have been minimally exposed to beryllium, such as a worker employed only in administration at a beryllium ceramics facility (Kreiss *et al.,* 1996).

The Agency's analysis of the Cullman dataset provided by NJMRC showed strong exposure-response trends using multiple analytical approaches, including examination of sensitization and disease prevalence by exposure categories and a proportional hazards modeling approach. In the prevalence analysis, cases of sensitization and disease were evident at all levels of exposure. The lowest prevalence of sensitization (2.0 percent) and CBD (1.0 percent) was observed among workers with LTW average exposure levels below 0.1 μg/m³, while those with LTW average exposure between 0.1–0.2 μg/m³ showed a marked increase in overall prevalence of sensitization (9.8 percent) and CBD (7.3 percent). Prevalence of sensitization and CBD also increased with cumulative exposure.

OSHA's proportional hazards analysis of the Cullman dataset found increasing risk of sensitization with both cumulative exposure and average exposure. OSHA also found a positive relationship between risk of CBD and cumulative exposure, but not between CBD and average exposure. The Agency used the cumulative exposure model results to estimate hazards ratios and risk of sensitization and CBD at the current PEL of 2 μg/m³ and each of the alternate PELs under consideration: 1 μg/m³, 0.5 μg/m³, 0.2 μg/m³, and 0.1 μg/m³. To estimate risk of CBD from a working lifetime of exposure, the Agency calculated the cumulative exposure associated with 45 years of exposure at each level, for total cumulative exposures of 90, 45, 22.5, 9, and 4.5 μg/m³-years. The risk estimates for sensitization and CBD ranged from 100–403 and 40–290 cases, respectively, per 1000 workers exposed at the current PEL of 2 μg/m³. The risks are projected to be substantially lower for both sensitization and CBD at 0.1 μg/m³ and range from 7.2–35 cases per 1000 and 3.1–26 cases per 1000, respectively. In these ways, the modeling results are similar to results observed from published studies of the Reading, Tucson, and Cullman plants and the OSHA analysis of sensitization and CBD prevalence within the Cullman plant.

OSHA has a high level of confidence in the finding of substantial risk of sensitization and CBD at the current PEL, and the Agency believes that a standard requiring a combination of more stringent controls on beryllium exposure will reduce workers' risk of both sensitization and CBD. Programs that have reduced median levels to below 0.1 μg/m³, tightly controlled both respiratory and dermal exposure, and incorporated stringent housekeeping measures have substantially reduced risk of sensitization within the first years of exposure. These conclusions are supported by the results of several studies conducted in state-of-the-art facilities dealing with a variety of production activities and physical forms of beryllium. In addition, these conclusions are supported by OSHA's statistical analysis of a dataset with highly detailed exposure and work history information on several hundred beryllium workers. While there is uncertainty regarding the precision of model-derived risk estimates, they provide further evidence that there is substantial risk of sensitization and CBD associated with exposure at the current PEL, and that this risk can be substantially lessened by stringent measures to reduce workers' beryllium exposure levels.

Furthermore, OSHA believes that beryllium-exposed workers' risk of lung cancer will be reduced by more stringent control of airborne beryllium exposures. The risk estimates from NIOSH's recent lung cancer study, described above, range from 33 to 140 excess lung cancers per 1000 workers exposed at the current PEL of 2 μg/m³. The NIOSH risk assessment's six best-fitting models each predict substantial reductions in risk with reduced exposure, ranging from 3 to 19 excess lung cancers per 1000 workers exposed at the proposed PEL of 0.1 μg/m³. The evidence of lung cancer risk from NIOSH's risk assessment provides additional support for OSHA's preliminary conclusions regarding the significance of risk to workers exposed to beryllium levels at and below the current PEL. However, the lung cancer risks require a sizable low dose extrapolation below beryllium exposure levels experienced by workers in the NIOSH study. As a result, there is a greater uncertainty in the lung cancer risk estimates and lesser confidence in their significance of risk below the current PEL than with beryllium sensitization and CBD. The preliminary conclusions with regard to significance of risk are presented and further discussed in section VIII of the preamble.

VII. Expert Peer Review of Health Effects and Preliminary Risk Assessment

In 2010, Eastern Research Group, Inc. (ERG), under contract to the Occupational Safety and Health Administration (OSHA) ,[10] conducted an independent, scientific peer review of (1) a draft Preliminary Beryllium Health Effects Evaluation (OSHA, 2010a), (2) a draft Preliminary Beryllium Risk Assessment (OSHA, 2010b), and (3) two NIOSH study manuscripts (Schubauer-Berigan *et al.,* 2011 and 2011a). This section of the preamble describes the review process and summarizes peer reviewers' comments and OSHA's responses.

ERG conducted a search for nationally recognized experts in the areas of occupational epidemiology, occupational medicine, toxicology, immunology, industrial hygiene/exposure assessment, and risk assessment/biostatistics as requested by OSHA. ERG sought experts familiar with beryllium health effects research and who had no conflict of interest (COI) or apparent bias in performing the review. Interested candidates submitted evidence of their qualifications and responded to detailed COI questions. ERG also searched the Internet to determine whether qualified candidates had made public statements or declared a particular bias regarding beryllium regulation.

From the pool of qualified candidates, ERG selected five experts to conduct the review, based on:

○ Their qualifications, including their degrees, years of relevant experience, number of related peer-reviewed publications, experience serving as a peer reviewer for OSHA or other government organizations, and committee and association memberships related to the review topic;

○ Lack of any actual, potential, or perceived conflict of interest; and

○ The need to ensure that the panel collectively was sufficiently broad and

[10] Task Order No. DOLQ59622303, Contract No. GS10F0125P, with a period of performance from May, 2010 through December, 2010.

diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge appropriate to the review.

OSHA reviewed the qualifications of the candidates proposed by ERG to verify that they collectively represented the technical areas of interest. ERG then contracted the following experts to perform the review.

(1) *John Balmes, MD, Professor of Medicine, University of California-San Francisco*

Expertise: pulmonary and occupational medicine, CBD, occupational lung disease, epidemiology, occupational exposures, medical surveillance.

(2) *Patrick Breysse, Ph.D., Professor, Johns Hopkins University Bloomberg School of Public Health*

Expertise: industrial hygiene, occupational/environmental health engineering, exposure monitoring/analysis, biomarkers, beryllium exposure assessment

(3) *Terry Gordon, Ph.D., Professor, New York University School of Medicine.*

Expertise: inhalation toxicology, pulmonary disease, beryllium toxicity and carcinogenicity, CBD genetic susceptibility, mode of action, animal models.

(4) *Milton Rossman, MD, Professor of Medicine, Hospital of the University of Pennsylvania School of Medicine.*

Expertise: pulmonary and clinical medicine, immunology, beryllium sensitization, BeLPT, clinical diagnosis for CBD.

(5) *Kyle Steenland, Ph.D., Professor, Emory University, Rollins School of Public Health.*

Expertise: occupational epidemiology, biostatistics, risk and exposure assessment, lung cancer, CBD, exposure-response models.

Reviewers were provided with the Technical Charge and Instructions (see ERG, 2010), a Request for Peer Review of NIOSH Manuscripts (see ERG, 2010), the draft Preliminary OSHA Health Effects Evaluation (OSHA, 2010a), the draft Preliminary Beryllium Risk Assessment (OSHA, 2010b), and access to relevant references. Each reviewer independently provided comments on the Health Effects, Risk Assessment, and NIOSH documents. A briefing call was held early in the review to ensure that reviewers understood the peer review process. ERG organized the call and OSHA representatives were available to respond to technical questions of clarification. Reviewers were invited to submit any subsequent questions of clarification.

The written comments from each reviewer were received and organized by ERG by charge questions. The unedited individual and reorganized comments were submitted to OSHA and the reviewers in preparation for a follow-up conference call. The conference call, organized and facilitated by ERG, provided an opportunity for OSHA to clarify individual reviewer's comments. After the call, reviewers were given the opportunity to revise their written comments to include the clarifications or additional information provided on the call. ERG submitted the revised comments to OSHA organized by both individual reviewer and by charge question. A final peer review report is available in the docket (ERG, 2010). Section VII.A of this preamble summarizes the comments received on the draft health effects document and OSHA's responses to those comments. Section VII.B summarizes comments received on the draft Preliminary Risk Assessment and the OSHA response.

A. Peer Review of Draft Health Effects Evaluation

The Technical Charge to peer reviewers posed general questions on the draft health effects document as well as specific questions pertaining to particle/chemical properties, kinetics and metabolism, acute beryllium disease, development of beryllium sensitization and CBD, genetic susceptibility, epidemiological studies of sensitization and CBD, animal models of chronic beryllium disease, genotoxicity, lung cancer epidemiological studies, animal cancer studies, other health effects, and preliminary conclusions drawn by OSHA.

OSHA asked the peer reviewers to generally comment on whether the draft health effects evaluation included the important studies, appropriately addressed their strengths and limitations, accurately described the results, and drew scientifically sound conclusions. Overall, the reviewers felt that the studies were described in sufficient detail, the interpretations accurate, and the conclusions reasonable. They agreed that the OSHA document covered the significant health endpoints related to occupational beryllium exposure. However, several reviewers requested that additional studies and other specific information be included in various sections of the document and these are discussed further below.

The reviewers had similar suggestions to improve the section V.A of this preamble on physical/chemical properties and section V.B on kinetics/metabolism. Dr. Balmes requested that physical and chemical characteristics of beryllium more clearly relate to development of sensitization and progression to CBD. Dr. Gordon requested greater consistency in the terminology used to describe particle characteristics, sampling methodologies, and the particle deposition in the respiratory tract. Dr. Breysse agreed and requested that the respiratory deposition discussion be better related to the onset of sensitization and CBD. Dr. Rossman suggested that the discussion of particle/chemical characteristics might be better placed after section V.D on the immunobiology of sensitization and CBD.

OSHA made a number of revisions to sections V.A and V.B to address the peer review comments above. Terminology used to describe particle characteristics in various studies was modified to be more consistent and better reflect the authors' intent in the published research articles. Section V.B.1 on respiratory kinetics of inhaled beryllium was modified to more clearly describe particle deposition in the different regions of the respiratory tract and their influence on CBD. At the recommendation of Dr. Gordon, a confusing figure was removed since it did not portray particle deposition in a clear manner. Rather than relocate the entire discussion of particle/chemical characteristics, a new section V.B.5 was added to specifically address the influence of beryllium particle characteristics and chemical form on the development of sensitization and CBD. Other section areas were shortened to remove information that was not necessarily relevant to the overall disease process. Statements were added on the effect of pre-existing diseases and smoking on beryllium clearance from the lung. It was made clear that the precise role of dermal exposure in beryllium sensitization is not completely understood. These smaller changes were made at the request of individual reviewers.

There were a couple of comments from reviewers pertaining to acute beryllium disease (ABD). Dr. Rossman commented that ABD did not make the development of CBD more likely. He requested that the document include a reference to the Van Ordstrand et al. (1943) article that first reported ABD in the U.S. Dr. Balmes pointed out that pathologists, rather than clinicians, interpret ABD pathology from lung tissue biopsy. Dr. Gordon commented that ABD is of lesser importance than CBD to the risk assessment and suggested that discussion of ABD be moved later in the document.

The Van Ordstrand reference was included in section V.C on acute beryllium diseases and statements were modified to address the peer review comments above. While OSHA agrees that ABD does not have a great impact on the Agency risk findings, the Agency believes the current organization does not create confusion on this point and decided not to move the ABD section later in the document. A statement that ABD is only relevant at exposures higher than the current PEL has been added to section V.C. Other reviewers did not feel the ABD discussion needed to be moved to a later section.

Most reviewers found the description of the development and pathogenesis of CBD in section V.D to be accurate and understandable. Dr. Breysse felt the section could better delineate the steps in disease development (*e.g.,* development of beryllium sensitization, CBD progression) and recommended the 2008 National Academy of Sciences report as a model. He and Dr. Gordon felt the section overemphasized the role of apoptosis in CBD development. Dr. Breysse and Dr. Balmes recommended avoiding the phrase 'subclinical' to describe sensitization and asymptomatic CBD, preferring the term 'early stage' as a more appropriate description. Dr. Balmes requested clarification regarding accumulation of inflammatory cells in the bronchoalveolar lavage (BAL) fluid during CBD development. Dr. Rossman suggested some additional description of beryllium binding with the HLA-class II receptor and subsequent interaction with the naïve $CD4^+$ T cells in the development of sensitization.

OSHA extensively reorganized section V.D to clearly delineate the disease process in a more linear fashion starting with the formation of beryllium antigen complex, its interaction with naïve T-cells to trigger $CD4^+$ T-cell proliferation, and development of beryllium sensitization. This is presented in section V.D.1. A figure has been added that schematically presents this process in its entirety and the steps at which dermal exposure and genetic factors are believed to influence disease development (Figure 2 in section V.D). Section V.D.2 describes how subsequent inhalation and the persistent residual presence of beryllium in the lung leads to $CD4^+$ T cell differentiation, cytokine production, accumulation of inflammatory cells in the alveolar region, granuloma formation, and progression of CBD. The section was modified to present apoptosis as only one of the plausible mechanisms for development/progression of CBD. The 'early stage' terminology was adopted and the role of inflammatory cells in BAL was clarified.

While peer reviewers felt genetic susceptibility was adequately characterized, Dr. Rossman, Dr. Gordon, and Dr. Breysse suggested that additional study data be discussed to provide more depth on the subject, particularly the role genetic polymorphisms in providing a negatively charged HLA protein binding site for the positively charged beryllium ion. Section V.D.3 on genetic susceptibility now includes more information on the importance of gene-environment interaction in the development of CBD in low-exposed workers. The section expands on HLA–DPB1 alleles that influence beryllium-hapten binding and its impact on CBD risk.

All reviewers found the definition of CBD to be clear and understandable. However, several reviewers commented on the document discussion of the BeLPT which operationally defines beryllium sensitization. Drs. Balmes and Rossman requested a more clear statement that two abnormal blood BeLPT results were generally necessary to confirm sensitization. Dr. Balmes and Dr. Breysse requested more discussion of historical changes in the BeLPT method that have led to improvement in test performance and reductions in interlaboratory variability. These comments were addressed in an expanded document section V.D.5.b on criteria for sensitization and CBD case definition following development of the BeLPT.

Reviewers made suggestions to improve presentation of the many epidemiological studies of sensitization and CBD in the draft health effects document. Dr. Breysse and Dr. Gordon recommended that common weaknesses that apply to multiple studies be more rigorously discussed. Dr. Gordon requested that the discussion of the Beryllium Case Registry be modified to clarify the case inclusion criteria. Most reviewers called for the addition of tables to assist in summarizing the epidemiological study information.

A paragraph has been added near the beginning of section V.D.5 that identifies the common challenges to interpreting the epidemiological evidence that supports the occurrence of sensitization and CBD at occupational beryllium exposures below the current PEL. These include studies with small numbers of subjects and CBD cases, potential exposure misclassification resulting from lack of personal and short-term exposure data prior to the late 1990s, and uncertain dermal contribution among other issues. Table A.1 summarizing the key sensitization and CBD epidemiological studies was added to this preamble in appendix A of section V. Subsection V.D.5.a on studies conducted prior to the BeLPT has been reorganized to more clearly present the need for the Registry prior to listing the inclusion criteria.

Several reviewers requested that the draft health effects document discuss additional occupational studies on sensitization and CBD. Dr. Balmes suggested including Bailey et al. (2010) on reduction in sensitization at a beryllium production plant and Arjomandi et al. (2010) on CBD among workers in a nuclear weapons facility. Dr. Breysse recommended adding a brief discussion of Taiwo et al. (2008) on sensitization in aluminum smelter workers. Dr. Gordon and Dr. Rossman suggested mention of Curtis, (1951) on cutaneous hypersensitivity to beryllium as important for the role of dermal exposure. Dr. Rossman also provided a reference to a number of other sensitization and CBD articles of historical significance.

The above studies have been incorporated in several subsections of V.D.5 on human epidemiological evidence. The 1951 Curtis study is mentioned in the introduction to section V.D.5 as evidence of sensitization from dermal exposure. The Bailey *et al.* (2010) study is discussed in subsection V.D.5.d on beryllium metal processing and alloy production. The Arjomandi *et al.* (2010) study is discussed subsection V.D.5.h on nuclear weapons facilities and cleanup of former facilities. The Taiwo *et al.* (2008) study is discussed in subsection V.D.5.i on aluminum smelting. The other historical studies of historical significance are referenced in subsection V.D.5.a on studies conducted prior to the BeLPT.

Dr. Gordon suggested that the draft health effects document make clear that limitations in study design and lack of an appropriate model limited extrapolation of animal findings to the human immune-based respiratory disease. Dr. Rossman also remarked on the lack of a good animal model that consistently demonstrates a specific cell-mediated immune response to beryllium. Section V.D.6 was modified to include a statement that lack of a dependable animal model combined with studies that used single doses, few animals or abbreviated observation periods have limited the utility of the data. Table A.2 was added that summarizes important information on key animal studies of beryllium-induced immune response and lung inflammation.

In general, peer reviewers considered the preliminary conclusions with regard to sensitization and CBD to be reasonable and well presented in the draft health effects evaluation. All reviewers agreed that the scientific evidence supports sensitization as a necessary condition and an early endpoint in the development of CBD.

The peer reviewers did not consider the presented evidence to convincingly show lung burden to be an important dose metric. Dr. Gordon explained that some animal studies in dogs have indicated that lung dose does influence granuloma formation but the importance of dose relative to genetic susceptibility, and physical/chemical form is unclear. He suggested the document indicate that many factors, including lung burden, affect the pulmonary tissue response to beryllium particles in the workplace.

There were other suggested improvements to the preliminary conclusion section of the draft document. Dr. Breysse felt that presenting the range of observed prevalence from occupational studies would help support the Agency findings. He also recommended that the preliminary conclusions make clear that CBD is a very complex disease and certain steps involved in the onset and progression are not yet clearly understood. Dr. Rossman pointed out that a report from Mroz *et al.* (2009) updated information on the rate at which beryllium sensitized individuals progress to CBD.

A statement has been added to section V.D.7 on the preliminary sensitization and CBD conclusions to indicate that all facets of development and progression of sensitization and CBD are not fully understood. Study references and prevalence ranges were provided to support the conclusion that epidemiological evidence demonstrates that sensitization and CBD occur from present-day exposures below OSHA's PEL. Statements were modified to indicate animal studies provide important insights into the roles of chemical form, genetic susceptibility, and residual lung burden in the development of beryllium lung disease. Updated information on rate of progression from sensitization to CBD was also included.

Reviewers made suggestions to improve presentation of the epidemiological studies of lung cancer that were similar to their comments on the CBD studies. Dr. Steenland requested that a table summarizing the lung cancer studies be added. He also recommended that more emphasis be placed on the SMR results from the Ward *et al.* (1992) study. Dr. Balmes felt that more detail was presented on the animal cancer studies than necessary to convey the relevant message. All reviewers thought that the Schubauer-Berigan *et al.* (2010) cohort mortality study that addressed some of the shortcomings of earlier lung cancer mortality studies should be discussed in the health effects document.

The recent Schubauer-Berigan *et al.* (2010) study conducted by the NIOSH Division of Surveillance, Hazard Evaluations, and Field Studies is now described and discussed in section V.E.2 on human epidemiology studies. Table A.3 summarizing the range of exposure measurements, study strengths and limitations, and other key lung cancer epidemiological study information was added to the health effects preamble. Section V.E.3 on the animal cancer studies already contained several tables that present study data so OSHA decided a summary table was not needed in this section.

Reviewers were asked two questions regarding the OSHA preliminary conclusions on beryllium-induced lung cancer: was the inflammation mechanism presented in the lung cancer section reasonable; and were there other mechanisms or modes of action to be considered? All reviewers agreed that inflammation was a reasonable mechanistic presentation as outlined in the document. Dr. Gordon requested OSHA clarify that inflammation may not be the sole mechanism for carcinogenicity. OSHA inserted statements in section V.E.5 on the preliminary lung cancer conclusions clarifying that tumorigenesis secondary to inflammation is a reasonable mechanism of action but other plausible mechanisms independent of inflammation may also contribute to the lung cancer associated with beryllium exposure.

There were a few comments from reviewers on health effects other than sensitization/CBD and lung cancer in the draft document. Dr. Balmes requested that the term ''beryllium poisoning'' not be used when referring to the hepatic effects of beryllium. He also offered language to clarify that the cardiovascular mortality among beryllium production workers in the Ward study cohort was probably due to ischemic heart disease and not the result of impaired lung function. Dr. Gordon requested removal of references to hepatic studies from in vitro and intravenous administration done at very high dose levels of little relevance to the occupational exposures of interest to OSHA. These changes were made to section V.F on other health effects.

B. Peer Review of the Draft Preliminary Risk Assessment

The Technical Charge to peer reviewers for review of the draft preliminary risk assessment was to ensure OSHA selected appropriate study data, assessed the data in a scientifically credible manner, and clearly explained its analysis. Specific charge questions were posed regarding choice of data sets, risk models, and exposure metrics; the role of dermal exposure and dermal protection; construction of the job exposure matrix; characterization of the risk estimates and their uncertainties; and whether a quantitative assessment of lung cancer risk, in addition to sensitization and CBD, was warranted.

Overall, the peer reviewers were highly supportive of the Agency's approach and major conclusions. They offered valuable suggestions for revisions and additional analysis to improve the clarity and certain technical aspects of the risk assessment. These suggestions and the steps taken by OSHA to address them are summarized here. A final peer review report (ERG, 2010c) and a risk assessment background document (OSHA, 2014a) are available in the docket.

OSHA asked peer reviewers a series of questions regarding its selection of surveys from a beryllium ceramics facility, a beryllium machining facility, and a beryllium alloy processing facility as the critical studies that form the basis of the preliminary risk assessment. Research showed that these workplaces had well characterized and relatively low beryllium exposures and underwent plant-wide screenings for sensitization and CBD before and after implementation of exposure controls. The reviewers were requested to comment on whether the study discussions were clearly presented, whether the role of dermal exposure and dermal protection were adequately addressed, and whether the preliminary conclusions regarding the observed exposure-related prevalence and reduction in risk were reasonable and scientifically credible. They were also asked to identify other studies that should be reviewed as part of the sensitization/CBD risk assessment.

Every peer reviewer felt the key studies were appropriate and their selection clearly explained in the document. Every peer reviewer regarded the preliminary conclusions from the OSHA review of these studies to be reasonable and scientifically sound. This conclusion stated that substantial risk of sensitization and CBD were observed in facilities where the highest exposed processes had median full-shift beryllium exposures around 0.2 μg/m^3 or higher and that the greatest reduction in risk was achieved when exposures for all processes were lowered to 0.1 μg/m^3 or below.

The reviewers suggested that three additional studies be added to the risk assessment review of the epidemiological literature. Dr. Balmes felt the document would be strengthened by including the Bailey *et al.* (2010) investigation of sensitization in a population of workers at the beryllium metal, alloy, and oxide production plant in Elmore, OH and the Arjomandi *et al.* (2010) publication on a group of 50 sensitized workers from a nuclear plant. Dr. Breysse suggested the study by Taiwo *et al.* (2008) on sensitization among workers in four aluminum smelters be considered.

A new subsection VI.A.3 was added to the preliminary risk assessment that describes the changes in beryllium exposure measurements, prevalence of sensitization and CBD, and implementation of exposure controls between 1992 and 2006 at the Elmore plant. This subsection includes a discussion of the Bailey *et al.* study. A summary of the Taiwo *et al.* (2008) study was added as subsection VI.A.5. A discussion of the Arjomandi *et al.* (2010) study was added in subsection VI.B as evidence that sensitized workers with primarily low beryllium exposure go on to develop CBD. However, the low rates of CBD among this group of sensitized workers also suggest that low beryllium exposure may reduce CBD risk when compared to worker populations with higher exposure levels.

While the majority of reviewers stated that OSHA adequately addressed the role of dermal exposure in sensitization and the importance of dermal protection for workers, a few had additional suggestions for OSHA's discussion. Dr. Breysse and Dr. Gordon pointed out that because the beryllium exposure control programs featured steps to reduce both skin contact and inhalation, it was difficult to distinguish between the effects of reducing airborne and dermal exposure. A statement was added to subsection VI.B that concurrent implementation of respirator use, dermal protection and engineering changes made it difficult to attribute reduced risk to any single control measure. Since the Cullman plant did not require glove use, OSHA believes it to be the best data set available for evaluating the effects of airborne exposure control on risk of sensitization.

Dr. Breysse requested additional discussion of the role of respiratory protection in achieving reduction in risk. Dr. Gordon suggested some additional clarification regarding mean and median exposure measures. Additional information on respiratory programs and exposure measures (*e.g.,* median, arithmetic and geometric means), where available, were presented for each of the studies discussed in subsection VI.A.

The peer reviewers generally agreed that it was reasonable to conclude that community-acquired CBD (CA–CBD) resulted from low beryllium exposures. Drs. Breysse, Balmes and others noted that higher short-term excursions could not be ruled out. Dr. Gordon suggested that genetic susceptibility may have a role in cases of CA–CBD. Dr. Rossman raised the possibility that some CA–CBD cases could occur from contact with beryllium workers. All these points were added to subsection VI.C.

OSHA asked the peer reviewers to evaluate the choice of the National Jewish Medical and Research Center (NJMRC) data set on the Cullman, AL machinist population as a basis for exposure-response analysis and the reliance on cumulative exposure as the basis for the exposure-response analysis of sensitization and CBD. All peer reviewers indicated that the choice of the NJMRC data set for exposure-response analysis was clearly explained and reasonable and that they knew of no better data set for the analysis. Dr. Rossman commented that the NJMRC data set was an excellent source of exposures to different levels of beryllium and testing and evaluation of the workers. Dr. Steenland and Dr. Gordon suggested that the results from the OSHA analysis of the NJMRC data be compared with the available data from the studies of other beryllium facilities discussed in the epidemiological literature analysis. While a rigorous quantitative comparison (*e.g.,* meta analysis) is difficult due to differences in the study designs and data types available for each study, subsection VI.E.4 compares the results of OSHA's prevalence analysis from the Cullman data with results from studies of the Tucson and Reading facilities.

OSHA asked the peer reviewers to evaluate methods used to construct the job exposure matrix (JEM) and to estimate beryllium exposure for each worker in the NJMRC data set. The JEM procedure was briefly summarized in the review document and described in detail as part of a risk assessment technical background document made available to the reviewers (OSHA, 2014a). Dr. Balmes felt that a more thorough discussion of the JEM would strengthen the preamble document. Dr. Gordon requested information about values assigned exposures below the limit of detection. Dr. Steenland requested that both the preamble and technical background document contain additional information on aspects of the JEM construction such as the job categories, job-specific exposure values, how jobs were grouped, and how non-machining jobs were handled in the JEM. He suggested the entire JEM be included in the technical background document. OSHA greatly expanded subsection VI.E.2 on air sampling and JEM to include more detailed discussion of the JEM construction. Exposure values for machining and non-machining job titles were provided in Tables VI–4 and VI–5. The procedures and rationale for grouping job-specific measurements into four time periods was explained. Jobs were not grouped in the JEM; rather, individual exposure estimates were created for each job in the work history data set. The technical background document further clarifies the JEM construction and the full JEM is included as an appendix to the revised background document (OSHA, 2014a). Subsection VI.E.3 on worker exposure reconstruction contains further detail about the work histories.

Peer reviewers fully supported OSHA's choice of the cumulative exposure metric to estimate risk of CBD from the NJMRC data set. As explained by Dr. Steenland, ''cumulative exposure is often the choice for many chronic diseases as opposed to average or highest exposure.'' He pointed out that the cumulative exposure metric also fit the CBD data better than other metrics. The reviewers generally felt that short-term peak exposure was probably the measure of airborne exposure most relevant to risk of beryllium sensitization. However, peer reviewers agreed that data required to capture workers' short-term peak exposures and to relate the peak exposure levels to sensitization were not available. Dr. Breysse explained that ''short-term (hrs to minutes) peak exposures may be important to sensitization risk, while long term averages are more important for CBD risk. Unfortunately data for short-term peak exposures may not exist.'' Dr. Steenland explained that of the available metrics ''cumulative exposure fits the sensitization data better than the two alternatives, and hence is the best metric.'' Statements were added to subsection VI.E.3 to indicate that while short-term exposures may be highly relevant to risk of sensitization, the individual peak exposures leading up to onset of sensitization was not able to be determined in the NJRMC Cullman study.

Peer reviewers found the methods used in the statistical exposure-response analysis to be clearly described. With the exception of Dr. Steenland, reviewers believed that a detailed critique of the statistical approach was beyond their level of expertise. Dr. Steenland supported OSHA's overall approach to the risk modeling and recommended additional analyses to explore the sensitivity of OSHA's results to alternate choices and to test the validity of aspects of the analysis. Dr. Steenland recommended that the logistic regression used by OSHA as a preliminary first analysis be dropped as an inappropriate model for a situation where it is important to account for changing exposures and case onset over time. Instead, he suggested a sensitivity analysis in which exposure-response coefficients generated using a traditional Cox proportionate hazards model be compared to the discrete time Cox model analog (*i.e.,* complementary log-log Cox model) used by OSHA. The sensitivity analysis would facilitate examination of the proportional hazard assumption implied by the use of these models. Dr. Steenland advocated that OSHA include a table that displayed the mean number of BeLPT tests for the study population in order to address whether the number of sensitization tests introduced a potential bias. He inquired about the possibility of determining a sensitization incidence rate using cumulative or average exposure. Dr. Steenland suggested that the model control for additional potential confounders, such as age, smoking status, race and gender. He wanted a more complete explanation of the model constant for the year of diagnosis in Tables VI–9 through VI–12 to be included in the preamble as it was in the technical background document. Dr. Steenland recommended a sensitivity analysis that excludes the highest 5 to 10 percent of cumulative exposures which might address potential model uncertainty at the high end exposures. He requested that the results of statistical tests for non-linearity be included and confidence intervals for the risk estimates in Tables VI–17 and VI–18 be determined.

Many of Dr. Steenland's comments were addressed in subsection VI.F on the statistical modeling. The logistic regression analysis was removed from the section. A sensitivity analysis using the standard Cox model that treats survival time as continuous rather than discrete was added to the risk assessment background document and results were described in subsection VI.F. The interaction between exposure and follow-up time was not significant in the models suggesting that the proportional hazard assumption should not be rejected. The model coefficients using the standard Cox model were similar to model coefficients for the discrete model. Given this, OSHA did not feel it necessary to further estimate risks using the continuous Cox model at specific exposure levels.

A table of the mean number of BeLPT tests across the study population was added to the risk assessment background document. Subsection VI.F describes the table results and its impact on the statistical modeling. Smoking status and age were included in the discrete Cox proportional hazards model and not found to be significant predictors of beryllium sensitization. However, the available study population composition did not allow a confounder analysis of race and gender. OSHA chose not to include a detailed explanation of the model constant for the year of diagnosis in the preamble section. OSHA agrees with Dr. Steenland that the risk assessment background document adequately describes the model terms. For that reason, OSHA prefers that the risk assessment preamble focus on the results and major points of the analysis and refer the reader to the more technical background document for an explanation of model parameters. The linearity assumption was assessed using a fractional polynomial approach. The best fitting polynomials did not fit significantly better than the linear model. The details of the analysis were included in the risk assessment background document. Tables VI–17 and VI–18 now include the upper 95 percent confidence limits on the model-predicted cases of sensitization and CBD for the current and alternative PELs.

Most peer reviewers felt the major uncertainties of the risk assessment were clearly and adequately discussed in the documents they reviewed. Dr. Breysse requested that the risk assessment cover potential underestimation of risk from exposure misclassification bias. He requested further discussion of the degree to which the risk estimates from the Cullman machining plant could be extrapolated to workplaces that use other physical (*e.g.,* particle size) and chemical forms of beryllium. He went on to question the strength of evidence that insoluble forms of beryllium cause CBD. Dr. Breysse also suggested that the assumptions used in the risk modeling be consolidated and more clearly presented. Dr. Steenland felt that there was potential underestimation of CBD risk resulting from exclusion of former workers and case status of current workers after employment.

Discussion of these uncertainties was added in the final paragraphs of section VI.F. The section was modified to more clearly identify assumptions with regard to the risk modeling such as an assumed linearity in exposure-response and cumulative dose equivalency when extrapolating risks over a 45-year working lifetime. Section VI.F recognizes the uncertainties in risk that can result from reconstructing individual exposures with very limited sampling data prior to 1994. The potential exposure misclassification can limit the strength of exposure-response relationships and result in the underestimation of risk. A more technical discussion of modeling assumptions and exposure measurement error are provided in the risk assessment background document. Section VI.F points out that the NJMRC data set does not capture CBD that occurred among workers who retired or left the Cullman plant. This and the short follow-up time is a source of uncertainty that likely leads to underestimation of risk. The section indicates that it is not unreasonable to expect the risk estimates to generally reflect onset of sensitization and CBD from exposure to beryllium forms that are relatively insoluble and enriched with respirable particles as encountered at the Cullman machining plant. Additional uncertainty is introduced when extrapolating the risk estimates to beryllium compounds of vastly different solubility and particle characteristics. OSHA does not agree with the comment suggesting that the association between CBD and insoluble forms of beryllium is weak. The principle sources of beryllium encountered at the Cullman machining plant, the Reading copper beryllium processing plant and the Tucson ceramics plant where excessive CBD was observed are insoluble forms of beryllium, such as beryllium metal, beryllium alloy, and beryllium oxide.

Finally, OSHA asked the peer reviewers to evaluate its treatment of lung cancer in the earlier draft preliminary risk assessment (OSHA, 2010b). When that document was prepared, OSHA had elected not to conduct a lung cancer risk assessment. The Agency believed that the exposure-response data available to conduct a lung cancer risk assessment from a Sanderson *et al.* study of a Reading, PA beryllium plant by was highly problematic. The Sanderson study primarily involved workers with extremely high and short-term exposures above airborne exposure levels of interest to OSHA (2 μg/m³ and below).

Just prior to arranging the peer review, a NIOSH study was published by Schubauer-Berigan *et al.* updating the Reading, PA cohort studied by Sanderson *et al.* and adding cohorts from two additional plants in Elmore, OH and Hazleton, PA (Schubauer-Berigan, 2011). At OSHA's request, the peer reviewers reviewed this study to determine whether it could provide a better basis for lung cancer risk analysis than the Sanderson *et al.* study. The reviewers found that the NIOSH update addressed the major concerns OSHA had expressed about the Sanderson study. In particular, they pointed out that workers in the Elmore and Hazleton cohorts had longer tenure at the plants and experienced lower exposures than those at the Reading, PA plant. Dr. Steenland recommended that ''OSHA consider the new NIOSH data and develop risk estimates for lung cancer as well as sensitization and CBD.'' Dr. Breysse believed that the NIOSH data ''suggest that a risk assessment for lung cancer should be conducted by OSHA and the results be compared to the CBD/sensitization risk assessment before recommending an appropriate exposure concentration.'' While acknowledging the improvements in the quality of the data, other reviewers were more restrained in their support for quantitative estimates of lung cancer risk. Dr. Gordon stated that despite improvements, there was ''still uncertainty associated with the paucity of data below the current PEL of 2 μg/m³.'' Dr. Rossman noted that the NIOSH study ''did not address the problem of the uncertainty of the mechanism of beryllium carcinogenicity.'' He felt that the updated NIOSH lung cancer mortality data ''should not change the Agency's rationale for choosing to establish its risk findings for the proposed rule on its analysis for beryllium sensitization and CBD.'' Dr. Balmes agreed that ''the agency will be on firmer ground by focusing on sensitization and CBD.''

The preliminary risk assessment preamble subsection VI.G on lung cancer includes a discussion of the quantitative lung cancer risk assessment published by NIOSH researchers in 2010 (Schubauer-Berigan, 2011). The discussion describes the lower exposure levels, longer tenure, fewer short-term workers and additional years of observation that make the data more suitable for risk assessment. NIOSH relied on several modeling approaches to show that lung cancer risk was significantly related to both mean and cumulative beryllium exposure. Subsection VI.G provides the excess lifetime lung cancer risks predicted from several best-fitting NIOSH models at beryllium exposures of interest to OSHA (Table VI–20). Using the piecewise log-linear proportional hazards model favored by NIOSH, there is a projected drop in excess lifetime lung cancer risks from approximately 61 cases per 1000 exposed workers at the current PEL of 2.0 μg/m³ to approximately 6 cases per 1000 at the proposed PEL of 0.2 μg/m³. Subsection VI.H on preliminary conclusions indicates that these projections support a reduced risk of lung cancer from more stringent control of beryllium exposures but that the lung cancer risk estimates are more uncertain than those for sensitization and CBD.

VIII. Significance of Risk

To promulgate a standard that regulates workplace exposure to toxic materials or harmful physical agents, OSHA must first determine that the standard reduces a ''significant risk'' of ''material impairment.'' The first part of this requirement, ''significant risk,'' refers to the likelihood of harm, whereas the second part, ''material impairment,'' refers to the severity of the consequences of exposure.

The Agency's burden to establish significant risk is based on the requirements of the OSH Act (29 U.S.C. 651 *et seq*). Section 3(8) of the Act requires that workplace safety and health standards be ''reasonably necessary or appropriate to provide safe or healthful employment'' (29 U.S.C. 652(8)). The Supreme Court, in the *Benzene* decision, interpreted section 3(8) to mean that ''before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe'' (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 642 (1980) (plurality opinion)). Examining section 3(8) more closely, the Court described OSHA's obligation to demonstrate significant risk:

> ''[S]afe'' is not the equivalent of ''risk-free.'' A workplace can hardly be considered ''unsafe'' unless it threatens the workers with a significant risk of harm. Therefore, before the Secretary can promulgate *any* permanent health or safety standard, he must make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices (*Id*).

As the Court made clear, the Agency has considerable latitude in defining significant risk and in determining the significance of any particular risk. The Court did not specify a means to distinguish significant from insignificant risks, but rather instructed OSHA to develop a reasonable approach to making a significant risk determination. The Court stated that ''it is the Agency's responsibility to determine in the first instance what it considers to be a 'significant' risk,'' (448 U.S. at 655) and it did not express ''any opinion on the . . . difficult question of what factual determinations would warrant a conclusion that significant risks are present which make promulgation of a new standard reasonably necessary or appropriate'' (448 U.S. at 659). The Court also stated that, while OSHA's significant risk determination must be supported by substantial evidence, the Agency ''is not required to support the finding that a significant risk exists with anything approaching scientific certainty'' (448 U.S. at 656). Furthermore:

> A reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge . . . . [T]he Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection [so long as such assumptions are based on] a body of reputable scientific thought (448 U.S. at 656).

Thus, to make the significance of risk determination for a new or proposed standard, OSHA uses the best available scientific evidence to identify material health impairments associated with potentially hazardous occupational exposures and to evaluate exposed workers' risk of these impairments.

The OSH Act also requires that the Agency make a finding that the toxic material or harmful physical agent at issue causes material impairment to worker health. In that regard, the Act directs the Secretary of Labor to set standards based on the available evidence where no employee, over his/her working life time, will suffer from material impairment of health or functional capacity, even if such employee has regular exposure to the hazard, to the extent feasible (29 U.S.C. 655(b)(5)).

As with significant risk, what constitutes material impairment in any given case is a policy determination for which OSHA is given substantial leeway. ''OSHA is not required to state with scientific certainty or precision the exact point at which each type of [harm] becomes a material impairment'' (*AFL–CIO* v. *OSHA,* 965 F.2d 962, 975 (11th Cir. 1992)). Courts have also noted that OSHA should consider all forms and degrees of material impairment—not just death or serious physical harm—and that OSHA may act with a ''pronounced bias towards worker safety'' (*Id; Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (D.C. Cir. 1988)). OSHA's long-standing policy is to consider 45 years as a ''working life,'' over which it must evaluate material impairment and risk.

In formulating this proposed beryllium standard, OSHA has reviewed the best available evidence pertaining to the adverse health effects of occupational beryllium exposure, including lung cancer and chronic beryllium disease (CBD), and has evaluated the risk of these effects from exposures allowed under the current standard as well as the expected impact of the proposed standard on risk. Based on its review of extensive epidemiological and experimental research, OSHA has preliminarily determined that long-term exposure at the current Permissible Exposure Limit (PEL) would pose a significant risk of material impairment to workers' health, and that adoption of the new PEL and other provisions of the proposed rule will substantially reduce this risk.

A. Material Impairment of Health

In this preamble at section V, Health Effects, OSHA reviewed the scientific evidence linking occupational beryllium exposure to a variety of adverse health effects, including CBD and lung cancer. Based on this review, OSHA preliminarily concludes that beryllium exposure causes these effects. The Agency's preliminary conclusion was strongly supported by a panel of independent peer reviewers, as discussed in section VII.

Here, OSHA discusses its preliminary conclusion that CBD and lung cancer constitute material impairments of health, and briefly reviews other adverse health effects that can result from beryllium exposure. Based on this preliminary conclusion and on the scientific evidence linking beryllium exposure to both CBD and lung cancer, OSHA concludes that occupational exposure to beryllium causes ''material impairment of health or functional capacity'' within the meaning of the OSH Act.

1. Chronic Beryllium Disease

CBD is a respiratory disease in which the body's immune system reacts to the presence of beryllium in the lung, causing a progression of pathological changes including chronic inflammation and tissue scarring. CBD can also impair other organs such as the liver, skin, spleen, and kidneys and cause adverse health effects such as granulomas of the skin and lymph nodes and cor pulmonale (*i.e.,* enlargement of the heart) (Conradi *et al.,* 1971; ACCP, 1965; Kriebel *et al.,* 1988a and b). In early, asymptomatic stages of CBD, small granulomatous lesions and mild inflammation occur in the lungs. Early stage CBD among some workers has been observed to progress to more serious disease even after the worker is removed from exposure (Mroz, 2009), probably because common forms of beryllium have slow clearance rates and can remain in the lung for years after exposure. Sood *et al.* has reported that cessation of exposure can sometimes have beneficial effects on lung function (Sood *et al.,* 2004). However, this was based on a small study of six patients with CBD, and more research is needed to better determine the relationship between exposure duration and disease progression. In general, progression of CBD from early to late stages is understood to vary widely, responding differently to exposure cessation and treatment for different individuals (Sood, 2009; Mroz, 2009).

Over time, the granulomas can spread and lead to lung fibrosis (scarring) and moderate to severe loss of pulmonary function, with symptoms including a persistent dry cough and shortness of breath (Saber and Dweik, 2000). Fatigue, night sweats, chest and joint pain, clubbing of fingers (due to impaired oxygen exchange), loss of appetite, and unexplained weight loss may occur as the disease progresses. Corticosteroid therapy, in workers whose beryllium exposure has ceased, has been shown to control inflammation, ease symptoms (*e.g.,* difficulty breathing, fever, cough, and weight loss) and in some cases prevent the development of fibrosis (Marchand-Adam *et al.,* 2008). Thus early treatment can lead to CBD regression in some patients, although there is no cure (Sood, 2004). Other patients have shown short-term improvements from corticosteroid treatment, but then developed serious fibrotic lesions (Marchand-Adam *et al.,* 2008). Once fibrosis has developed in the lungs, corticosteroid treatment cannot reverse the damage (Sood, 2009). Persons with late-stage CBD experience severe respiratory insufficiency and may require supplemental oxygen (Rossman, 1991). Historically, late-stage CBD often ended in death (NAS, 2008).

While the use of steroid therapy has mitigated CBD mortality, treatment with corticosteroids has side effects that need to be measured against the possibility of progression of disease (Trikudanathan and McMahon, 2008; Lipworth, 1999; Gibson *et al.,* 1996; Zaki *et al.,* 1987). Adverse effects associated with long-term corticosteroid use include, but are not limited to, increased risk of opportunistic infections (Lionakis and Kontoyiannis, 2003; Trikudanathan and McMahon, 2008); accelerated bone loss or osteoporosis leading to increased risk of fractures or breaks (Hamida *et al.,* 2011; Lehouck *et al.,* 2011; Silva *et al.,* 2011; Sweiss *et al.,* 2011; Langhammer *et al.,* 2009); psychiatric effects including depression, sleep disturbances, and psychosis (Warrington and Bostwick, 2006; Brown, 2009); adrenal suppression (Lipworth, 1999; Frauman, 1996); ocular effects including cataracts, ocular hypertension, and glaucoma (Ballonzolli and Bourchier, 2010; Trikudanathan and McMahon, 2008; Lipworth, 1999); an increase in glucose intolerance (Trikudanathan and McMahon, 2008); excessive weight gain (McDonough *et al.,* 2008; Torres and Nowson, 2007; Dallman *et al.,* 2007; Wolf, 2002; Cheskin *et al.,* 1999); increased risk of atherosclerosis and other cardiovascular syndromes (Franchimont *et al.,* 2002); skin fragility (Lipworth, 1999); and poor wound healing (de Silva and Fellows, 2010). Studies relating the long-term effect of corticosteroid use for the treatment of CBD need to be undertaken to evaluate the treatment's overall effectiveness against the risk of adverse side effects from continued usage.

OSHA considers late-stage CBD to be a material impairment of health, as it involves permanent damage to the pulmonary system, causes additional serious adverse health effects, can have adverse occupational and social consequences, requires treatment associated with severe and lasting side effects, and may in some cases be life-threatening. Furthermore, OSHA believes that material impairment begins prior to the development of symptoms of the disease.

Although there are no symptoms associated with early-stage CBD, during which small lesions and inflammation appear in the lungs, the Agency has preliminarily concluded that the earliest stage of CBD is material impairment of health. OSHA bases this conclusion on evidence showing that early-stage CBD is a measurable change in the state of health which, with and sometimes without continued exposure, can progress to symptomatic disease. Thus, prevention of the earliest stages of CBD will prevent development of more serious disease. The OSHA Lead Standard established the Agency's position that a 'subclinical' health effect may be regarded as a material impairment of health. In the preamble to that standard, the Agency said:

> OSHA believes that while incapacitating illness and death represent one extreme of a spectrum of responses, other biological effects such as metabolic or physiological changes are precursors or sentinels of disease which should be prevented . . . Rather than revealing beginnings of illness the standard must be selected to prevent an earlier point

of measurable change in the state of health which is the first significant indicator of possibly more severe ill health in the future. The basis for this decision is twofold—first, pathophysiologic changes are early stages in the disease process which would grow worse with continued exposure and which may include early effects which even at early stages are irreversible, and therefore represent material impairment themselves. Secondly, prevention of pathophysiologic changes will prevent the onset of the more serious, irreversible and debilitating manifestations of disease.[11] (43 FR 52952, 52954, November 14, 1978)

Since the Lead rulemaking, OSHA has also found other non-symptomatic health conditions to be material impairments of health. In the Bloodborne Pathogens (BP) rulemaking, OSHA maintained that material impairment includes not only workers with clinically ''active'' hepatitis from the hepatitis B virus (HBV) but also includes asymptomatic HBV ''carriers'' who remain infectious and are able to put others at risk of serious disease through contact with body fluids (*e.g.,* blood, sexual contact) (56 FR 64004, December 6, 1991). OSHA stated: ''Becoming a carrier [of Hepatitis B] is a material impairment of health even though the carrier may have no symptoms. This is because the carrier will remain infectious, probably for the rest of his or her life, and any person who is not immune to HBV who comes in contact with the carrier's blood or certain other body fluids will be at risk of becoming infected'' (56 FR 64004, 64036).

OSHA preliminarily finds that early-stage CBD is the type of asymptomatic health effect the Agency determined to be a material impairment of health in the lead standard. Early stage CBD involves lung tissue inflammation without symptomatology that can worsen with—or without—continued exposure. The lung pathology progresses over time from a chronic inflammatory response to tissue scarring and fibrosis accompanied by moderate to severe loss in pulmonary function. Early stage CBD is clearly a precursor of advanced clinical disease, prevention of which will prevent symptomatic disease. OSHA argued in the Lead standard that such precursor effects should be considered material health impairments in their own right, and that the Agency should act to prevent them when it is feasible to do so. Therefore, OSHA preliminarily finds all stages of CBD to be material impairments of health.

2. Lung Cancer

OSHA considers lung cancer, a frequently fatal disease, to be a material impairment of health. OSHA's finding that inhaled beryllium causes lung cancer is based on the best available epidemiological data, reflects evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations (see this preamble at section V, Health Effects). For example, the International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), and American Conference of Governmental Industrial Hygienists (ACGIH) have all classified beryllium as a known human carcinogen (IARC, 2009).

The Agency's epidemiological evidence comes from multiple studies of U.S. beryllium workers (Sanderson *et al.,* 2001a; Ward *et al.,* 1992; Wagoner *et al.,* 1980; Mancuso *et al.,* 1979). Most recently, a NIOSH cohort study found significantly increased lung cancer mortality among workers at seven beryllium processing facilities (Schubauer-Berigan *et al.,* 2011). The cohort was exposed, on average, to lower levels of beryllium than those in most previous studies, had fewer short-term workers, and had sufficient follow-up time to observe lung cancer in the population. OSHA considers the Schubauer-Berigan study to be the best available epidemiological evidence regarding the risk of lung cancer from beryllium at exposure levels near the PEL.[12]

Supporting evidence of beryllium carcinogenicity comes from various animal studies as well as in vitro genotoxicity and other studies (EPA, 1998; ATSDR, 2002; Gordon and Bowser, 2003; NAS, 2008; Nickell-Brady *et al.,* 1994; NTP, 1999 and 2005; IARC, 1993 and 2009). Multiple mechanisms may be involved in the carcinogenicity of beryllium, and factors such as epigenetics, mitogenicity, reactive oxygen-mediated indirect genotoxicity, and chronic inflammation may contribute to the lung cancer associated with beryllium exposure, although the results of studies testing the direct genotoxicity of beryllium are mixed (EPA summary, 1998). While there is uncertainty regarding the exact mechanism of carcinogenesis for beryllium, the overall weight of evidence for the carcinogenicity of beryllium is strong. Therefore, the Agency has preliminarily determined beryllium to be an occupational carcinogen.

3. Other Impairments

While OSHA has relied primarily on the relationship between occupational beryllium exposure and CBD and lung cancer to demonstrate the necessity of the standard, the Agency has also determined that several other adverse health effects can result from exposure to beryllium. Inhalation of high airborne concentrations of beryllium (well above the 2 $\mu g/m^3$ OSHA PEL) can cause acute beryllium disease, a severe (sometimes fatal), rapid-onset inflammation of the lungs. Hepatic necrosis, damage to the heart and circulatory system, chronic renal disease, mucosal irritation and ulceration, and urinary tract cancer have also reportedly been associated with occupational exposures well above the current PEL (see this preamble at section V, Health Effects, subsection E, Epidemiological Studies, and subsection F, Other Health Effects). These adverse systemic effects and acute beryllium disease mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1972 (OSHA, 1971; ACGIH, 1971; ANSI, 1970) and 1974 (EPA, 1974) and therefore are less relevant today than in the past. Because they occur only rarely in current-day occupational environments, they are not addressed in OSHA's risk analysis or significance of risk determination.

The Agency has also determined that beryllium sensitization, a precursor which occurs before early stage CBD and is an essential step for worker development of the disease, can result from exposure to beryllium. The Agency takes no position at this time on whether sensitization constitutes a material impairment of health, because it was unnecessary to do so as part of this rulemaking. As discussed in Section V, Health Effects, only sensitized individuals can develop CBD (NAS, 2008). OSHA's risk assessment for sensitization informs the Agency's understanding of what exposure control measures have been successful in preventing sensitization, which in turn prevents development of CBD. Therefore sensitization is considered in the next section on significance of risk.

[11] Even if asymptomatic CBD were not itself a material impairment of health, the D.C. Circuit upheld OSHA's authority to regulate to prevent subclinical health effects as precursors to disease in *United Steelworkers of America, AFL–CIO* v. *Marshall,* 647 F.2d 1189, 1252 (D.C. Cir. 1980), which reviewed the Lead standard. Without deciding whether the early symptoms of disease were themselves a material impairment, the court concluded that OSHA may regulate subclinical effects if it can demonstrate on the basis of substantial evidence that preventing subclinical effects would help prevent the clinical phase of disease (*Id.*).

[12] The scientific peer review panel for OSHA's Preliminary Risk Assessment agreed with the Agency that the Schubauer-Berigan analysis improves upon the previously available data for lung cancer risk assessment.

In *AFL–CIO* v. *Marshall,* 617 F.2d 636, 654 n.83 (D.C. Cir. 1979) (*Cotton Dust*), the D.C. Circuit upheld OSHA's authority to regulate to prevent precursors to a material impairment of health without deciding whether the precursors themselves constituted material impairment of health.

B. Significance of Risk and Risk Reduction

To evaluate the significance of the health risks that result from exposure to hazardous chemical agents, OSHA relies on the best available epidemiological, toxicological, and experimental evidence. The Agency uses both qualitative and quantitative methods to characterize the risk of disease resulting from workers' exposure to a given hazard over a working lifetime at levels of exposure reflecting compliance with current standards and compliance with the new standards being proposed.

As discussed above, the Agency's characterization of risk is guided in part by the *Benzene* decision. In *Benzene,* the Court broadly describes the range of risks OSHA might determine to be significant:

> It is the Agency's responsibility to determine in the first instance what it considers to be a ''significant'' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it (*Benzene,* 448 U.S. at 655).

The Court further stated, ''The requirement that a 'significant' risk be identified is not a mathematical straitjacket. . . . Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe', ''and proceed to promulgate a regulation (*Id.*).

In this preamble at section VI, Preliminary Risk Assessment, OSHA finds that the available epidemiological data are sufficient to evaluate risk for beryllium sensitization, CBD, and lung cancer among beryllium-exposed workers. The preliminary findings from this assessment are summarized below.

1. Risk of Beryllium Sensitization and CBD

OSHA's preliminary risk assessment for CBD and beryllium sensitization relies on studies conducted at a Tucson, AZ beryllium ceramics plant (Kreiss *et al.,* 1996; Henneberger *et al.,* 2001; Cummings *et al.,* 2006); a Reading, PA alloy processing plant (Schuler *et al.,* 2005; Thomas *et al.,* 2009); a Cullman, AL beryllium machining plant (Kelleher *et al.,* 2001; Madl *et al.,* 2007); and an Elmore, OH metal, alloy, and oxide production plant (Kreiss *et al.,* 1997; Bailey *et al.,* 2010; Schuler *et al.,* 2012). The Agency uses these studies to demonstrate the significance of risk at the current PEL and the significant reduction in risk expected with reduction of the PEL. In addition to the effects OSHA anticipates from reduction of airborne beryllium exposure, the Agency expects that dermal protection provisions in the proposed rule will further reduce risk. Studies conducted in the 1950s by Curtis *et al.* showed that soluble beryllium particles could penetrate the skin and cause beryllium sensitization (Curtis 1951, NAS 2008). Tinkle *et al.* established that 0.5- and 1.0-μm particles can penetrate intact human skin surface and reach the epidermis, where beryllium particles would encounter antigen-presenting cells and initiate sensitization (Tinkle *et al.,* 2003). Tinkle *et al.* further demonstrated that beryllium oxide and beryllium sulfate, applied to the skin of mice, generate a beryllium-specific, cell-mediated immune response similar to human beryllium sensitization (Tinkle *et al.,* 2003). In the epidemiological studies discussed below, the exposure control programs that most effectively reduced the risk of beryllium sensitization and CBD incorporated both respiratory and dermal protection. OSHA has preliminarily determined that an effective exposure control program should incorporate both airborne exposure reduction and dermal protection provisions.

In the Tucson ceramics plant, 4,133 short-term breathing zone measurements collected between 1981 and 1992 had a median of 0.3 μg/m^3. Kreiss *et al.* reported that eight (5.9 percent) of 136 workers tested for beryllium sensitization in 1992 were sensitized, six (4.4 percent) of whom were diagnosed with CBD. Exposure control programs were initiated in 1992 to reduce workers' airborne beryllium exposure, but the programs did not address dermal exposure. Full-shift personal samples collected between 1994 and 1999 showed a median beryllium exposure of 0.2 μg/m^3 in production jobs and 0.1 μg/m^3 in production support (Cummings *et al.,* 2007). In 1998, a second screening found that 6, (9 percent) of 69 tested workers hired after the 1992 screening, were sensitized, of whom 1 was diagnosed with CBD. All of the sensitized workers had been employed at the plant for less than 2 years (Henneberger *et al.,* 2001), too short a time period for most people to develop CBD following sensitization. Of the 77 Tucson workers hired prior to 1992 who were tested in 1998, 8 (10.4 percent) were sensitized and all but 1 of these (9.7 percent) were diagnosed with CBD (Henneberger *et al.,* 2001).

Kreiss *et al.,* studied workers at a beryllium metal, alloy, and oxide production plant in Elmore, OH. Workers participated in a BeLPT survey in 1992 (Kreiss *et al.,* 1997). Personal lapel samples collected during 1990–1992 had a median value of 1.0 μg/m^3. Kreiss *et al.* reported that 43 (6.9 percent) of 627 workers tested in 1992 were sensitized, 6 of whom were diagnosed with CBD (4.4 percent).

Newman *et al.* conducted a series of BeLPT screenings of workers at a Cullman, AL precision machining facility between 1995 and 1999 (Newman *et al.,* 2001). Personal lapel samples collected at this plant in the early 1980s and in 1995 from all machining processes combined had a median of 0.33 μg/m^3 (Madl *et al.,* 2007). After a sentinel case of CBD was diagnosed at the plant in 1995, the company implemented engineering and administrative controls and PPE designed to reduce workers' beryllium exposures in machining operations. Personal lapel samples collected extensively between 1996 and 1999 in machining jobs have an overall median of 0.16 μg/m^3, showing that the new controls reduced machinists' exposures during this period. However, the results of BeLPT screenings conducted in 1995–1999 showed that the exposure control program initiated in 1995 did not sufficiently protect workers from beryllium sensitization and CBD. In a group of 60 workers who had been employed at the plant for less than a year, and thus would not have been working there prior to 1995, 4 (6.7 percent) were found to be sensitized. Two of these workers (3.35 percent) were diagnosed with CBD. (Newman *et al.,* 2001).

Sensitization and CBD were studied in a population of workers at a Reading, PA copper beryllium plant, where alloys containing a low level of beryllium were processed (Schuler *et al.,* 2005). Personal lapel samples were collected in production and production support jobs between 1995 and May 2000. These samples showed primarily very low airborne beryllium levels, with a median of 0.073 μg/m^3. The wire annealing and pickling process had the highest personal lapel sample values, with a median of 0.149 μg/m³. Despite these low exposure levels, a BeLPT screening conducted in 2000 showed that 5, (11.5 percent) workers of 43 hired after 1992 were sensitized (evaluation for CBD not reported). Two of the sensitized workers had been hired less than a year before the screening (Thomas *et al.,* 2009).

In summary, the epidemiological literature on beryllium sensitization and CBD that OSHA's risk assessment relied on show sensitization prevalences ranging from 6.5 percent to 11.5 percent and CBD prevalences ranging from 1.3 percent to 9.7 percent among workers who had full-shift exposures well below the current PEL and median full-shift exposures at or below the proposed PEL, and whose follow-up time was less than 45 years. As referenced earlier, OSHA is interested in the risk associated with a 45-year (*i.e.,* working lifetime) exposure. Because CBD often develops over the course of years following sensitization, the risk of CBD that would result from 45 years' occupational exposure to airborne beryllium is likely to be higher than the prevalence of CBD observed among these workers.[13] In either case, based on these studies, the risks to workers appear to be significant.

The available epidemiological evidence shows that reducing workers' levels of airborne beryllium exposure can substantially reduce risk of beryllium sensitization and CBD. The best available evidence on effective exposure control programs comes partly from studies of programs introduced around 2000 at Reading, Tucson, and Elmore that used a combination of engineering controls, dermal and respiratory PPE, and stringent housekeeping measures to reduce workers' dermal exposures and airborne exposures to levels well below the proposed PEL of 0.2 μg/m³. These programs have substantially lowered the risk of sensitization among new workers. As discussed earlier, prevention of beryllium sensitization prevents subsequent development of CBD.

In the Reading, PA copper beryllium plant, full-shift airborne exposures in all jobs were reduced to a median of 0.1 μg/m³ or below and dermal protection was required for production-area workers beginning in 2000–2001 (Thomas *et al.,* 2009). After these adjustments were made, 2 (5.4 percent) of 37 newly hired workers became sensitized. Thereafter, in 2002, the process with the highest exposures (median 0.1 μg/m³) was enclosed and workers involved in that process were required to use respiratory protection. As a result, the remaining jobs had very low exposures (medians ~ 0.03 μg/m³). Among 45 workers hired after the enclosure was built and respiratory protection instituted, 1 was found to be sensitized (2.2 percent). This is a sharp reduction in sensitization from the 11.5 percent of 43 workers, discussed above, who were hired after 1992 and had been sensitized by the time of testing in 2000.

In the Tucson beryllium ceramics plant, respiratory and skin protection was instituted for all workers in production areas in 2000. BeLPT testing done in 2000–2004 showed that only 1 (1 percent) worker had been sensitized out of 97 workers hired during that time period (Cummings *et al.*, 2007; testing for CBD not reported). This contrasts with the prevalence of sensitization in the 1998 Tucson BeLPT screening, which found that 6 (9 percent) of 69 workers hired after 1992 were sensitized (Cummings *et al.,* 2007).

The modern Elmore facility provides further evidence that combined reductions in respiratory exposure (via respirator use) and dermal exposure are effective in reducing risk of beryllium sensitization. In Elmore, historical beryllium exposures were higher than in Tucson, Reading, and Cullman. Personal lapel samples collected at Elmore in 1990–1992 had a median of 1.0 μg/m³. In 1996–1999, the company took steps to reduce workers' beryllium exposures, including engineering and process controls (Bailey *et al.*, 2010; exposure levels not reported). Skin protection was not included in the program until after 1999. Beginning in 1999 all new employees were required to wear loose-fitting powered air-purifying respirators (PAPR) in manufacturing buildings (Bailey *et al.*, 2010). Skin protection became part of the protection program for new employees in 2000, and glove use was required in production areas and for handling work boots beginning in 2001. Bailey *et al.*, (2010) compared the occurrence of beryllium sensitization and CBD in 2 groups of workers: 1) 258 employees who began work at the Elmore plant between January 15, 1993 and August 9, 1999 (the ''pre-program group'') and were tested in 1997 and 1999, and 2) 290 employees who were hired between February 21, 2000 and December 18, 2006 and underwent BeLPT testing in at least one of frequent rounds of testing conducted after 2000 (the ''program group''). They found that, as of 1999, 23 (8.9 percent) of the pre-program group were sensitized to beryllium. The prevalence of sensitization among the ''program group'' workers, who were hired after the respiratory protection and PPE measures were put in place, was around 2–3 percent. Respiratory protection and skin protection substantially reduced, but did not eliminate, risk of sensitization. Evaluation of sensitized workers for CBD was not reported.

OSHA's preliminary risk assessment also includes analysis of a data set provided to OSHA by the National Jewish Research and Medical Center (NJMRC). The data set describes a population of 319 beryllium-exposed workers at a Cullman, AL machining facility. It includes exposure samples collected between 1980 and 2005, and has updated work history and screening information for over three hundred workers through 2003. Seven (2.2 percent) workers in the data set were reported as sensitized only. Sixteen (5.0 percent) workers were listed as sensitized and diagnosed with CBD upon initial clinical evaluation. Three (1.0 percent) workers, first shown to be sensitized only, were later diagnosed with CBD. The data set includes workers exposed at airborne beryllium levels near the proposed PEL, and extensive exposure data collected in workers' breathing zones, as is preferred by OSHA. Unlike the Tucson, Reading, and Elmore facilities, respirator use was not generally required for workers at the Cullman facility. Thus, analysis of this data set shows the risk associated with varying levels of airborne exposure, rather than the virtual elimination of airborne exposure via respiratory PPE. Also unlike the Tucson, Elmore, and Reading facilities, glove use was not reported to be mandatory in the Cullman facility. Thus, OSHA believes reductions in risk at the Cullman facility to be the result of airborne exposure control, rather than the combination of airborne and dermal exposure controls at the Tucson, Elmore, and Reading facilities.

OSHA analyzed the prevalence of beryllium sensitization and CBD among workers at the Cullman facility who were exposed to airborne beryllium levels at and below the current PEL of 2 μg/m³. In addition, a statistical modeling analysis of the NJMRC Cullman data set was conducted under contract with Dr. Roslyn Stone of the University of Pittsburgh Graduate School of Public Heath, Department of Biostatistics. OSHA summarizes these analyses briefly below, and in more detail in this preamble at section VI, Preliminary Risk Assessment.

[13] This point was emphasized by members of the scientific peer review panel for OSHA's Preliminary Risk Assessment (see this preamble at section VII).

Tables 1 and 2 below present the prevalence of sensitization and CBD cases across several categories of lifetime-weighted (LTW) average and highest-exposed job (HEJ) exposure at the Cullman facility. The HEJ exposure is the exposure level associated with the highest-exposure job and time period experienced by each worker. The columns ''Total'' and ''Total percent'' refer to all sensitized workers in the dataset, including workers with and without a diagnosis of CBD.

TABLE 1—PREVALENCE OF SENSITIZATION AND CBD BY LIFETIME WEIGHTED AVERAGE EXPOSURE QUARTILE, CULLMAN, AL MACHINING FACILITY

LTW Average exposure (μg/m³)	Group size	Sensitized only	CBD	Total	Total %	CBD %
0.0–0.080	91	1	1	2	2.2	1.0
0.081–0.18	73	2	4	6	8.2	5.5
0.19–0.51	77	0	6	6	7.8	7.8
0.51–2.15	78	4	8	12	15.4	10.3
Total	319	7	19	26	8.2	6.0

Source: Section VI, Preliminary Risk Assessment.

TABLE 2—PREVALENCE OF SENSITIZATION AND CBD BY HIGHEST-EXPOSED JOB EXPOSURE QUARTILE, CULLMAN, AL MACHINING FACILITY

HEJ Exposure (μg/m³)	Group size	Sensitized only	CBD	Total	Total %	CBD %
0.0–0.086	86	1	0	1	1.2	0.0
0.091–0.214	81	1	6	7	8.6	7.4
0.387–0.691	76	2	9	11	14.5	11.8
0.954–2.213	76	3	4	7	9.2	5.3
Total	319	7	19	26	8.2	6.0

Source: Section VI, Preliminary Risk Assessment.

The current PEL of 2 μg/m³ is close to the upper bound of the highest quartile of LTW average (0.51–2.15 μg/m³) and HEJ (0.954–2.213) exposure levels. In the highest quartile of LTW average exposure, there were 12 cases of sensitization (15.4 percent), including 8 (10.3 percent) diagnosed with CBD. Notably, the Cullman workers had been exposed to beryllium dust for considerably less than 45 years at the time of testing. A high prevalence of sensitization (9.2 percent) and CBD (5.3 percent) is seen in the top quartile of HEJ exposure as well, with even higher prevalences in the third quartile (0.387–0.691 μg/m³).[14]

The proposed PEL of 0.2 μg/m³ is close to the upper bound of the second quartile of LTW average (0.81–0.18 μg/m³) and HEJ (0.091–0.214 μg/m³) exposure levels and to the lower bound of the third quartile of LTW average (0.19–0.50 μg/m³) exposures. The second quartile of LTW average exposure shows a high prevalence of beryllium-related health effects, with six workers sensitized (8.2 percent), of whom four (5.5 percent) were diagnosed with CBD. The second quartile of HEJ exposure also shows a high prevalence of beryllium-related health effects, with seven workers sensitized (8.6 percent), of whom 6 (7.4 percent) were diagnosed with CBD. Among six sensitized workers in the third quartile of LTW average exposures, all were diagnosed with CBD (7.8 percent). The prevalence of CBD among workers in these quartiles was approximately 5–8 percent, and overall sensitization (including workers with and without CBD) was about 8 percent. OSHA considers these rates as evidence that the risk of developing CBD is significant among workers exposed at and below the current PEL, even down to the proposed PEL. Much lower prevalences of sensitization and CBD were found among workers with exposure levels less than or equal to about 0.08 μg/m³. Two sensitized workers (2.2 percent), including 1 case of CBD (1.0 percent), were found among workers with LTW average exposure levels and HEJ exposure levels less than or equal to 0.08 μg/m³ and 0.086 μg/m³, respectively. Strict control of airborne exposure to levels below 0.1 μg/m³ can, therefore, significantly reduce risk of sensitization and CBD. Although OSHA recognizes that maintaining exposure levels below 0.1 μg/m³ may not be feasible in some operations (see this preamble at section IX, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis), the Agency believes that workers in facilities that meet the proposed action level of 0.1 μg/m³ will be at less risk of sensitization and CBD than workers in facilities that cannot meet the action level.

Table 3 below presents the prevalence of sensitization and CBD cases across cumulative exposure quartiles, based on the same Cullman data used to derive Tables 1 and 2. Cumulative exposure is the sum of a worker's exposure across the duration of his employment.

[14] This exposure-response pattern is sometimes attributed to a ''healthy worker effect'' or to exposure misclassification, as discussed in this preamble at section VI, Preliminary Risk Assessment.

TABLE 3—PREVALENCE OF SENSITIZATION AND CBD BY CUMULATIVE EXPOSURE QUARTILE CULLMAN, AL MACHINING FACILITY

Cumulative exposure (μg/m³ yrs)	Group size	Sensitized only	CBD	Total	Total %	CBD %
0.0–0.147	81	2	2	4	4.9	2.5
0.148–1.467	79	0	2	2	2.5	2.5
1.468–7.008	79	3	8	11	13.9	8.0
7.009–61.86	80	2	7	9	11.3	8.8
Total	319	7	19	26	8.2	6.0

Source: Section VI, Preliminary Risk Assessment.

A 45-year working lifetime of occupational exposure at the current PEL would result in 90 μg/m³-years, a value far higher than the cumulative exposures of workers in this data set, who worked for periods of time less than 45 years and whose exposure levels were mostly well below the PEL. Workers with 45 years of exposure to the proposed PEL would have a cumulative exposure (9 μg/m³-years) in the highest quartile for this worker population. As with the average and HEJ exposures, the greatest risk of sensitization and CBD appears at high exposure levels (≤ 1.468 μg/m³-years). The third cumulative quartile, at which a sharp increase in sensitization and CBD appears, is bounded by 1.468 and 7.008 μg/m³-years. This is equivalent to 0.73–3.50 years of exposure at the current PEL of 2 μg/m³, or 7.34–35.04 years of exposure at the proposed PEL of 0.2 μg/m³. Prevalence of both sensitization and CBD is substantially lower in the second cumulative quartile (0.148–1.467 μg/m³-years). This is equivalent to approximately 0.7 to 7 years at the proposed PEL of 0.2 μg/m³, or 1.5 to 15 years at the proposed action level of 0.1 μg/m³. This supports that maintaining exposure levels below the proposed PEL, where feasible, will help to protect long-term workers against risk of beryllium sensitization and early stage CBD.

As discussed in the Health Effects section (V.D), CBD often worsens with increased time and level of exposure. In a longitudinal study, workers initially identified as beryllium sensitized through workplace surveillance developed early stage CBD defined by granulomatous inflammation but no apparent physiological abnormalities (Newman *et al.,* 2005). A study of workers with this early stage CBD showed significant declines in breathing capacity and gas exchange over the 30 years from first exposure (Mroz *et al.,* 2009). Many of the workers went on to develop more severe disease that required immunosuppressive therapy despite being removed from exposure. While precise beryllium exposure levels were not available on the individuals in these studies, most started work in the 1980s and 1990s and were likely exposed to average levels below the current 2 μg/m³ PEL. The evidence for time-dependent disease progression indicates that the CBD risk estimates for a 45-year lifetime exposure at the current PEL will include a higher proportion of individuals with advanced clinical CBD than found among the workers in the NJMRC data set.

Studies of community-acquired (CA) CBD support the occurrence of advanced clinical CBD from long-term exposure to airborne beryllium (Eisenbud, 1998; Maier *et al.,* 2008). A discussion of the study findings can be found in this preamble at section VI.C, Preliminary Risk Assessment. For example, one study evaluated 16 potential cases of CA–CBD in individuals that resided near a beryllium production facility in the years between 1943 and 2001 (Maier *et al.,* 2008). Five cases of definite CBD and three cases of probable CBD were found. Two of the subjects with probable cases died before they could be confirmed with the BeLPT; the third had an abnormal BeLPT and radiography consistent with CBD, but granulomatous disease was not pathologically proven. The individuals with CA–CBD identified in this study suffered significant health impacts from the disease, including obstructive, restrictive, and gas exchange pulmonary defects. Six of the eight cases required treatment with prednisone, a step typically reserved for severe cases due to the adverse side effects of steroid treatment. Despite treatment, three had died of respiratory impairment as of 2002. There was insufficient information to estimate exposure to the individuals, but the limited amount of ambient air sampling in the 1950s suggested that average beryllium levels in the area where the cases resided were below 2 μg/m³. The authors concluded that ''low levels of exposures with significant disease latency can result in significant morbidity and mortality'' (Maier *et al.,* 2008, p. 1017).

OSHA believes that the literature review, prevalence analysis, and the evidence for time-dependent progression of CBD described above provide sufficient information to draw preliminary conclusions about significance of risk, and that further quantitative analysis of the NJMRC data set is not necessary to support the proposed rule. The studies OSHA used to support its preliminary conclusions regarding risk of beryllium sensitization and CBD were conducted at modern industrial facilities with exposure levels in the range of interest for this rulemaking, so a model is not needed to extrapolate risk estimates from high to low exposures, as has often been the case in previous rules. Nevertheless, the Agency felt further quantitative analysis might provide additional insight into the exposure-response relationship for sensitization and CBD.

Using the NJMRC data set, Dr. Stone ran a complementary log-log proportional hazards model, an extension of logistic regression that allows for time-dependent exposures and differential time at risk. Relative risk of sensitization increased with cumulative exposure ($p = 0.05$). A positive, but not statistically significant association was observed with LTW average exposure ($p = 0.09$). There was little association with highest-exposed job (HEJ) exposure ($p = 0.3$). Similarly, the proportional hazards models for the CBD endpoint showed positive relationships with cumulative exposure ($p = 0.09$), but LTW average exposure and HEJ exposure were not closely related to relative risk of CBD (p-values > 0.5). Dr. Stone used the cumulative exposure models to generate risk estimates for sensitization and CBD.

Tables 4 and 5 below present risk estimates from these models, assuming 5, 10, 20, and 45 years of beryllium exposure. The tables present sensitization and CBD risk estimates based on year-specific intercepts, as explained in the section on Risk Assessment and the accompanying background document. Each estimate represents the number of sensitized workers the model predicts in a group of 1000 workers at risk during the given year with an exposure history at the specified level and duration. For example, in the exposure scenario for 1995, if 1000 workers were occupationally exposed to 2 μg/m^3 for 10 years, the model predicts that about 56 (55.7) workers would be identified as sensitized. The model for CBD predicts that about 42 (41.9) workers would be diagnosed with CBD that year. The year 1995 shows the highest risk estimates generated by the model for both sensitization and CBD, while 1999 and 2002 show the lowest risk estimates generated by the model for sensitization and CBD, respectively. The corresponding 95 percent confidence intervals are based on the uncertainty in the exposure coefficient.

TABLE 4a—PREDICTED CASES OF SENSITIZATION PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATE PELs BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 1995 BASELINE.

1995	Exposure duration							
Exposure level (μg/m^3)	5 years		10 years		20 years		45 years	
	Cumulative (μg/m^3-yrs)	cases/1000	μg/m^3-yrs	cases/1000	μg/m^3-yrs	cases/1000	μg/m^3-yrs	cases/1000
2.0	10.0	41.1 30.3–56.2	20.0	55.7 30.3–102.9	40.0	101.0 30.3–318.1	90.0	394.4 30.3–999.9
1.0	5.0	35.3 30.3–41.3	10.0	41.1 30.3–56.2	20.0	55.7 30.3–102.9	45.0	116.9 30.3–408.2
0.5	2.5	32.7 30.3–35.4	5.0	35.3 30.3–41.3	10.0	41.1 30.3–56.2	22.5	60.0 30.3–119.4
0.2	1.0	31.3 30.3–32.3	2.0	32.2 30.3–34.3	4.0	34.3 30.3–38.9	9.0	39.9 30.3–52.9
0.1	0.5	30.8 30.3–31.3	1.0	31.3 30.3–32.3	2.0	32.2 30.3–34.3	4.5	34.8 30.3–40.1

Source: Section VI, Preliminary Risk Assessment.

TABLE 4b—PREDICTED CASES OF SENSITIZATION PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATE PELs BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 1999 BASELINE.

1999	Exposure duration							
Exposure level (μg/m^3)	5 years		10 years		20 years		45 years	
	Cumulative (μg/m^3-yrs)	cases/1000	μg/m^3-yrs	cases/1000	μg/m^3-yrs	cases/1000	μg/m^3-yrs	cases/1000
2.0	10.0	8.4 6.2–11.6	20.0	11.5 6.2–21.7	40.0	21.3 6.2–74.4	90.0	96.3 6.2–835.4
1.0	5.0	7.2 6.2–8.5	10.0	8.4 6.2–11.6	20.0	11.5 6.2–21.7	45.0	24.8 6.2–100.5
0.5	2.5	6.7 6.2–7.3	5.0	7.2 6.2–8.5	10.0	8.4 6.2–11.6	22.5	12.4 6.2–25.3
0.2	1.0	6.4 6.2–6.6	2.0	6.6 6.2–7.0	4.0	7.0 6.2–8.0	9.0	8.2 6.2–10.9
0.1	0.5	6.3 6.2–6.4	1.0	6.4 6.2–6.6	2.0	6.6 6.2–7.0	4.5	7.1 6.2–8.2

Source: Section VI, Preliminary Risk Assessment.

TABLE 5a—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELs BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 1995 BASELINE.

1995	Exposure duration							
Exposure level (μg/m^3)	5 years		10 years		20 years		45 years	
	Cumulative (μg/m^3-yrs)	Estimated cases/1000 (95% c.i.)	μg/m^3-yrs	Estimated cases/1000 (95% c.i.)	μg/m^3-yrs	Estimated cases/1000 (95% c.i.)	μg/m^3-yrs	Estimated cases/1000 (95% c.i.)
2.0	10.0	30.9 22.8–44.0	20.0	41.9 22.8–84.3	40.0	76.6 22.8–285.5	90.0	312.9 22.8–999.9
1.0	5.0	26.6 22.8–31.7	10.0	30.9 22.8–44.0	20.0	41.9 22.8–84.3	45.0	88.8 22.8–375.0

TABLE 5a—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 1995 BASELINE.—Continued

1995	Exposure duration							
	5 years		10 years		20 years		45 years	
Exposure level (μg/m³)	Cumulative (μg/m³-yrs)	Estimated cases/1000 (95% c.i.)	μg/m³-yrs	Estimated cases/1000 (95% c.i.)	μg/m³-yrs	Estimated cases/1000 (95% c.i.)	μg/m³-yrs	Estimated cases/1000 (95% c.i.)
0.5	2.5	24.6 22.8–26.9	5.0	26.6 22.8–31.7	10.0	30.9 22.8–44.0	22.5	45.2 22.8–98.9
0.2	1.0	23.5 22.8–24.3	2.0	24.2 22.8–26.0	4.0	25.8 22.8–29.7	9.0	30.0 22.8–41.3
0.1	0.5	23.1 22.8–23.6	1.0	23.5 22.8–24.3	2.0	24.2 22.8–26.0	4.5	26.2 22.8–30.7

Source: Section VI, Preliminary Risk Assessment.

TABLE 5b—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 2002 BASELINE.

2002	Exposure duration							
	5 years		10 years		20 years		45 years	
Exposure level (μg/m³)	Cumulative (μg/m³-yrs)	Estimated cases/1000 (95% c.i.)	μg/m³-yrs	Estimated cases/1000 (95% c.i.)	μg/m³-yrs	Estimated cases/1000 (95% c.i.)	μg/m³-yrs	Estimated cases/1000 (95% c.i.)
2.0	10.0	3.7 2.7–5.3	20.0	5.1 2.7–10.4	40.0	9.4 2.7–39.2	90.0	43.6 2.7–679.8
1.0	5.0	3.2 2.7–3.8	10.0	3.7 2.7–5.3	20.0	5.1 2.7–10.4	45.0	11.0 2.7–54.3
0.5	2.5	3.0 2.7–3.2	5.0	3.2 2.7–3.8	10.0	3.7 2.7–5.3	22.5	5.5 2.7–12.3
0.2	1.0	2.8 2.7–2.9	2.0	2.9 2.7–3.1	4.0	3.1 2.7–3.6	9.0	3.6 2.7–5.0
0.1	0.5	2.8 2.7–2.8	1.0	2.8 2.7–2.9	2.0	2.9 2.7–3.1	4.5	3.1 2.7–3.7

Source: Section VI, Preliminary Risk Assessment.

As shown in Tables 4 and 5, the exposure-response models Dr. Stone developed based on the Cullman data set predict a high risk of both sensitization (about 96–394 cases per 1000 exposed workers) and CBD (about 44–313 cases per 1000) at the current PEL of 2 μg/m³ for an exposure duration of 45 years (90 μg/m³-yr). For a 45-year exposure at the proposed PEL of 0.2 μg/m³, risk estimates for sensitization (about 8–40 cases per 1000 exposed workers) and CBD (about 4–30 per 1000 exposed workers) are substantially reduced. Thus, the model predicts that the risk of sensitization and CBD at a PEL of 0.2 μg/m³ will be about 10 percent of the risk at the current PEL of 2 μg/m³.

OSHA does not believe the risk estimates generated by these exposure-response models to be highly accurate. Limitations of the analysis include the size of the dataset, relatively sparse exposure data from the plant's early years, study size-related constraints on the statistical analysis of the dataset, and limited follow-up time on many workers. The Cullman study population is a relatively small group and can support only limited statistical analysis. For example, its size precludes inclusion of multiple covariates in the exposure-response models or a two-stage exposure-response analysis to model both sensitization and the subsequent development of CBD within the subpopulation of sensitized workers. The limited size of the Cullman dataset is characteristic of studies on beryllium-exposed workers in modern, low-exposure environments, which are typically small-scale processing plants (up to several hundred workers, up to 20–30 cases).

Despite these issues with the statistical analysis, OSHA believes its main policy determinations are well supported by the best available evidence, including the literature review and careful examination of the prevalence of sensitization and CBD among workers with exposure levels comparable to the current and proposed PELs in the NJMRC data set. The previously described literature analysis and prevalence analysis demonstrate that workers with occupational exposure to airborne beryllium at the current PEL face a risk of becoming sensitized to beryllium and progressing to both early and advanced stages of CBD that far exceeds the value of 1 in 1000 used by OSHA as a benchmark of clearly significant risk. Furthermore, OSHA's preliminary risk assessment indicates that risk of beryllium sensitization and CBD can be significantly reduced by reduction of airborne exposure levels, along with respiratory and dermal protection measures, as demonstrated in facilities such as the Tucson ceramics plant, the Elmore beryllium production facility, and the Reading copper beryllium facility described in the literature review.

OSHA's preliminary risk assessment also indicates that despite the reduction in risk expected with the proposed PEL, the risk to workers with average exposure levels of 0.2 μg/m³ is still clearly significant (see this preamble at section VI). In the prevalence analysis, workers with LTW average or HEJ exposures close to 0.2 μg/m³ experienced high levels of sensitization and CBD. This finding is corroborated by the literature analysis, which showed that workers exposed to mean plant-wide airborne exposures between 0.1 and 0.5 μg/m³ had a similarly high prevalence of sensitization and CBD. Given the significant risk at these levels of exposure, the Agency believes that the proposed action level of 0.1 μg/m³, dermal protection requirements, and other ancillary provisions of the proposed rule are key to reducing the risk of beryllium sensitization and CBD among exposed workers. OSHA preliminarily concludes that the proposed standard, including the PEL of 0.2 μg/m³, the action level of 0.1 μg/m³, and provisions to limit dermal exposure to beryllium, together will significantly reduce workers' risk of beryllium sensitization and CBD from occupational beryllium exposure.

2. Risk of Lung Cancer

OSHA's review of epidemiological studies of lung cancer mortality among beryllium workers found that most did not characterize exposure levels sufficiently to characterize risk of lung cancer at the current and proposed PELs. However, as discussed in this preamble at section V, Health Effects and section VI, Preliminary Risk Assessment, NIOSH recently published a quantitative risk assessment based on beryllium exposure and lung cancer mortality among 5436 male workers employed at beryllium processing plants in Reading, PA; Elmore, OH; and Hazleton, PA, prior to 1970 (Schubauer-Berigan *et al.,* 2010b). This new risk assessment addresses important sources of uncertainty for previous lung cancer analyses, including the sole prior exposure-response analysis for beryllium and lung cancer, conducted by Sanderson *et al.* (2001) on workers from the Reading plant alone. Workers from the Elmore and Hazleton plants who were added to the analysis by Schubauer-Berigan *et al.* were, in general, exposed to lower levels of beryllium than those at the Reading plant. The median worker from Hazleton had a mean exposure across his tenure of less than 2 μg/m³, while the median worker from Elmore had a mean exposure of less than 1 μg/m³. The Elmore and Hazleton worker populations also had fewer short-term workers than the Reading population. Finally, the updated cohorts followed the worker populations through 2005, increasing the length of follow-up time compared to the previous exposure-response analysis. For these reasons, OSHA based its preliminary risk assessment for lung cancer on the Schubauer-Berigan risk analysis.

Schubauer-Berigan *et al.* (2011) analyzed the data set using a variety of exposure-response modeling approaches, described in this preamble at section VI, Preliminary Risk Assessment. The authors found that lung cancer mortality risk was strongly and significantly related to mean, cumulative, and maximum measures of workers' exposure to beryllium (all models reported in Schubauer-Berigan *et al.,* 2011). They selected the best-fitting models to generate risk estimates for male workers with a mean exposure of 0.5 μg/m³ (the current NIOSH Recommended Exposure Limit for beryllium). In addition, they estimated the mean exposure that would be associated with an excess lung cancer mortality risk of one in one thousand. At OSHA's request, the authors also estimated excess risks for workers with mean exposures at each of the other alternate PELs under consideration: 1 μg/m³, 0.2 μg/m³, and 0.1 μg/m³. Table 6 presents the estimated excess risk of lung cancer mortality associated with various levels of beryllium exposure allowed under the current rule, based on the final models presented in Schubauer-Berigan *et al*'s risk assessment.

TABLE 6—EXCESS RISK OF LUNG CANCER MORTALITY PER 1000 MALE WORKERS AT ALTERNATE PELS (NIOSH MODELS)

Exposure-response model	Mean exposure				
	0.1 μg/m³	0.2 μg/m³	0.5 μg/m³	1 μg/m³	2 μg/m³
Best monotonic PWL—all workers	7.3	15	45	120	200
Best monotonic PWL—excluding professional and asbestos workers	3.1	6.4	17	39	61
Best categorical—all workers	4.4	9	25	59	170
Best categorical—excluding professional and asbestos workers	1.4	2.7	7.1	15	33
Power model—all workers	12	19	30	40	52
Power model—excluding professional and asbestos workers	19	30	49	68	90

Source: Section VI, Preliminary Risk Assessment.

The lowest estimate of excess lung cancer deaths from the six final models presented by Schubauer-Berigan *et al.* is 33 per 1000 workers exposed at a mean level of 2 μg/m³, the current PEL. Risk estimates as high as 200 lung cancer deaths per 1000 result from the other five models presented. Regardless of the model chosen, the excess risk of about 33 to 200 per 1000 workers is clearly significant, falling well above the level of risk the Supreme Court indicated a reasonable person might consider acceptable (See *Benzene,* 448 U.S. at 655). The proposed PEL of 0.2 μg/m³ is expected to reduce these risks significantly, to somewhere between 2.7–30 excess lung cancer deaths per 1000 workers. These risk estimates still fall above the threshold of 1 in 1000 that OSHA considers clearly significant. However, the Agency believes the lung cancer risks should be regarded with a greater degree of uncertainty than the risk estimates for CBD discussed previously. While the risk estimates for CBD at the proposed PEL were determined from exposure levels observed in occupational studies, the lung cancer risks are extrapolated from much higher exposure levels.

C. Conclusions

As discussed above, OSHA used the best available scientific evidence to identify adverse health effects of occupational beryllium exposure, and to evaluate exposed workers' risk of these impairments. The Agency reviewed extensive epidemiological and experimental research pertaining to adverse health effects of occupational beryllium exposure, including lung cancer, immunological sensitization to beryllium, and CBD, and has evaluated the risk of these effects from exposures allowed under the current and proposed standards. The Agency has, additionally, reviewed previous policy determinations and case law regarding material impairment of health, and has preliminarily determined that CBD, in all stages, and lung cancer constitute material health impairments. Furthermore, OSHA has preliminarily determined that long-term exposure to beryllium at the current PEL would pose a risk of CBD and lung cancer greater than the risk of 1 per 1000 exposed workers the Agency considers clearly significant. OSHA's risk assessment for beryllium indicates that adoption of the new PEL, action level, and dermal protection provisions of the proposed rule will significantly reduce this risk. OSHA therefore believes it has met the statutory requirements pertaining to significance of risk, consistent with the OSH Act, Supreme Court precedent, and the Agency's previous policy decisions.

IX. Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis

A. Introduction and Summary

OSHA's Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA) addresses issues related to the costs, benefits, technological and economic feasibility, and the economic impacts (including impacts on small entities) of this proposed respirable beryllium rule and evaluates regulatory alternatives to the proposed rule. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity), unless a statute requires another regulatory approach. Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The full PEA has been placed in OSHA rulemaking docket OSHA–H005C–2006–0870. This rule is an economically significant regulatory action under Sec. 3(f)(1) of Executive Order 12866 and has been reviewed by the Office of Information and Regulatory Affairs in the Office of Management and Budget, as required by executive order.

The purpose of the PEA is to:

- Identify the establishments and industries potentially affected by the proposed rule;
- Estimate current exposures and the technologically feasible methods of controlling these exposures;
- Estimate the benefits resulting from employers coming into compliance with the proposed rule in terms of reductions in cases of lung cancer and chronic beryllium disease;
- Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the proposed rule;
- Assess the economic feasibility of the proposed rule for affected industries; and
- Assess the impact of the proposed rule on small entities through an Initial Regulatory Flexibility Analysis (IRFA), to include an evaluation of significant regulatory alternatives to the proposed rule that OSHA has considered.

The PEA contains the following chapters:

Chapter I. Introduction
Chapter II. Assessing the Need for Regulation
Chapter III. Profile of Affected Industries
Chapter IV. Technological Feasibility
Chapter V. Costs of Compliance
Chapter VI. Economic Feasibility Analysis and Regulatory Flexibility Determination
Chapter VII. Benefits and Net Benefits
Chapter VIII. Regulatory Alternatives
Chapter IX. Initial Regulatory Flexibility Analysis

The PEA includes all of the economic analyses OSHA is required to perform, including the findings of technological and economic feasibility and their supporting materials required by the OSH Act as interpreted by the courts (in Chapters III, IV, V, and VI); those required by EO 12866 and EO 13563 (primarily in Chapters III, V, and VII, though these depend on material in other chapters); and those required by the Regulatory Flexibility Act (in Chapters VI, VIII, and IX, though these depend, in part, on materials presented in other chapters).

Key findings of these chapters are summarized below and in sections IX.B through IX.I of this PEA summary.

Profile of Affected Industries

This proposed rule would affect employers and employees in many different industries across the economy. As described in Section IX.C and reported in Table IX–2 of this preamble, OSHA estimates that a total of 35,051 employees in 4,088 establishments are potentially at risk from exposure to beryllium.

Technological Feasibility

As described in more detail in Section IX.D of this preamble and in Chapter IV of the PEA, OSHA assessed, for all affected sectors, the current exposures and the technological feasibility of the proposed PEL of 0.2 μg/m³.

Tables IX–5 in section IX.D of this preamble summarizes all nine application groups (industry sectors and production processes) studied in the technological feasibility analysis. The technological feasibility analysis includes information on current exposures, descriptions of engineering controls and other measures to reduce exposures, and a preliminary assessment of the technological feasibility of compliance with the proposed PELs.

The preliminary technological feasibility analysis shows that for the majority of the job groups evaluated, exposures are either already at or below the proposed PEL, or can be adequately controlled with additional engineering and work practice controls. Therefore, OSHA preliminarily concludes that the proposed PEL of 0.2 μg/m³ is technologically feasible for most operations most of the time.

Based on the currently available evidence, it is more difficult to determine whether an alternative PEL of 0.1 μg/m³ would also be feasible in most operations. For some application groups, a PEL of 0.1 μg/m³ would almost certainly be feasible. In other application groups, a PEL of 0.1 μg/m³ appears feasible, except for establishments working with high beryllium content alloys. For application groups with the highest exposure, the exposure monitoring data necessary to more fully evaluate the effectiveness of exposure controls adopted after 2000 are not currently available to OSHA, which makes it difficult to determine the feasibility of achieving exposure levels at or below 0.1 μg/m³.

OSHA also evaluated the feasibility of a STEL of 2.0 μg/m³. The majority of the available short-term measurements are below 2.0 μg/m³; therefore OSHA preliminarily concludes that the proposed STEL of 2.0 μg/m³ can be achieved for most operations most of the time. OSHA recognizes that for a small number of tasks, short-term exposures may exceed the proposed STEL, even after feasible control measures to reduce TWA exposure to below the proposed PEL have been implemented, and therefore assumes that the use of respiratory protection will continue to be required for some short-term tasks. It is more difficult based on the currently available evidence to determine whether the alternative STEL of 1.0 μg/m³ would also be feasible in most operations based on lack of detail in the activities of the workers presented in the data. OSHA expects additional use of respiratory protection would be required for tasks in which peak exposures can be reduced to less than 2.0 μg/m³ but not less than 1.0 μg/m³. Due to limitations in the available sampling data and the higher detection limits for short term measurements, OSHA could not determine the percentage of the STEL measurements that are less than or equal to 0.5 μg/m³.

Costs of Compliance

As described in more detail in Section IX.E and reported, by application group and NAICS code, in Table IX–7 of this preamble, the total annualized cost of compliance with the proposed standard is estimated to be about $37.6 million. The major cost elements associated with the revisions to the standard are housekeeping ($12.6 million), engineering controls ($9.5 million), training ($5.8 million), and medical surveillance ($2.9 million).

The compliance costs are expressed as annualized costs in order to evaluate economic impacts against annual revenue and annual profits, to be able to compare the economic impact of the rulemaking with other OSHA regulatory actions, and to be able to add and track Federal regulatory compliance costs and economic impacts in a consistent manner. Annualized costs also represent a better measure for assessing the longer-term potential impacts of the rulemaking. The annualized costs were calculated by annualizing the one-time costs over a period of 10 years and applying a discount rate of 3 percent (and an alternative discount rate of 7 percent).

The estimated costs for the proposed beryllium standard represent the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that has already been achieved with regard to the new requirements or costs necessary to achieve compliance with existing beryllium requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

Economic Impacts

To assess the nature and magnitude of the economic impacts associated with compliance with the proposed rule, OSHA developed quantitative estimates of the potential economic impact of the new requirements on entities in each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide an assessment of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts.

As described in greater detail in Section IX.F of this preamble and in Chapter VI of the PEA, the costs of compliance with the proposed rulemaking are not large in relation to the corresponding annual financial flows associated with each of the affected industry sectors. The estimated annualized costs of compliance represent about 0.11 percent of annual revenues and about 1.52 percent of annual profits, on average, across all affected firms. Compliance costs do not represent more than 1 percent of revenues or more than 16.25 percent of profits in any affected industry.

Based on its analysis of the relative inelasticity of demand for beryllium-containing inputs and products and of possible international trade effects, OSHA concluded that most or all costs arising from this proposed beryllium rule would be passed on in higher prices rather than absorbed in lost profits and that any price increases would result in minimal loss of business to foreign competition.

Given the minimal potential impact on prices or profits in the affected industries, OSHA has preliminarily concluded that compliance with the requirements of the proposed rulemaking would be economically feasible in every affected industry sector.

Benefits, Net Benefits, and Cost-Effectiveness

As described in more detail in Section VIII.G of this preamble, OSHA estimated the benefits, net benefits, and incremental benefits of the proposed beryllium rule. That section also contains a sensitivity analysis to show how robust the estimates of net benefits are to changes in various cost and benefit parameters. A full explanation of the derivation of the estimates presented there is provided in Chapter VII of the PEA for the proposed rule.

OSHA estimated the benefits associated with the proposed beryllium PEL of 0.2 μg/m³ and, for analytical purposes to comply with OMB Circular A–4, with alternative beryllium PELs of .1 μg/m³ and .5 μg/m³ by applying the dose-response relationship developed in the Agency's preliminary risk assessment—summarized in Section VI of this preamble—to current exposure levels. OSHA determined current exposure levels by first developing an exposure profile for industries with workers exposed to beryllium, using OSHA inspection and site-visit data, and then applying this exposure profile to the total current worker population. The industry-by-industry exposure profile is summarized in Table IX–3 in Section IX.C of this preamble.

By applying the dose-response relationship to estimates of current exposure levels across industries, it is possible to project the number of cases of the following diseases expected to occur in the worker population given current exposure levels (the ''baseline''):

- fatal cases of lung cancer,
- fatal cases of chronic beryllium disease (CBD), and
- morbidity related to chronic beryllium disease.

Table IX–1 provides a summary of OSHA's best estimate of the costs and benefits of the proposed rule. As shown, the proposed rule, once it is fully effective, is estimated to prevent 96 fatalities and 50 non-fatal beryllium-related illnesses annually, and the monetized annualized benefits of the proposed rule are estimated to be $575.8 million using a 3-percent discount rate and $255.3 million using a 7-percent discount rate. Also as shown in Table IX–1, the estimated annualized cost of the rule is $37.6 million using a 3-percent discount rate and $39.1 million using a 7-percent discount rate. The proposed rule is estimated to generate net benefits of $538.2 million annually using a 3-percent discount rate and $216.2 million annually using a 7-percent discount rate. The estimated costs and benefits of the proposed rule, disaggregated by industry sector, were previously presented in Table I–1 in this preamble.

TABLE IX–1—ANNUALIZED COSTS, BENEFITS AND NET BENEFITS OF OSHA'S PROPOSED BERYLLIUM STANDARD OF 0.2 μg/m³

Discount Rate		3%	7%

TABLE IX–1—ANNUALIZED COSTS, BENEFITS AND NET BENEFITS OF OSHA'S PROPOSED BERYLLIUM STANDARD OF 0.2 μg/m³—Continued

Annualized Costs			
Engineering Controls		$9,540,189	$10,334,036
Respirators		249,684	252,281
Exposure Assessment		2,208,950	2,411,851
Regulated Areas and Beryllium Work Areas		629,031	652,823
Medical Surveillance		2,882,076	2,959,448
Medical Removal		148,826	166,054
Exposure Control Plan		1,769,506	1,828,766
Protective Clothing and Equipment		1,407,365	1,407,365
Hygiene Areas and Practices		389,241	389,891
Housekeeping		12,574,921	12,917,944
Training		5,797,535	5,826,975
Total Annualized Costs (Point Estimate)		37,597,325	39,147,434
Annual Benefits: Number of Cases Prevented			
Fatal Lung Cancer	4.0		
CBD-Related Mortality	92.0		
Total Beryllium Related Mortality	96.0	$572,981,864	$253,743,368
Morbidity	49.5	2,844,770	1,590,927
Monetized Annual Benefits (midpoint estimate)		575,826,633	255,334,295
Net Benefits		538,229,308	216,186,861

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Initial Regulatory Flexibility Analysis

OSHA has prepared an Initial Regulatory Flexibility Analysis (IRFA) in accordance with the requirements of the Regulatory Flexibility Act, as amended in 1996. Among the contents of the IRFA are an analysis of the potential impact of the proposed rule on small entities and a description and discussion of significant alternatives to the proposed rule that OSHA has considered. The IRFA is presented in its entirety both in Chapter IX of the PEA and in Section IX.I of this preamble.

The remainder of this section (Section IX) of the preamble is organized as follows:

B. The Need for Regulation
C. Profile of Affected Industry
D. Technological Feasibility Analysis
E. Costs of Compliance
F. Economic Feasibility Analysis and Regulatory Flexibility Determination
G. Benefits and Net Benefits
H. Regulatory Alternatives
I. Initial Regulatory Flexibility Analysis.

B. Need for Regulation

Employees in work environments addressed by the proposed beryllium rule are exposed to a variety of significant hazards that can and do cause serious injury and death. As described in Chapter II of the PEA in support of the proposed rule, the risks to employees are excessively large due to the existence of various types of market failure, and existing and alternative methods of overcoming these negative consequences—such as workers' compensation systems, tort liability options, and information dissemination programs—have been shown to provide insufficient worker protection.

After carefully weighing the various potential advantages and disadvantages of using a regulatory approach to improve upon the current situation, OSHA preliminarily concludes that, in the case of beryllium exposure, the proposed mandatory standards represent the best choice for reducing the risks to employees. In addition, rulemaking is necessary in this case in order to replace older existing standards with updated, clear, and consistent health standards.

C. Profile of Affected Industries

1. Introduction

Chapter III of the PEA presents a profile of industries that use beryllium, beryllium oxide, and/or beryllium alloys. The discussion below summarizes the findings in that chapter. For each industry sector identified, the Agency describes the uses of beryllium and estimates the number of establishments and employees that may be affected by this proposed rulemaking. Employee exposure to beryllium can also occur as a result of certain processes such as welding that are found in many industries. OSHA uses the umbrella term ''application group'' to refer either to an industrial sector or a cross-industry group with a common process. These groups are all mutually exclusive and are analyzed in separate sections in Chapter III of the PEA. These sections briefly describe each application group and then explain how OSHA estimated the number of establishments working with beryllium and the number of employees exposed to beryllium. Beryllium is rarely used by all establishments in any particular application group because its unique properties and relatively high cost typically result in only very specific and limited usage within a portion of a group.

The information in Chapter III of the PEA is based on reports prepared under task order by Eastern Research Group (ERG), an OSHA contractor; information collected during OSHA's Small Business Advocacy Review Panel (OSHA 2008b); and Agency research and analysis. Technological feasibility reports (summarized in Chapter IV of the PEA) for each beryllium-using application group provide a detailed presentation of processes and occupations with beryllium exposure, including available sampling exposure measurements and estimates of how many employees are affected in each specific occupation.

OSHA has identified nine application groups that would be potentially affected by the proposed beryllium standard:

1. Beryllium Production
2. Beryllium Oxide Ceramics and Composites
3. Nonferrous Foundries
4. Secondary Smelting, Refining, and Alloying
5. Precision Turned Products
6. Copper Rolling, Drawing, and Extruding
7. Fabrication of Beryllium Alloy Products
8. Welding
9. Dental Laboratories

These application groups are broadly defined, and some include establishments in several North

American Industrial Classification System (NAICS) codes. For example, the Copper Rolling and Drawing, and Extruding application group is made up both of NAICS 331421 Copper Rolling, Drawing, and Extruding and NAICS 331422 Copper Wire Drawing. While an application group may contain numerous NAICS six-digit industry codes, in most cases only a fraction of the establishments in any individual six-digit NAICS industry use beryllium and would be affected by the proposed rule. For example, not all companies in the above application group work with copper that contains beryllium.

One application group, welding, reflects industrial activities or processes that take place in various industry sectors. All of the industries in which a given activity or process may result in worker exposure to beryllium are identified in the sections on the application group. The section on each application group describes the production processes where occupational contact with beryllium can occur and contains estimates of the total number of firms, employees, affected establishments, and affected employees.

Chapter III of the PEA presents formulas in the text, usually in parentheses, to help explain the derivation of estimates. Because the values used in the formulas shown in the text are sometimes rounded, while the actual spreadsheet formulas used to create final costs are not, the calculation using the presented formula will sometimes differ slightly from the total presented in the text—which is the actual total as shown in the tables.

At the end of Chapter III in the PEA, OSHA discusses other industry sectors that have reportedly used beryllium in the past or for which there are anecdotal or informal reports of beryllium use. The Agency was unable to verify beryllium use in these sectors that would be affected by the proposed standard, and seeks further information in this rulemaking on these or other industries where there may be significant beryllium use and employee exposure.

2. Summary of Affected Establishments and Employers

As shown in Table IX–2, OSHA estimates that a total of 35,051 workers in 4,088 establishments will be affected by the proposed beryllium standard. Also shown are the estimated annual revenues for these entities.

Table IX-2

CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR BERYLLIUM—ALL ENTITIES

NAICS	Industry	Total Entities [a]	Total Establishments [a]	Total Employees [a]	Affected Entities [b]	Affected Establishments	Affected Employees	Total Revenues	Revenues/Entit	Revenues/Establishment ($1,000)
Beryllium Production										
331419	Primary Smelting and	140	161	8,943	1	1	616	$8,524,863	$60,892	$52,949
Beryllium Oxide Ceramics and Composites										
327113a	Porcelain electrical supply	94	106	4,310	2	2	83	789,731	$8,401	$7,450
327113b	Porcelain electrical supply	94	106	4,310	12	14	168	789,731	$8,401	$7,450
334220	Cellular telephones	724	810	79,732	9	10	120	35,475,343	$48,999	$43,797
334310	Compact disc players	460	464	8,858	5	5	60	3,975,351	$8,642	$8,568
334411	Electron Tube	62	79	4,884	16	21	252	1,220,476	$19,685	$15,449
334415	Electronic resistor	50	61	3,722	10	12	144	560,967	$11,219	$9,196
334419	Other electronic	1,058	1,133	46,836	8	9	108	10,013,730	$9,465	$8,838
334510	Electromedical equipment	555	629	66,107	8	9	108	27,480,966	$49,515	$43,690
336322b	Other motor vehicle	585	636	38,475	9	10	120	12,152,053	$20,773	$19,107
Nonferrous Foundries										
331521	Aluminum die-casting	228	254	18,017	6	7	98	4,310,021	$18,904	$16,969
331522	Nonferrous (except	137	140	6,362	37	38	534	1,510,799	$11,028	$10,791
331524	Aluminum foundries	366	394	15,178	7	7	98	2,518,097	$6,880	$6,391
331525a	Copper foundries (except	201	208	5,123	19	20	281	1,205,574	$5,998	$5,796
331525b	Copper foundries (except	201	208	5,123	24	25	393	1,205,574	$5,998	$5,796
Secondary Smelting, Refining, and Alloying										
331314	Secondary smelting &	98	122	4,846	1	1	9	4,837,129	$49,358	$39,649
331421b	Copper rolling, drawing,	70	96	9,849	1	1	9	12,513,425	$178,763	$130,348
331423	Secondary smelting,	23	24	789	3	3	27	723,759	$31,468	$30,157
331492	Secondary Smelting,	217	248	9,696	26	30	270	8,195,807	$37,769	$33,048
Precision Machining										
332721a	Precision turned product	3,057	3,124	78,749	18	18	222	13,262,706	$4,338	$4,245
332721b	Precision turned product	3,057	3,124	78,749	288	294	3,542	13,262,706	$4,338	$4,245

Table IX-2, continued

CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR BERYLLIUM—ALL ENTITIES

NAICS	Industry	Total Entities [a]	Total Establishments [a]	Total Employees [a]	Affected Entities [b]	Affected Establishments	Affected Employees	Total Revenues	Revenues/Entit	Revenues/Establishment ($1,000)
Copper Rolling, Drawing and Extruding										
331422	Copper wire (except	84	114	9,847	43	59	5,096	6,471,491	$77,042	$56,767
331421a	Copper rolling, drawing,	70	96	9,849	11	15	1,539	12,513,425	$178,763	$130,348
Stamping, Spring, and Connector Manufacturing										
332612	Light gauge spring	269	323	10,329	269	323	2,071	2,167,977	$8,059	$6,712
332116	Metal stamping	1,413	1,484	48,855	70	74	496	9,749,800	$6,900	$6,570
334417	Electronic connector	198	231	19,538	40	46	310	5,029,508	$25,402	$21,773
336322a	Other motor vehicle	585	636	38,475	146	159	1,066	12,152,053	$20,773	$19,107
Dental Laboratories										
339116	Dental laboratories	6,718	6,995	44,030	1,680	1,749	8,148	4,100,626	$610	$586
621210	Offices of dentists	123,322	129,830	846,092	226	238	1,107	100,431,324	$814	$774
Arc and Gas Welding										
331111	Iron and Steel Mills	461	587	94,089	5	7	27	$92,726,004	$201,141	$157,966
331221	Rolled Steel Shape	134	161	9,971	1	1	6	8,376,271	$62,509	$52,027
331513	Steel Foundries (except	203	220	13,874	1	1	5	4,251,852	$20,945	$19,327
332117	Powder Metallurgy Part	121	133	6,707	1	1	4	1,414,108	$11,687	$10,632
332212	Hand and Edge Tool	999	1,066	25,098	3	3	12	5,077,868	$5,083	$4,763
332312	Fabricated Structural	3,081	3,407	89,728	51	56	224	26,119,614	$8,478	$7,666
332313	Plate Work Manufacturing	1,252	1,288	28,400	21	21	85	6,023,356	$4,811	$4,677
332322	Sheet Metal Work	3,907	4,173	91,364	64	69	274	17,988,908	$4,604	$4,311
332323	Ornamental and	2,314	2,354	30,029	38	39	155	5,708,707	$2,467	$2,425
332439	Other Metal Container	321	370	12,553	6	7	27	3,565,875	$11,109	$9,638
332919	Other Metal Valve and	240	265	14,688	2	3	11	4,584,082	$19,100	$17,298
332999	All Other Miscellaneous	3,195	3,262	65,821	33	33	134	13,963,184	$4,370	$4,281
333111	Farm Machinery and	975	1,041	53,133	19	20	80	$24,067,145	$24,684	$23,119
333414a	Heating Equipment	433	460	16,768	6	6	24	4,781,561	$11,043	$10,395
333911	Pump and Pumping	445	571	31,272	5	7	27	12,395,387	$27,855	$21,708
333922	Conveyor and Conveying	737	776	26,970	9	9	36	6,569,120	$8,913	$8,465
333924	Industrial Truck, Tractor,	347	374	19,974	4	4	17	7,444,451	$21,454	$19,905
333999	All Other Miscellaneous	1,463	1,524	43,401	17	18	71	10,972,258	$7,500	$7,200
336211	Motor Vehicle Body	652	742	38,587	13	15	60	$9,877,558	$15,150	$13,312
336214	Travel Trailer and Camper	602	683	30,803	12	14	55	7,465,024	$12,400	$10,930
336399a	All Other Motor Vehicle	1,156	1,350	95,426	6	7	30	32,279,766	$27,924	$23,911
336510	Railroad Rolling Stock	157	226	24,491	2	3	11	$11,927,191	$75,969	$52,775
336999	All Other Transportation	366	374	10,846	4	4	14	5,250,368	$14,345	$14,038
337215	Showcase, Partition,	1,144	1,194	33,195	3	3	13	5,815,404	$5,083	$4,871
811310	Commercial and Industrial	20,299	21,960	181,220	132	143	571	31,650,469	$1,559	$1,441

Table IX-2, continued

CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR BERYLLIUM—ALL ENTITIES

NAICS	Industry	Total Entities [a]	Total Establishments [a]	Total Employees [a]	Affected Entities [b]	Affected Establishments	Affected Employees	Total Revenues	Revenues/Entit	Revenues/Establishment ($1,000)
Resistance Welding										
333411	Air Purification Equipment	303	358	14,521	21	25	379	3,060,744	$10,101	$8,550
333412	Industrial and Commercial	135	151	6,908	9	11	160	1,681,585	$12,456	$11,136
333414b	Heating Equipment	433	460	16,768	30	32	487	4,781,561	$11,043	$10,395
333415	Air-Conditioning, Warm	695	843	79,651	49	59	893	25,454,383	$36,625	$30,195
335211	Electric Housewares and	101	106	5,980	5	5	80	2,209,657	$21,878	$20,846
335212	Household Vacuum	29	34	2,577	1	2	26	891,600	$30,745	$26,224
335221	Household Cooking	91	96	9,730	5	5	73	3,757,849	$41,295	$39,144
335222	Household Refrigerator	16	22	9,731	1	1	17	4,489,845	$280,615	$204,084
335224	Household Laundry	9	11	8,051	1	1	8	3,720,514	$413,390	$338,229
335228	Other Major Household	34	38	9,023	2	2	29	3,499,273	$102,920	$92,086
336311	Carburetor, Piston, Piston	97	109	7,370	5	5	82	1,715,429	$17,685	$15,738
336312	Gasoline Engine and	697	742	36,896	35	37	561	20,000,705	$28,695	$26,955
336321	Vehicular Lighting	86	93	9,218	4	5	70	2,322,610	$27,007	$24,974
336322c	Other Motor Vehicle	585	636	38,475	29	32	481	12,152,053	$20,773	$19,107
336330	Motor Vehicle Steering	209	246	26,118	10	12	186	8,856,584	$42,376	$36,002
336340	Motor Vehicle Brake	159	199	20,245	8	10	150	8,147,826	$51,244	$40,944
336350	Motor Vehicle	397	476	51,171	20	24	360	21,862,014	$55,068	$45,929
336360	Motor Vehicle Seating and	305	403	39,805	15	20	305	15,168,862	$49,734	$37,640
336370	Motor Vehicle Metal	599	736	66,985	30	37	557	19,809,238	$33,071	$26,915
336391	Motor Vehicle Air-	72	80	11,207	4	4	61	3,798,464	$52,756	$47,481
336399b	All Other Motor Vehicle	1,156	1,350	95,426	58	68	1,021	32,279,766	$27,924	$23,911
Total	All Affected Industries				3,795	4,088	35,051			

[a] US Census Bureau, Statistics of US Businesses, 2010.

[b] OSHA estimates of employees potentially exposed to beryllium and associated entities and establishments. Affected entities and establishments constrained to be less than or equal to the number of affected employees.

[c] Estimates based on 2007 receipts and payroll data from US Census Bureau, Statistics of US Businesses, 2007, and payroll data from the US Census Bureau, Statistics of US Businesses, 2010. Receipts are not reported for 2010 but were estimated assuming the ratio of receipts to payroll remained unchanged from 2007 to 2010.

Source: US Dept. of Labor, OSHA, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, based on ERG, 2012.

3. Beryllium Exposure Profile of At-Risk Workers

The technological feasibility analyses presented in Chapter IV of the PEA contain data and discussion of worker exposures to beryllium throughout industry. Exposure profiles, by job category, were developed from individual exposure measurements that were judged to be substantive and to contain sufficient accompanying description to allow interpretation of the circumstance of each measurement. The resulting exposure profiles show the job categories with current overexposures to beryllium and, thus, the workers for whom beryllium controls would be implemented under the proposed rule.

Table IX–3 summarizes, from the exposure profiles, the number of workers at risk from beryllium exposure and the distribution of 8-hour TWA respirable beryllium exposures by affected job category and sector. Exposures are grouped into the following ranges: Less than 0.1 μg/m³; ≥ 0.1 μg/m³ and ≤ 0.2 μg/m³; > 0.2 μg/m³ and ≤ 0.5 μg/m³; > 0.5 μg/m³ and ≤ 1.0 μg/m³; > 1.0 μg/m³ and ≤ 2.0 μg/m³; and greater than 2.0 μg/m³. These frequencies represent the percentages of production employees in each job category and sector currently exposed at levels within the indicated range.

Table IX–4 presents data by NAICS code on the estimated number of workers currently at risk from beryllium exposure, as well as the estimated number of workers at risk of beryllium exposure above 0 μg/m³, at or above 0.1 μg/m³, at or above 0.2 μg/m³, at or above 0.5 μg/m³, at or above 1.0 μg/m³, and at or above 2.0 μg/m³. As shown, an estimated 12,101 workers currently have beryllium exposures at or above the proposed action level of 0.1 μg/m³; and an estimated 8,091 workers currently have beryllium exposures above the proposed PEL of 0.2 μg/m³.

Table IX-3

Distribution of Beryllium Exposures by Sector and Job Category or Activity

Sector		Beryllium Exposure Range						
Beryllium Production	Job Category/Activity	<0.1 μg/m³	0.1 - 0.2 μg/m³	0.2 - 0.5 μg/m³	0.5 - 1.0 μg/m³	1.0 - 2.0 μg/m³	>2.0 μg/m³	Total
	Administrative	84.91%	9.17%	3.98%	1.02%	0.61%	0.31%	100.00%
	Wastewater Treatment	58.70%	17.39%	19.57%	4.35%	0.00%	0.00%	100.00%
	Boiler Operators	27.78%	27.78%	44.44%	0.00%	0.00%	0.00%	100.00%
	Decontamination	35.42%	25.00%	14.58%	14.58%	6.25%	4.17%	100.00%
	Other Site Support	86.31%	9.78%	2.74%	0.78%	0.39%	0.00%	100.00%
	Mix/Makeup	27.45%	17.65%	33.33%	9.80%	9.80%	1.96%	100.00%
	Scrap Recycling	12.61%	23.42%	27.03%	12.61%	9.91%	14.41%	100.00%
	Maintenance/Furnace & Tools	10.34%	8.62%	27.59%	20.69%	8.62%	24.14%	100.00%
	Other Production Support	70.20%	13.88%	6.55%	3.59%	3.43%	2.34%	100.00%
	Machining	55.48%	21.23%	15.53%	2.51%	3.20%	2.05%	100.00%
	Other Cold Work	78.63%	11.97%	5.13%	1.71%	2.56%	0.00%	100.00%
	Welding	0.00%	26.67%	40.00%	26.67%	0.00%	6.67%	100.00%
	Other Hot Work	72.70%	18.44%	8.16%	0.71%	0.00%	0.00%	100.00%
	Impact Grinding	19.23%	3.85%	23.08%	23.08%	26.92%	3.85%	100.00%
	Compact loading/Sintering	15.79%	31.58%	26.32%	0.00%	15.79%	10.53%	100.00%
	NNS Operator	0.00%	22.22%	40.74%	29.63%	3.70%	3.70%	100.00%
	Chemical Operations	5.00%	10.00%	50.00%	20.00%	10.00%	5.00%	100.00%
	Alloy Arc Furnace	0.00%	2.63%	15.79%	36.84%	18.42%	26.32%	100.00%
	Alloy Induction Furnace	5.15%	13.40%	31.96%	26.80%	13.40%	9.28%	100.00%
	Vacuum Cast	0.00%	33.33%	22.22%	11.11%	22.22%	11.11%	100.00%
Be Oxide - Primary	Atomization	0.00%	0.00%	0.00%	30.77%	0.00%	69.23%	100.00%
	Beryllium Oxide Furnace	20.00%	20.00%	20.00%	6.67%	20.00%	13.33%	100.00%
	Material preparations operators	12.99%	15.58%	31.17%	19.48%	10.39%	10.39%	100.00%
	Forming operators - pressing	30.96%	25.06%	28.26%	10.57%	3.69%	1.47%	100.00%
Be Oxide - Secondary	Forming operators - extruding	30.96%	25.06%	28.26%	10.57%	3.69%	1.47%	100.00%
	Kiln operators	0.00%	0.00%	100.00%	0.00%	0.00%	0.00%	100.00%
	Machining operators	40.00%	22.56%	22.31%	10.26%	2.82%	2.05%	100.00%
	Metallization Workers	55.56%	13.89%	27.78%	2.78%	0.00%	0.00%	100.00%
Sand foundries	Production support	74.79%	13.45%	6.72%	2.52%	0.84%	1.68%	100.00%
	Administrative	93.51%	4.32%	1.08%	0.54%	0.54%	0.00%	100.00%
	Molder	0.00%	0.00%	62.50%	25.00%	0.00%	12.50%	100.00%
	Material Handler	0.00%	0.00%	0.00%	100.00%	0.00%	0.00%	100.00%
	Furnace operator	0.00%	18.18%	9.09%	18.18%	18.18%	36.36%	100.00%
	Pouring operator	0.00%	40.00%	0.00%	0.00%	20.00%	40.00%	100.00%
	Shakeout operator	0.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%
	Abrasive blaster	0.00%	100.00%	0.00%	0.00%	0.00%	0.00%	100.00%
Non Sand foundries	Grinding/finishing operator	6.25%	31.25%	31.25%	6.25%	6.25%	18.75%	100.00%
	Maintenance	20.51%	29.49%	23.08%	14.10%	8.97%	3.85%	100.00%
	Molder	0.00%	0.00%	62.50%	25.00%	0.00%	12.50%	100.00%
	Material Handler	0.00%	0.00%	0.00%	100.00%	0.00%	0.00%	100.00%
	Furnace operator	0.00%	18.18%	9.09%	18.18%	18.18%	36.36%	100.00%
	Pouring operator	0.00%	40.00%	0.00%	0.00%	20.00%	40.00%	100.00%
Smelting - Be Alloys	Abrasive blaster	0.00%	100.00%	0.00%	0.00%	0.00%	0.00%	100.00%
	Grinding/finishing operator	6.25%	31.25%	31.25%	6.25%	6.25%	18.75%	100.00%
Smelting - Precious met	Mechanical processing operator	25.00%	75.00%	0.00%	0.00%	0.00%	0.00%	100.00%
	Furnace operator	0.00%	0.00%	0.00%	0.00%	25.00%	75.00%	100.00%
Machining (high)	Mechanical processing operator	25.00%	75.00%	0.00%	0.00%	0.00%	0.00%	100.00%
Machining (low)	Furnace operator	50.00%	0.00%	50.00%	0.00%	0.00%	0.00%	100.00%
Rolling	Machinist (high)	13.56%	11.86%	44.07%	15.25%	6.78%	8.47%	100.00%
	Machinist (low)	73.75%	11.25%	7.50%	2.50%	1.25%	3.75%	100.00%
	Administrative	98.53%	1.47%	0.00%	0.00%	0.00%	0.00%	100.00%
	Other Production support	97.96%	2.04%	0.00%	0.00%	0.00%	0.00%	100.00%
Drawing	Wastewater treatment operator	33.33%	33.33%	33.33%	0.00%	0.00%	0.00%	100.00%
	Production	92.81%	4.69%	1.88%	0.63%	0.00%	0.00%	100.00%
	Administrative	98.53%	1.47%	0.00%	0.00%	0.00%	0.00%	100.00%
	Other Production support	97.96%	2.04%	0.00%	0.00%	0.00%	0.00%	100.00%
Springs	Wastewater treatment operator	33.33%	33.33%	33.33%	0.00%	0.00%	0.00%	100.00%
	Production	70.00%	13.33%	10.48%	1.90%	1.90%	2.38%	100.00%
	Assembly operator	92.86%	7.14%	0.00%	0.00%	0.00%	0.00%	100.0%
Stamping	Deburring Operator	85.71%	0.00%	14.29%	0.00%	0.00%	0.00%	100.0%
	Chemical process operator	88.37%	6.98%	4.65%	0.00%	0.00%	0.00%	100.0%
	Assembly operator	92.86%	7.14%	0.00%	0.00%	0.00%	0.00%	100.0%
	Deburring Operator	85.71%	0.00%	14.29%	0.00%	0.00%	0.00%	100.0%
Dental labs	Chemical process operator	88.37%	6.98%	4.65%	0.00%	0.00%	0.00%	100.0%
Welding_GI	Mechanical processing operator	25.00%	75.00%	0.00%	0.00%	0.00%	0.00%	100.0%
Resistance Welding	Dental technicians	30.43%	21.74%	13.04%	17.39%	4.35%	13.04%	100.0%
	Welder	56.76%	13.51%	16.22%	10.81%	0.00%	2.70%	100.0%
	Welder	100.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.0%

Source: OSHA Office of Regulatory Analysis-Health

Table IX-4
Numbers of Workers Exposed to Beryllium (by Affected Industry and Exposure Level (μg/m³)

NAICs	Industry	No. of Establishments	No. of Employees	Numbers Exposed to Beryllium					
				> 0	>=0.1 μg/m³	>=0.2 μg/m³	>=0.5 μg/m³	>=1.0 μg/m³	>=2.0 μg/m³
327113	Porcelain Electrical Supply	106	4,310	251	117	80	23	8	3
331111	Iron and Steel Mills	587	94,089	27	11	8	4	1	1
331221	Rolled Steel Shape Manufacturing	161	9,971	6	2	2	1	0	0
331314	Secondary Smelting and Alloying of	122	4,846	9	8	6	6	6	5
331419	Primary Smelting and Refining of	161	8,943	616	250	166	91	53	28
331421	Copper Rolling, Drawing, and Extruding	96	9,849	1,548	97	35	12	6	5
331422	Copper Wire (except Mechanical)	114	9,847	5,096	995	531	190	132	73
331423	Secondary Smelting, Refining, and	24	789	27	25	18	18	18	14
331492	Secondary Smelting, Refining, and	248	9,696	270	158	90	0	0	0
331513	Steel Foundries (except Investment)	220	13,874	5	2	2	1	0	0
331521	Aluminum Die-Casting Foundries	254	18,017	98	94	72	40	21	15
331522	Nonferrous (except Aluminum) Die-	140	6,362	534	512	393	219	115	83
331524	Aluminum Foundries (except Die-	394	15,178	98	94	72	40	21	15
331525	Copper Foundries (except Die-Casting)	208	5,123	674	647	507	300	177	99
332116	Metal Stamping	1,484	48,855	496	58	45	0	0	0
332117	Powder Metallurgy Part Manufacturing	133	6,707	4	2	1	0	0	0
332212	Hand and Edge Tool Manufacturing	1,066	25,098	12	5	3	2	0	0
332312	Fabricated Structural Metal	3,407	89,728	224	97	67	30	6	6
332313	Plate Work Manufacturing	1,288	28,400	85	37	25	11	2	2
332322	Sheet Metal Work Manufacturing	4,173	91,364	274	119	81	37	7	7
332323	Ornamental and Architectural Metal	2,354	30,029	155	67	46	21	4	4
332439	Other Metal Container Manufacturing	370	12,553	27	12	8	4	1	1
332612	Spring (Light Gauge) Manufacturing	323	10,329	2,071	185	74	0	0	0
332721	Precision Turned Product Manufacturing	3,124	78,749	3,764	1,122	697	333	211	152
332919	Other Metal Valve and Pipe Fitting	265	14,688	11	5	3	1	0	0
332999	All Other Miscellaneous Fabricated	3,262	65,821	134	58	40	18	4	4
333111	Farm Machinery and Equipment	1,041	53,133	80	34	24	11	2	2
333411	Air Purification Equipment	358	14,521	379	0	0	0	0	0
333412	Industrial and Commercial Fan and	151	6,908	160	0	0	0	0	0
333414	Heating Equipment (except Warm Air	460	16,768	511	10	7	3	1	1
333415	Air-Conditioning, Warm Air Heating, and	843	79,651	893	0	0	0	0	0
333911	Pump and Pumping Equipment	571	31,272	27	11	8	4	1	1
333922	Conveyor and Conveying Equipment	776	26,970	36	16	11	5	1	1
333924	Industrial Truck, Tractor, Trailer, and	374	19,974	17	8	5	2	0	0
333999	All Other Miscellaneous General	1,524	43,401	71	31	21	10	2	2
334220	Radio and Television Broadcasting and	810	79,732	120	37	22	8	3	1
334310	Audio and Video Equipment	464	8,858	60	19	11	4	1	1
334411	Electron Tube Manufacturing	79	4,884	252	79	46	18	6	3
334415	Electronic Resistor Manufacturing	61	3,722	144	45	26	10	3	1
334417	Electronic Connector Manufacturing	231	19,538	310	36	28	0	0	0
334419	Other Electronic Component	1,133	46,836	108	34	20	8	3	1
334510	Electromedical and Electrotherapeutic	629	66,107	108	34	20	8	3	1
335211	Electric Housewares and Household Fan	106	5,980	80	0	0	0	0	0
335212	Household Vacuum Cleaner	34	2,577	26	0	0	0	0	0
335221	Household Cooking Appliance	96	9,730	73	0	0	0	0	0

Table IX-4, continued

Numbers of Workers Exposed to Beryllium (by Affected Industry and Exposure Level (μg/m³))

NAICs	Industry	No. of Establishments	No. of Employees	Numbers Exposed to Beryllium					
				> 0	>=0.1 μg/m³	>=0.2 μg/m³	>=0.5 μg/m³	>=1.0 μg/m³	>=2.0 μg/m³
335222	Household Refrigerator and Home	22	9,731	17	0	0	0	0	0
335224	Household Laundry Equipment	11	8,051	8	0	0	0	0	0
335228	Other Major Household Appliance	38	9,023	29	0	0	0	0	0
336211	Motor Vehicle Body Manufacturing	742	38,587	60	26	18	8	2	2
336214	Travel Trailer and Camper	683	30,803	55	24	16	7	1	1
336311	Carburetor, Piston, Piston Ring, and	109	7,370	82	0	0	0	0	0
336312	Gasoline Engine and Engine Parts	742	36,896	561	0	0	0	0	0
336321	Vehicular Lighting Equipment	93	9,218	70	0	0	0	0	0
336322	Other Motor Vehicle Electrical and	636	38,475	1,667	163	120	8	3	1
336330	Motor Vehicle Steering and Suspension	246	26,118	186	0	0	0	0	0
336340	Motor Vehicle Brake System	199	20,245	150	0	0	0	0	0
336350	Motor Vehicle Transmission and Power	476	51,171	360	0	0	0	0	0
336360	Motor Vehicle Seating and Interior Trim	403	39,805	305	0	0	0	0	0
336370	Motor Vehicle Metal Stamping	736	66,985	557	0	0	0	0	0
336391	Motor Vehicle Air-Conditioning	80	11,207	61	0	0	0	0	0
336399	All Other Motor Vehicle Parts	1,350	95,426	1,051	13	9	4	1	1
336510	Railroad Rolling Stock Manufacturing	226	24,491	11	5	3	1	0	0
336999	All Other Transportation Equipment	374	10,846	14	6	4	2	0	0
337215	Showcase, Partition, Shelving, and	1,194	33,195	13	6	4	2	0	0
339116	Dental Laboratories	6,995	44,030	8,148	5,668	3,897	2,834	1,417	1,063
621210	Offices of Dentists	129,830	846,092	1,107	770	529	385	192	144
811310	Commercial and Industrial Machinery	21,960	181,220	571	247	170	77	15	15
	Totals	200,970	2,892,762	35,051	12,101	8,091	4,822	2,454	1,761

Source: County Business Patterns, 2010;

D. Technological Feasibility Analysis of the Proposed Permissible Exposure Limit to Beryllium Exposures

This section summarizes the technological feasibility analysis presented in Chapter IV of the PEA (OSHA, 2014). The technological feasibility analysis includes information on current exposures, descriptions of engineering controls and other measures to reduce exposures, and a preliminary assessment of the technological feasibility of compliance with the proposed standard, including a reduction in OSHA's permissible exposure limits (PELs) in nine affected application groups. The current PELs for beryllium are 2.0 μg/m³ as an 8-hour time weighted average (TWA), and 5.0 μg/m³ as an acceptable ceiling concentration. OSHA is proposing a PEL of 0.2 μg/m³ as an 8-hour TWA and is additionally considering alternative TWA PELs of 0.1 and 0.5 μg/m³. OSHA is also proposing a 15-minute short-term exposure limit (STEL) of 2.0 μg/m³, and is considering alternative STELs of 0.5, 1.0 and 2.5 μg/m³.

The technological feasibility analysis includes nine application groups that correspond to specific industries or production processes that OSHA has preliminarily determined fall within the scope of the proposed standard. Within each of these application groups, exposure profiles have been developed that characterize the distribution of the available exposure measurements by job title or group of jobs. Descriptions of existing engineering controls for operations that create sources of beryllium exposure, and of additional engineering and work practice controls that can be used to reduce exposure are also provided. For each application group, a preliminary determination is made regarding the feasibility of achieving the proposed permissible exposure limits. For application groups in which the median exposures for some jobs exceed the proposed TWA PEL, a more detailed analysis is presented by job or group of jobs within the application group. The analysis is based on the best information currently available to the Agency, including a comprehensive review of the industrial hygiene literature, National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations and case studies of beryllium exposure, site visits conducted by an OSHA contractor (Eastern Research Group (ERG)), submissions to OSHA's rulemaking docket, and inspection data from OSHA's Integrated Management Information System (IMIS). OSHA also obtained information on production processes, worker exposures, and the effectiveness of existing control measures from the primary beryllium producer in the United States, Materion Corporation, and from interviews with industry experts.

The nine application groups included in this analysis were identified based on information obtained during preliminary rulemaking activities that included a SBRFA panel, a comprehensive review of the published literature, stakeholder input, and an analysis of IMIS data collected during OSHA workplace inspections where detectable airborne beryllium was found. The nine application groups and their corresponding section numbers in Chapter IV of the PEA are:

- Section 3—Beryllium Production,
- Section 4—Beryllium Oxide Ceramics and Composites,
- Section 5—Nonferrous Foundries,
- Section 6—Secondary Smelting, Refining, and Alloying,
- Section 7—Precision Turned Products,
- Section 8—Copper Rolling, Drawing, and Extruding,
- Section 9—Fabrication of Beryllium Alloy Products,
- Section 10—Welding, and
- Section 11—Dental Laboratories.

OSHA developed exposure profiles by job or group of jobs using exposure data at the application, operation or task level to the extent that such data were available. In those instances where there were insufficient exposure data to create a profile, OSHA used analogous operations to characterize the operations. The exposure profiles represent baseline conditions with existing controls for each operation with potential exposure. For job groups where exposures were above the proposed TWA PEL of 0.2 μg/m³, OSHA identified additional controls that could be implemented to reduce employee exposures to beryllium. These included engineering controls, such as process containment, local exhaust ventilation and wet methods for dust suppression, and work practices, such as improved housekeeping and the prohibition of compressed air for cleaning beryllium-contaminated surfaces.

For the purposes of this technological feasibility assessment, these nine application groups can be divided into three general categories based on current exposure levels:

(1) application groups in which current exposures for most jobs are already below the proposed PEL of 0.2 μg/m³;

(2) application groups in which exposures for most jobs are below the current PEL, but exceed the proposed PEL of 0.2 μg/m³, and therefore additional controls would be required; and

(3) application groups in which exposures in one or more jobs routinely exceed the current PEL, and therefore substantial reductions in exposure would be required to achieve the proposed PEL.

The majority of exposure measurements taken in the application groups in the first category are already at or below the proposed PEL of 0.2 μg/m³, and most of the jobs with exposure to beryllium in these four application groups have median exposures below the alternative PEL of 0.1 μg/m³ (See Table IX–5). These four application groups include rolling, drawing, and extruding; fabrication of beryllium alloy products; welding; and dental laboratories.

The two application groups in the second category include: precision turned products and secondary smelting. For these two groups, the median exposures in most jobs are below the current PEL, but the median exposure levels for some job groups currently exceed the proposed PEL. Additional exposure controls and work practices could be implemented that the Agency has preliminarily concluded would reduce exposures to or below the proposed PEL for most jobs most of the time. One exception is furnace operations in secondary smelting, in which the median exposure exceeds the current PEL. Furnace operations involve high temperatures that produce significant amounts of fumes and particulate that can be difficult to contain. Therefore, the proposed PEL may not be feasible for most furnace operations involved with secondary smelting, and in some cases, respiratory protection would be required to adequately protect furnace workers when exposures exceed 0.2 μg/m³ despite the implementation of all feasible controls.

Exposures in the third category of application groups routinely exceed the current PEL for several jobs. The three application groups in this category include: Beryllium production, beryllium oxide ceramics production, and nonferrous foundries. The individual job groups for which exposures exceed the current PEL are discussed in the application group specific sections later in this summary, and described in greater detail in the PEA. For the jobs that routinely exceed the current PEL, OSHA identified additional exposure controls and work practices that the Agency preliminarily concludes would reduce exposures to or below the proposed PEL most of the time, with three exceptions: Furnace operations in primary beryllium production and nonferrous foundries, and shakeout operations at nonferrous foundries. For these jobs, OSHA recognizes that even after installation of feasible controls, respiratory protection may be needed to adequately protect workers.

In conclusion, the preliminary technological feasibility analysis shows that for the majority of the job groups evaluated, exposures are either already at or below the proposed PEL, or can be adequately controlled with additional engineering and work practice controls. Therefore, OSHA preliminarily concludes that the proposed PEL of 0.2 μg/m³ is feasible for most operations most of the time. The preliminary feasibility determination for the proposed PEL is also supported by Materion Corporation, the sole primary beryllium production company in the U.S., and by the United Steelworkers, who jointly submitted a draft proposed standard that specified an exposure limit of 0.2 μg/m³ to OSHA (Materion and USW, 2012). The technological feasibility analysis conducted for each application group is briefly summarized below, and a more detailed discussion is presented in Sections 3 through 11 of Chapter IV of the PEA (OSHA, 2014).

Based on the currently available evidence, it is more difficult to determine whether an alternative PEL of

0.1 μg/m³ would also be feasible in most operations. For some application groups, such as fabrication of beryllium alloy products, a PEL of 0.1 μg/m³ would almost certainly be feasible. In other application groups, such as precision turned products, a PEL of 0.1 μg/m³ appears feasible, except for establishments working with high beryllium content alloys. For application groups with the highest exposure, the exposure monitoring data necessary to more fully evaluate the effectiveness of exposure controls adopted after 2000 are not currently available to OSHA, which makes it difficult to determine the feasibility of achieving exposure levels at or below 0.1 μg/m³.

OSHA also evaluated the feasibility of a STEL of 2.0 μg/m³, and alternative STELs of 0.5 and 1.0 μg/m³. An analysis of the available short-term exposure measurements indicates that elevated exposures can occur during short-term tasks such as those associated with the operation and maintenance of furnaces at primary beryllium production facilities, at nonferrous foundries, and at secondary smelting operations. Peak exposure can also occur during the transfer and handling of beryllium oxide powders. OSHA believes that in many cases, reducing short-term exposures will be necessary to reduce workers' TWA exposures to or below the proposed PEL. The majority of the available short-term measurements are below 2.0 μg/m³, therefore OSHA preliminarily concludes that the proposed STEL of 2.0 μg/m³ can be achieved for most operations most of the time. OSHA recognizes that for a small number of tasks, short-term exposures may exceed the proposed STEL, even after feasible control measures to reduce TWA exposure to below the proposed PEL have been implemented, and therefore assumes that the use of respiratory protection will continue to be required for some short-term tasks. It is more difficult based on the currently available evidence to determine whether the alternative STEL of 1.0 μg/m³ would also be feasible in most operations based on lack of detail in the activities of the workers presented in the data. OSHA expects additional use of respiratory protection would be required for tasks in which peak exposures can be reduced to less than 2.0 μg/m³ but not less than 1.0 μg/m³. Due to limitations in the available sampling data and the higher detection limits for short term measurements, OSHA could not determine the percentage of the STEL measurements that are less than or equal to 0.5 μg/m³. A detailed discussion of the STELs being considered by OSHA is presented in Section 12 of Chapter IV of the PEA (OSHA, 2014).

OSHA requests available exposure monitoring data and comments regarding the effectiveness of currently implemented control measures and the feasibility of the PELs under consideration, particularly the proposed TWA PEL of 0.2 μg/m³, the alternative TWA PEL of 0.1 μg/m³, the proposed STEL of 2.0 μg/m³, and the alternative STEL of 1.0 μg/m³ to inform the Agency's final feasibility determinations.

Application Group Summaries

This section summarizes the technological feasibility analysis for each of the nine application groups affected by the proposed standard. Chapter IV of the PEA, Technological Feasibility Analysis, identifies specific jobs or job groups with potential exposure to beryllium, and presents exposure profiles for each of these job groups (OSHA, 2014). Control measures and work practices that OSHA believes can reduce exposures are described along with preliminary conclusions regarding the feasibility of the proposed PEL. Table IX–5, located at the end of this summary, presents summary statistics for the personal breathing zone samples taken to measure full-shift exposures to beryllium in each application group. For the five application groups in which the median exposure level for at least one job group exceeds the proposed PEL, the sampling results are presented by job group. Table IX–5 displays the number of measurements; the range, the mean and the median of the measurement results; and the percentage of measurements less than 0.1 μg/m³, less than or equal to the proposed PEL of 0.2 μg/m³, and less than or equal to the current PEL of 2.0 μg/m³. A more detailed discussion of exposure levels by job or job group for each application group is provided in Chapter IV of the PEA, sections 3 through 11, along with a description of the available exposure measurement data, existing controls, and additional controls that would be required to achieve the proposed PEL.

Beryllium Production

Only one primary beryllium production facility is currently in operation in the United States, a plant owned and operated by Materion Corporation,[15] located in Elmore, Ohio. OSHA identified eight job groups at this facility in which workers are exposed to beryllium. These include: Chemical operations, powdering operations, production support, cold work, hot work, site support, furnace operations, and administrative work.

The Agency developed an exposure profile for each of these eight job groups to analyze the distribution of exposure levels associated with primary beryllium production. The job exposure profiles are based primarily on full-shift personal breathing zone (PBZ) (lapel-type) sample results from air monitoring conducted by Brush Wellman's primary production facility in 1999 (Brush Wellman, 2004). Starting in 2000, the company developed the Materion Worker Protection Program (MWPP), a multi-faceted beryllium exposure control program designed to reduce airborne exposures for the vast majority of workers to less than an internally established exposure limit of 0.2 μg/m³. According to information provided by Materion, a combination of engineering controls, work practices, and housekeeping were used together to reduce average exposure levels to below 0.2 μg/m³ for the majority of workers (Materion Information Meeting, 2012). Also, two operations with historically high exposures, the wet plant and pebble plants, were decommissioned in 2000, thereby reducing average exposure levels. Therefore, the samples taken prior to 2000 may overestimate current exposures.

Additional exposure samples were taken by NIOSH at the Elmore facility from 2007 through 2008 (NIOSH, 2011). This dataset, which was made available to OSHA by Materion, contains fewer samples than the 1999 survey. OSHA did not incorporate these samples into the exposure profile due to the limited documentation associated with the sampling data. The lack of detailed information for individual samples has made it difficult for OSHA to correlate job classifications and identify the working conditions associated with the samples. Sampling data provided by Materion for 2007 and 2008 were not incorporated into the exposure profiles because the data lacked specific information on jobs and workplace conditions. In a meeting in May 2012 held between OSHA and Materion Corporation at the Elmore facility, the Agency was able to obtain some general information on the exposure control modifications that Materion Corporation made between 1999 and 2007, but has been unable to determine what specific

[15] Materion Corporation was previously named Brush Wellman. In 2011, subsequent to the collection of the information presented in this chapter, the name changed. ''Brush Wellman'' is used whenever the data being discussed pre-dated the name change.

controls were in place at the time NIOSH conducted sampling (Materion Information Meeting, 2012).

In five of the primary production job groups (*i.e.*, hot work, cold work, production support, site support, and administrative work), the baseline exposure profile indicates that exposures are already lower than the proposed PEL of 0.2 μg/m³. Median exposure values for these job groups range from nondetectable to 0.08 μg/m³.

For three of the job groups involved with primary beryllium production, (*i.e.*, chemical operations, powdering, and furnace operations), the median exposure level exceeds the proposed PEL of 0.2 μg/m³. Median exposure values for these job groups are 0.47, 0.37, and 0.68 μg/m³ respectively, and only 17 percent to 29 percent of the available measurements are less than or equal to 0.2 μg/m³. Therefore, additional control measures for these job groups would be required to achieve compliance with the proposed PEL. OSHA has identified several engineering controls that the Agency preliminarily concludes can reduce exposures in chemical processes and powdering operations to less than or equal to 0.2 μg/m³. In chemical processes, these include fail-safe drum-handling systems, full enclosure of drum-handling systems, ventilated enclosures around existing drum positions, automated systems to prevent drum overflow, and automated systems for container cleaning and disposal such as those designed for hazardous powders in the pharmaceutical industry. Similar engineering controls would reduce exposures in powdering operations. In addition, installing remote viewing equipment (or other equally effective engineering controls) to eliminate the need for workers to enter the die-loading hood during die filling will reduce exposures associated with this powdering task and reduce powder spills. Based on the availability of control methods to reduce exposures for each of the major sources of exposure in chemical operations, OSHA preliminarily concludes that exposures at or below the proposed 0.2 μg/m³ PEL can be achieved in most chemical and powdering operations most of the time. OSHA believes furnace operators' exposures can be reduced using appropriate ventilation, including fume capture hoods, and other controls to reduce overall beryllium levels in foundries, but is not certain whether the exposures of furnace operators can be reduced to the proposed PEL with currently available technology. OSHA requests additional information on current exposure levels and the effectiveness of potential control measures for primary beryllium production operations to further refine this analysis.

Beryllium Oxide Ceramics Production

OSHA identified seven job groups involved with beryllium oxide ceramics production. These include: Material preparation operator, forming operator, machining operator, kiln operator, production support, metallization, and administrative work. Four of these jobs (material preparation, forming operator, machining operator and kiln operator) work directly with beryllium oxides, and therefore these jobs have a high potential for exposure. The other three job groups (production support work, metallization, and administrative work) have primarily indirect exposure that occurs only when workers in these jobs groups enter production areas and are exposed to the same sources to which the material preparation, forming, machining and kiln operators are directly exposed. However, some production support and metallization activities do require workers to handle beryllium directly, and workers performing these tasks may at times be directly exposed to beryllium.

The Agency developed exposure profiles for these jobs based on air sampling data from four sources: (1) Samples taken between 1994 and 2003 at a large beryllium oxide ceramics facility, (2) air sampling data obtained during a site visit to a primary beryllium oxide ceramics producer, (3) a published report that provides information on beryllium oxide ceramics product manufacturing for a slightly earlier time period, and (4) exposure data from OSHA's Integrated Management Information System (OSHA, 2009). The exposure profile indicates that the three job groups with mostly indirect exposure (production support work, metallization, and administrative work) already achieve the proposed PEL of 0.2 μg/m³. Median exposure sample values for these job groups did not exceed 0.06 μg/m³.

The four job groups with direct exposure had higher exposures. In forming operations and machining operations, the median exposure levels of 0.18 and 0.15 ug/m³, respectively, are below the proposed PEL, while the median exposure levels for material preparation and kiln operations of 0.41 μg/m³ and 0.25 μg/m³, respectively, exceed the proposed PEL.

The profile for the directly exposed jobs may overestimate exposures due to the preponderance of data from the mid-1990s, a time period prior to the implementation of a variety of exposure control measures introduced after 2000. In forming operations, 44 percent of sample values in the exposure profile exceeded 0.2 ug/m³. However, the median exposure levels for some tasks, such as small-press and large-press operation, based on sampling conducted in 2003 were below 0.1 μg/m³. The exposure profile for kiln operation was based on three samples taken from a single facility in 1995, and are all above 0.2 ug/m³. Since then, exposures at the facility have declined due to changes in operations that reduced the amount of time kiln operators spend in the immediate vicinity of the kilns, as well as the discontinuation of a nearby high-exposure process. More recent information communicated to OSHA suggests that current exposures for kiln operators at the facility are currently below 0.1 ug/m³. Exposures in machining operations, most of which were already below 0.2 ug/m³ during the 1990s, may have been further reduced since then through improved work practices and exposure controls (PEA Chapter IV, Section 7). For forming, kiln, and machining operations, OSHA preliminarily concludes that the installation of additional controls such as machine interlocks (for forming) and improved enclosures and ventilation will reduce exposures to or below the proposed PEL most of the time. OSHA requests information on recent exposure levels and controls in beryllium oxide forming and kiln operations to help the Agency evaluate the effectiveness of available exposure controls for this application group.

In the exposure profile for material preparation, 73 percent of sample values exceeded 0.2 ug/m³. As with other parts of the exposure profile, exposure values from the mid-1990s may overestimate airborne beryllium levels for current operations. During most material preparation tasks, such as material loading, transfer, and spray drying, OSHA preliminarily concludes that exposures can be reduced to or below 0.2 μg/m³ with process enclosures, ventilation hoods, and improved housekeeping procedures. However, OSHA acknowledges that peak exposures from some short-term tasks such as servicing of the spray chamber might continue to drive the TWA exposures above 0.2 μg/m³ on days when these material preparation tasks are performed. Respirators may be needed to protect workers from exposures above the proposed TWA PEL during these tasks.[16] OSHA notes that material preparation for production of beryllium oxide ceramics currently takes place at only two facilities in the United States.

Nonferrous Foundries

OSHA identified eight job groups in aluminum and copper foundries with beryllium exposure: Molding, material handling, furnace operation, pouring, shakeout operation, abrasive blasting, grinding/finishing, and maintenance. The Agency developed exposure profiles based on an air monitoring survey conducted by NIOSH in 2007, a Health Hazard Evaluation (HHE) conducted by NIOSH in 1975, a site visit by ERG in 2003, a site visit report from 1999 by the California Cast Metals Association (CCMA); and two sets of data from air monitoring surveys obtained from Materion in 2004 and 2010.

The exposure profile indicates that in foundries processing beryllium alloys, six of the eight job groups have median exposures that exceed the proposed PEL of 0.2 μg/m³ with baseline working conditions. One exception is grinding/finishing operations, where the median value is 0.12 μg/m³ and 73 percent of exposure samples are below 0.2 μg/m³. The other exception is abrasive blasting. The samples for abrasive blasting used in the exposure profile were obtained during blasting operations using enclosed cabinets, and all 5 samples were below 0.2 μg/m³. Exposures for other job groups ranged from just below to well above the proposed PEL, including molder (all samples above 0.2 μg/m³), material handler (1 sample total, above 0.2 μg/m³), furnace operator (81.8 percent of samples above 0.2 μg/m³), pouring operator (60 percent of samples above 0.2 μg/m³), shakeout operator (1 sample total, above 0.2 μg/m³), and maintenance worker (50 percent of samples above 0.2 μg/m³).

In some of the foundries at which the air samples included in the exposure profile were collected, there are indications that the ventilation systems were not properly used or maintained, and dry sweeping or brushing and the use of compressed air systems for cleaning may have contributed to high dust levels. OSHA believes that exposures in foundries can be substantially reduced by improving and properly using and maintaining the ventilation systems; switching from dry brushing, sweeping and compressed air to wet methods and use of HEPA-filtered vacuums for cleaning molds and work areas; enclosing processes; automation of high-exposure tasks; and modification of processes (*e.g.*, switching from sand-based to alternative casting methods). OSHA preliminarily concludes that these additional engineering controls and modified work practices can be implemented to achieve the proposed PEL most of the time for molding, material handling, maintenance, abrasive blasting, grinding/finishing, and pouring operations at foundries that produce aluminum and copper beryllium alloys.

The Agency is less confident that exposure can be reliably reduced to the proposed PEL for furnace and shakeout operators. Beryllium concentrations in the proximity of the furnaces are typically higher than in other areas due to the fumes generated and the difficulty of controlling emissions during furnace operations. The exposure profile for furnace operations shows a median beryllium exposure level of 1.14 μg/m³. OSHA believes that furnace operators' exposures can be reduced using local exhaust ventilation and other controls to reduce overall beryllium levels in foundries, but it is not clear that they can be reduced to the proposed PEL with currently available technology. In foundries that use sand molds, the shakeout operation typically involves removing the freshly cast parts from the sand mold using a vibrating grate that shakes the sand from castings. The shakeout equipment generates substantial amounts of airborne dust that can be difficult to contain, and therefore shakeout operators are typically exposed to high dust levels. During casting of beryllium alloys, the dust may contain beryllium and beryllium oxide residues dislodged from the casting during the shakeout process. The exposure profile for the shakeout operations contains only one result of 1.3 μg/m³. This suggests that a substantial reduction would be necessary to achieve compliance with a proposed PEL of 0.2 μg/m³. OSHA requests additional information on recent employee exposure levels and the effectiveness of dust controls for shakeout operations for copper and aluminum alloy foundries.

Secondary Smelting, Refining, and Alloying

OSHA identified two job groups in this application group with exposure to beryllium: Mechanical process operators and furnace operations workers. Mechanical operators handle and treat source material, and furnace operators run heating processes for refining, melting, and casting metal alloy. OSHA developed exposure profiles for these jobs based on exposure data from ERG site visits to a precious/base metals recovery facility and a facility that melts and casts beryllium-containing alloys, both conducted in 2003. The available exposure data for this application group are limited, and therefore, the exposure profile is supplemented in part by summary data presented in secondary sources of information on beryllium exposures in this application group.

The exposure profile for mechanical processing operators indicates low exposures (3 samples less than 0.2 μg/m³), even though these samples were collected at a facility where the ventilation system was allowing visible emissions to escape exhaust hoods. Summary data from studies and reports published in 2005–2009 showed that mechanical processing operator exposures averaged between 0.01 and 0.04 μg/m³ at facilities where mixed or electronic waste including beryllium alloy parts were refined. Based on these results, OSHA preliminarily concludes that the proposed PEL is already achieved for most mechanical processing operations most of the time, and exposures could be further reduced through improved ventilation system design and other measures, such as process enclosures.

As with furnace operations examined in other application groups, the exposure profile indicates higher worker exposures for furnace operators in the secondary smelting, refining, and alloying application group (six samples with a median of 2.15 μg/m³, and 83.3 percent above 0.2 μg/m³). The two lowest samples in this job's exposure profile (0.03 and 0.5 μg/m³) were collected at a facility engaged in recycling and recovery of precious metals where work with beryllium-containing material is incidental. At this facility, the furnace is enclosed and fumes are ducted into a filtration system. The four higher samples, ranging from 1.92 to 14.08 μg/m³, were collected at a facility engaged primarily in beryllium alloying operations, where beryllium content is significantly higher than in recycling and precious metal recovery activities, the furnace is not enclosed, and workers are positioned directly in the path of the exhaust ventilation over the furnace. OSHA believes these exposures could be reduced by enclosing the furnace and repositioning the worker, but is not certain whether the reduction achieved would be enough to bring exposures down to the proposed PEL. Based on the limited number of samples in the exposure profile and surrogate data from furnace operations, the proposed PEL

[16] One facility visited by ERG has reportedly modified this process to reduce worker exposures, but OSHA has no data to quantify the reduction.

may not be feasible for furnace work in beryllium recovery and alloying, and respirators may be necessary to protect employees performing these tasks.

Precision Turned Products

OSHA's preliminary feasibility analysis for precision turned products focuses on machinists who work with beryllium-containing alloys. The Agency also examined the available exposure data for non-machinists and has preliminarily concluded that, in most cases, controlling the sources of exposures for machinists will also reduce exposures for other job groups with indirect exposure when working in the vicinity of machining operations.

OSHA developed exposure profiles based on exposure data from four NIOSH surveys conducted between 1976 and 2008; ERG site visits to precision machining facilities in 2002, 2003, and 2004; case study reports from six facilities machining copper-beryllium alloys; and exposure data collected between 1987 and 2001 by the U.S. Navy Environmental Health Center (NEHC). Analysis of the exposure data showed a substantial difference between the median exposure level for workers machining pure beryllium and/or high-beryllium alloys compared to workers machining low-beryllium alloys. Most establishments in the precision turned products application group work only with low-beryllium alloys, such as copper-beryllium. A relatively small number of establishments (estimated at 15) specialize in precision machining of pure beryllium and/or high-beryllium alloys.

The exposure profile indicates that machinists working with low-beryllium alloys have mostly low exposure to airborne beryllium. Approximately 85 percent of the 80 exposure results are less than or equal to 0.2 μg/m^3, and 74 percent are less than or equal to 0.1 μg/m^3. Some of the results below 0.1 μg/m^3 were collected at a facility where machining operations were enclosed, and metal cutting fluids were used to control the release of airborne contaminants. Higher results (0.1 μg/m^3–1.07 μg/m^3) were found at a facility where cutting and grinding operations were conducted in partially enclosed booths equipped with LEV, but some LEV was not functioning properly. A few very high results (0.77 μg/m^3–24 μg/m^3) were collected at a facility where exposure controls were reportedly inadequate and poor work practices were observed (*e.g.,* improper use of downdraft tables, use of compressed air for cleaning). Based on these results, OSHA preliminarily concludes that exposures below 0.2 μg/m^3 can be achieved most of the time for most machinists at facilities dealing primarily with low-beryllium alloys. OSHA recognizes that higher exposures may sometimes occur during some tasks where exposures are difficult to control with engineering methods, such as cleaning, and that respiratory protection may be needed at these times.

Machinists working with high-beryllium alloys have higher exposure than those working with low-beryllium alloys. This difference is reflected in the exposure profile for this job, where the median of exposure is 0.31 μg/m^3 and 75 percent of samples exceed the proposed PEL of 0.2 μg/m^3. The exposure profile was based on two machining facilities at which LEV was used and machining operations were performed under a liquid coolant flood. Like most facilities where pure beryllium and high-beryllium alloys are machined, these facilities also used some combination of full or partial enclosures, as well as work practices to minimize exposure such as prohibiting the use of compressed air and dry sweeping and implementing dust migration control practices to prevent the spread of beryllium contamination outside production areas. At one facility machining high-beryllium alloys, where all machining operations were fully enclosed and ventilated, exposures were mostly below 0.1 μg/m^3 (median 0.035 μg/m^3, range 0.02–0.11 μg/m^3). Exposures were initially higher at the second facility, where some machining operations were not enclosed, existing LEV system were in need of upgrades, and some exhaust systems were improperly positioned. Samples collected there in 2003 and 2004 were mostly below the proposed PEL in 2003 (median 0.1 μg/m^3) but higher in 2004 (median 0.25 μg/m^3), and high exposure means in both years (1.65 and 0.68 μg/m^3 respectively) show the presence of high exposure spikes in the facility. However, the facility reported that measures to reduce exposure brought almost all machining exposures below 0.2 μg/m^3 in 2006. With the use of fully enclosed machines and LEV and work practices that minimize worker exposures, OSHA preliminarily concludes that the proposed PEL is feasible for the vast majority of machinists working with pure beryllium and high-beryllium alloys. OSHA recognizes that higher exposures may sometimes occur during some tasks where exposures are difficult to control with engineering methods, such as machine cleaning and maintenance, and that respiratory protection may be needed at these times.

Copper Rolling, Drawing, and Extruding

OSHA's exposure profile for copper rolling, drawing, and extruding includes four job groups with beryllium exposure: strip metal production, rod and wire production, production support, and administrative work. Exposure profiles for these jobs are based on personal breathing zone lapel sampling conducted at the Brush Wellman Reading, Pennsylvania, rolling and drawing facility from 1977 to 2000.

Prior to 2000, the Reading facility had limited engineering controls in place. Equipment in use included LEV in some operations, HEPA vacuums for general housekeeping, and wet methods to control loose dust in some rod and wire production operations. The exposure profile shows very low exposures for all four job groups. All had median exposure values below 0.1 μg/m^3, and in strip metal production, production support, and administrative work, over 90 percent of samples were below 0.1 μg/m^3. In rod and wire production, 70 percent of samples were below 0.1 μg/m^3.

To characterize exposures in extrusion, OSHA examined the results of an industrial hygiene survey of a copper-beryllium extruding process conducted in 2000 at another facility. The survey reported eight PBZ samples, which were not included in the exposure profile because of their short duration (2 hours). Samples for three of the four jobs involved with the extrusion process (press operator, material handler, and billet assembler) were below the limit of detection (LOD) (level not reported). The two samples for the press operator assistant, taken when the assistant was buffing, sanding, and cleaning extrusion tools, were very high (1.6 and 1.9 μg/m^3). Investigators recommended a ventilated workstation to reduce exposure during these activities.

In summary, exposures at or below 0.2 μg/m^3 have already been achieved for most jobs in rolling, drawing, and extruding operations, and OSHA preliminarily concludes that the proposed PEL of 0.2 μg/m^3 is feasible for this application group. For jobs or tasks with higher exposures, such as tool refinishing, use of exposure controls such as local exhaust ventilation can help reduce workers' exposures. The Agency recognizes the limitations of the available data, which were drawn from two facilities and did not include full-shift PBZ samples for extrusion. OSHA requests additional exposure data from other facilities in this application group, especially data from facilities where extrusion is performed.

Fabrication of Beryllium Alloy Products

This application group includes the fabrication of beryllium alloy springs, stampings, and connectors for use in electronics. The exposure profile is based on a study conducted at four precision stamping companies; a NIOSH report on a spring and stamping company; an ERG site visit to a precision stamping, forming, and plating establishment; and exposure monitoring results from a stamping facility presented at the American Industrial Hygiene Conference and Exposition in 2007. The exposure profiles for this application group include three jobs: chemical processing operators, deburring operators, and assembly operators. Other jobs for which all samples results were below 0.1 μg/m³ are not shown in the profile.

For the three jobs in the profile, the majority of exposure samples were below 0.1 μg/m³ (deburring operators, 79 percent; chemical processing operators, 81 percent; assembly operators, 93 percent). Based on these results, OSHA preliminarily concludes that the proposed PEL is feasible for this application group. The Agency notes that a few exposures above the proposed PEL were recorded for the chemical processing operator (in plating and bright cleaning) and for deburring (during corn cob deburring in an open tumbling mill). OSHA believes the use of LEV, improved housekeeping, and work practice modifications would reduce the frequency of excursions above the proposed PEL.

Welding

Most of the samples in OSHA's exposure profile for welders in general industry were collected between 1994 and 2001 at two of Brush Wellman's alloy strip distribution centers, and in 1999 at Brush Wellman's Elmore facility. At these facilities, tungsten inert gas (TIG) welding was conducted on beryllium alloy strip. Seven samples in the exposure profile came from a case study conducted at a precision stamping facility, where airborne beryllium levels were very low (see previous summary, Fabrication of Beryllium Alloy Products). At this facility, resistance welding was performed on copper-beryllium parts, and welding processes were automated and enclosed.

Most of the sample results in the welding exposure profile were below 0.2 μg/m³. Of the 44 welding samples in the profile, 75 percent were below 0.2 μg/m³ and 64 percent were below 0.1 μg/m³, with most values between 0.01 and 0.05 μg/m³. All but one of the 16 exposure samples above 0.1 μg/m³ were collected in Brush Wellman's Elmore facility in 1999. According to company representatives, these higher exposure levels may have been due to beryllium oxide that can form on the surface of the material as a result of hot rolling. All seven samples from the precision stamping facility were below the limit of detection. Based on these results, OSHA preliminarily concludes that the proposed PEL of 0.2 μg/m³ is feasible for most welding operations in general industry.

Dental Laboratories

OSHA's exposure profile for dental technicians includes sampling results from a site visit conducted by ERG in 2003; a study of six dental laboratories published by Rom *et al.* in 1984; a data set of exposure samples collected between 1987 and 2001, on dental technicians working for the U.S. Navy; and a docket submission from CMP Industries including two samples from a large commercial dental laboratory using nickel-beryllium alloy. Information on exposure controls in these facilities suggests that controls in some cases may have been absent or improperly used.

The exposure profile indicates that 52 percent of samples are less than or equal to 0.2 μg/m³. However, the treatment of nondetectable samples in the feasibility analysis may overestimate many of the sample values in the exposure profile. Twelve of the samples in the profile are nondetectable for beryllium. In the exposure profile, these were assigned the highest possible value, the limit of detection (LOD). For eight of the nondetectable samples, the LOD was reported as 0.2 μg/m³. For the other four nondetectable samples, the LOD was between 0.23 and 0.71 μg/m³. If the true values for these four nondetectable samples are actually less than or equal to the assigned value of 0.2 μg/m³, then the true percentage of profile sample values less than or equal to 0.2 μg/m³ is between 52 and 70 percent. Of the sample results with detectable beryllium above 0.2 μg/m³, some were collected in 1984 at facilities studied by Rom *et al.,* who reported that they occurred during grinding with LEV that was improperly used or, in one case, not used at all. Others were collected at facilities where little contextual information was available to determine what control equipment or work practices might have reduced exposures.

Based on this information, OSHA preliminarily concludes that beryllium exposures for most dental technicians are already below 0.2 μg/m³ most of the time. OSHA furthermore believes that exposure levels can be reduced to or below 0.1 μg/m³ most of the time via material substitution, engineering controls, and work practices. Beryllium-free alternatives for casting dental appliances are readily available from commercial sources, and some alloy suppliers have stopped carrying alloys that contain beryllium. For those dental laboratories that continue to use beryllium alloys, exposure control options include properly designed, installed, and maintained LEV systems (equipped with HEPA filters) and enclosures; work practices that optimize LEV system effectiveness; and housekeeping methods that minimize beryllium contamination in the workplace. In summary, OSHA preliminarily concludes that the proposed PEL is feasible for dental laboratories.

TABLE IX–5—BERYLLIUM FULL-SHIFT PBZ SAMPLES BY APPLICATION/JOB GROUP (µg/m³)

Application/Job group	N	Range	Mean	Median	%<0.1	%≤0.2	%≤2.0
Be Production Operations (Section 3)							
Furnace Operations	172	0.05 to 254	3.80	0.68	5	17	82
Chemical Operations	20	0.05 to 9.6	1.02	0.47	5	15	95
Powdering Operations	72	0.06 to 11.5	0.82	0.37	11	29	94
Production Support	861	0.02 to 22.7	0.51	0.08	56	71	94
Cold Work	555	0.04 to 24.9	0.31	0.08	61	80	98
Hot Work	297	0.01 to 2.21	0.12	0.06	69	88	99
Site Support	879	0.05 to 4.22	0.11	0.05	81	92	99
Administrative	981	0.05 to 4.54	0.10	0.05	85	94	99
Be Oxide Ceramics (Section 4)							
Material Preparation Operator	77	0.02 to 10.6	1.01	0.41	13	27	90
Forming Operator	408	0.02 to 53.2	0.48	0.18	27	56	99
Machining Operator	355	0.01 to 5.0	0.32	0.15	37	63	98
Kiln Operator	3	0.22 to 0.36	0.28	0.25	0	0	100
Production Support Worker	119	0.02 to 7.7	0.21	0.05	68	88	98
Metallization Worker	36	0.02 to 0.62	0.15	0.06	55	69	100
Administrative	185	0.02 to 1.2	0.06	0.05	93	98	100
Aluminum and Copper Foundries (Section 5)							
Furnace Operator	11	0.2 to 19.76	4.41	1.14	0	18	64
Pouring Operator	5	0.2 to 2.2	1.21	1.40	0	40	60
Shakeout Operator	1	1.3	1.30	1.30	0	0	100
Material Handler	1	0.93	0.93	0.93	0	0	100
Molder	8	0.24 to 2.29	0.67	0.45	0	0	88
Maintenance	78	0.05 to 22.71	0.87	0.21	15	50	96
Abrasive Blasting Operator	5	0.05 to 0.15	0.11	0.12	40	100	100
Grinding/finishing Operator	56	0.01 to 4.79	0.31	0.05	59	73	95
Secondary Smelting (Section 6)							
Furnace operations worker	6	0.03 to 14.1	3.85	2.15	17	17	50
Mechanical processing operator	3	0.03 to 0.2	0.14	0.20	33	100	100
Precision Turned Products (Section 7)							
High Be Content Alloys	80	0.02 to 7.2	0.72	0.31	14	25	92
Low Be Content Alloys	59	0.005 to 24	0.45	0.01	74	85	96
Rolling, Drawing, and Extruding (Section 8)	650	0.006 to 7.8	0.11	0.024	86	93	99
Alloy Fabrication (Section 9)	71	0.004 to 0.42	0.056	0.025	83	94	100
Welding: Beryllium Alloy (Section 10)	44	0.005 to 2.21	0.19	0.02	64	75	98
Dental Laboratories (Section 11)	23	0.02 to 4.4	0.74	0.2	13	52	87

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

E. Costs of Compliance

Chapter V of the PEA in support of the proposed beryllium rule provides a detailed assessment of the costs to establishments in all affected application groups of reducing worker exposures to beryllium to an eight-hour time-weighted average (TWA) permissible exposure limit (PEL) of 0.2 μg/m³ and to the proposed short-term exposure limit (STEL) of 2.0 μg/m³, as well as of complying with the proposed standard's ancillary provisions. OSHA describes its methodology and sources in more detail in Chapter V. OSHA's preliminary cost assessment is based on the Agency's technological feasibility analysis presented in Chapter IV of the PEA; analyses of the costs of the proposed standard conducted by OSHA's contractor, Eastern Research Group (ERG); and the comments submitted to the docket in response to the request for information (RFI) and as part of the SBREFA process.

As shown in Table IX–7 at the end of this section, OSHA estimates that the proposed standard would have an annualized cost of $37.6 million. All cost estimates are expressed in 2010 dollars and were annualized using a discount rate of 3 percent, which—along with 7 percent—is one of the discount rates recommended by OMB.[17] Annualization periods for expenditures on equipment are based on equipment life, and one-time costs are annualized over a 10-year period.

The estimated costs for the proposed beryllium rule represent the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that may already have been achieved with regard to existing beryllium requirements or costs necessary to achieve compliance with existing beryllium requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

Throughout this section and in the PEA, OSHA presents cost formulas in the text, usually in parentheses, to help explain the derivation of cost estimates for individual provisions. Because the values used in the formulas shown in the text are shown only to the second decimal place, while the actual spreadsheet formulas used to create final costs are not limited to two decimal places, the calculation using the presented formula will sometimes differ slightly from the presented total in the text, which is the actual and mathematically correct total as shown in the tables.

[17] Appendix V–A of the PEA presents costs by NAICS industry and establishment size categories using, as alternatives, a 7 percent discount rate—shown in Table V–A–1—and a 0 percent discount rate—shown in Table V–A–2.

1. Compliance With the Proposed PEL/STEL

OSHA's estimate of the costs for affected employers to comply with the proposed PEL of 0.2 μg/m³ and the proposed STEL of 2.0 μg/m³ consists of two parts. First, costs are estimated for the engineering controls, additional studies and custom design requirements to implement those controls, work practices, and specific training required for those work practices (as opposed to general training in compliance with the rule) needed for affected employers to meet the proposed PEL and STEL, as well as opportunity costs (lost productivity) that may result from working with some of the new controls. In most cases, the PEA breaks out these costs, but in other instances some or all of the costs are shortened simply to ''engineering controls'' in the text, for convenience. Second, for employers unable to meet the proposed PEL and STEL using engineering controls and work practices alone, costs are estimated for respiratory protection sufficient to reduce worker exposure to the proposed PEL and STEL or below.

In the technological feasibility analysis presented in Chapter IV of the PEA, OSHA concluded that implementing all engineering controls and work practices necessary to reach the proposed PEL will, except for a small residual group (accounting for about 6 percent of all exposures above the STEL), also reduce exposures below the STEL. However, based on the nature of the processes this residual group is likely to be engaged in, the Agency expects that employees would already be using respirators to comply with the PEL under the proposed standard. Therefore, with the proposed STEL set at ten times the proposed PEL, the Agency has preliminarily determined that engineering controls, work practices, and (when needed) respiratory protection sufficient to meet the proposed PEL are also sufficient to meet the proposed STEL. For that reason, OSHA has taken no additional costs for affected employers to meet the proposed STEL. The Agency invites comment and requests that the public provide data on this issue.

a. Engineering Controls

For this preliminary cost analysis, OSHA estimated the necessary engineering controls and work practices for each affected application group according to the exposure profile of current exposures by occupation presented in Chapter III of the PEA. Under the requirements of the proposed standard, employers would be required to implement engineering or work practice controls whenever beryllium exposures exceed the proposed PEL of 0.2 μg/m³ or the proposed STEL of 2.0 μg/m³.

In addition, even if employers are not exposed above the proposed PEL or proposed STEL, paragraph (f)(2) of the proposed standard would require employers at or above the action level to use at least one engineering or work practice control to minimize worker exposure. Based on the technological feasibility analysis presented in Chapter IV of the PEA, OSHA has determined that, for only two job categories in two application groups—chemical process operators in the Stamping, Spring and Connection Manufacture application group and machinists in the Machining application group—do the majority of facilities at or above the proposed action level, but below the proposed PEL, lack the baseline engineering or work controls required by paragraph (f)(2). Therefore, OSHA has estimated costs, where appropriate, for employers in these two application groups to comply with paragraph (f)(2).

By assigning controls based on application group, the Agency is best able to identify those workers with exposures above the proposed PEL and to design a control strategy for, and attribute costs specifically to, these groups of workers. By using this approach, controls are targeting those specific processes, emission points, or procedures that create beryllium exposures. Moreover, this approach allows OSHA to assign costs for technologies that are demonstrated to be the most effective in reducing exposures resulting from a particular process.

In developing cost estimates, OSHA took into account the wide variation in the size or scope of the engineering or work practice changes necessary to minimize beryllium exposures based on technical literature, judgments of knowledgeable consultants, industry observers, and other sources. The resulting cost estimates reflect the representative conditions for the affected workers in each application group and across all work settings. In all but a handful of cases (with the exceptions noted in the PEA), all wage costs come from the 2010 Occupational Employment Statistics (OES) of the Bureau of Labor Statistics (BLS, 2010a) and utilize the median wage for the appropriate occupation. The wages used include a 30.35 percent markup for fringe benefits as a percentage of total compensation, which is the average percentage markup for fringe benefits for all civilian workers from the 2010 Employer Costs for Employee Compensation of the BLS (BLS, 2010b). All descriptions of production processes are drawn from the relevant sections of Chapter IV of the PEA.

The specific engineering costs for each of the applications groups, and the NAICS industries that contain those application groups, are discussed in Chapter V of the PEA. Like the industry profile and technological feasibility analysis presented in other PEA chapters, Chapter V of the PEA presents engineering control costs for the following application groups:

Beryllium Production
Beryllium Oxide, Ceramics & Composites Production
Nonferrous Foundries
Stamping, Spring and Connection Manufacture
Secondary Smelting, Refining, and Alloying
Copper Rolling, Drawing, and Extruding
Secondary Smelting, Refining, and Alloying
Precision Machining
Welding
Dental Laboratories

The costs within these application groups are estimated by occupation and/or operation. One application group could have multiple occupations, operations, or activities where workers are exposed to levels of beryllium above the proposed PEL, and each will need its own set of controls. The major types of engineering controls needed to achieve compliance with the proposed PEL include ventilation equipment, pharmaceutical-quality high-containment isolators, decontainment chambers, equipment with controlled water sprays, closed-circuit remote televisions, enclosed cabs, conveyor enclosures, exhaust hoods, and portable local-exhaust-ventilation (LEV) systems. Capital costs and annual operation and maintenance (O&M) costs, as well as any other annual costs, are estimated for the set of engineering controls estimated to be necessary for limiting beryllium exposures for each occupation or operation within each application group.

Tables V–2 through V–10 in Chapter V of the PEA summarize capital, maintenance, and operating costs for each application group disaggregated by NAICS code. Table IX–7 at the end of this section breaks out the costs of engineering controls/work practices by application group and NAICS code.

Some engineering control costs are estimated on a per-worker basis and then multiplied by the estimated number of affected workers—as identified in Chapter III: Profile of Affected Industries in the PEA—to arrive at a total cost for a particular control within a particular application group. This worker-based method is necessary because—even though OSHA has data on the number of firms in each affected industry, the occupations and industrial activities that result in worker exposure to beryllium, and the exposure profile of at-risk occupations—the Agency does not have a way to match up these data at the firm level. Nor does the Agency have establishment-specific data on worker exposure to beryllium for all establishments, or even establishment-specific data on the level of activity involving worker exposure to beryllium. Thus, OSHA could not always directly estimate per-affected-establishment costs, but instead first had to estimate aggregate compliance costs (using an estimated per-worker cost multiplied by the number of affected workers) and then calculate the average per-affected-establishment costs by dividing those aggregate costs by the number of affected establishments. This method, while correct on average, may under- or over-state costs for certain firms. For other controls that are implemented on a fixed-cost basis per establishment (*e.g.,* creating a training program, writing a control program), the costs are estimated on an establishment basis, and these costs were multiplied by the number of affected establishments in the given application group to obtain total control costs.

In developing cost estimates, the Agency sometimes had to make case-specific judgments about the number of workers affected by each engineering control. Because work environments vary within occupations and across establishments, there are no definitive data on how many workers are likely to have their exposures reduced by a given set of controls. In the smallest establishments, especially those that might operate only one shift per day, some controls would limit exposures for only a single worker in one specific affected occupation. More commonly, however, several workers are likely to benefit from each enhanced engineering control. Many controls were judged to reduce exposure for employees in multi-shift work or where workstations are used by more than one worker per shift.

In general, improving work practices involves operator training, actual work practice modifications, and better enforcement or supervision to minimize potential exposures. The costs of these process improvements consist of the supervisor and worker time involved and would include the time spent by supervisors to develop a training program.

Unless otherwise specified, OSHA viewed the extent to which exposure controls are already in place to be reflected in the distribution of exposures at levels above the proposed PEL among affected workers. Thus, for example, if 50 percent of workers in a given occupation are found to be exposed to beryllium at levels above the proposed PEL, OSHA judged this equivalent to 50 percent of facilities lacking adequate exposure controls. The facilities may have, for example, the correct equipment installed but without adequate ventilation to provide protection to workers exposed to beryllium. In this example, the Agency would expect that the remaining 50 percent of facilities to either have installed the relevant controls to reduce beryllium exposures below the PEL or that they engage in activities that do not require that the exposure controls be in place (for example, they do not perform any work with beryllium-containing materials). To estimate the need for incremental controls on a per-worker basis, OSHA used the exposure profile information as the best available data. OSHA recognizes that a very small percentage of facilities might have all the relevant controls in place but are still unable, for whatever reason, to achieve the proposed PEL through controls alone. ERG's review of the industrial hygiene literature and other source materials (ERG, 2007b), however, suggest that the large majority of workplaces where workers are exposed to high levels of beryllium lack at least some of the relevant controls. Thus, in estimating the costs associated with the proposed standard, OSHA has generally assumed that high levels of exposure to beryllium occur due to the absence of suitable controls. This assumption likely results in an overestimate of costs since, in some cases, employers may not need to install and maintain new controls in order to meet the proposed PEL but merely need to upgrade or better maintain existing controls, or to improve work practices.

b. Respiratory Protection Costs

Based on the findings of the technological feasibility analysis, a small subset of employees working with a few processes in a handful of application groups will need to use respirators, in addition to required engineering controls and improved work practices, to reduce employee exposures to meet the proposed PEL. Specifically, furnace operators—both in non-ferrous foundries (both sand and non-sand) and in secondary smelting, refining, and alloying—as well as welders in a few other processes, will need to wear half-mask respirators. In beryllium production, workers who rebuild or otherwise maintain furnaces and furnace tools will need to wear full-face powered air-purifying respirators. Finally, the Agency recognizes the possibility that, after all feasible engineering and other controls are in place, there may still be a residual group with potential exposure above the proposed PEL and/or STEL. To account for these residual cases, OSHA estimates that 10 percent of the workers, across all application groups and job categories, who are above the proposed PEL before the beryllium proposed standard is in place (according to the baseline exposure profile presented in Chapter III of the PEA), would still be above the PEL after all feasible controls are implemented and, hence, would need to use half-mask respirators to achieve compliance with the proposed PEL.

There are five primary costs for respiratory protection. First, there is a cost per establishment to set up a written respirator program in accordance with the respiratory protection standard (29 CFR 1910.134). The respiratory protection standard requires written procedures for the proper selection, use, cleaning, storage, and maintenance of respirators. As derived in the PEA, OSHA estimates that, when annualized over 10 years, the annualized per-establishment cost for a written respirator program is $207.

For reasons unrelated to the proposed standard, certain establishments will already have a respirator program in place. Table V–11 in Chapter V of the PEA presents OSHA's estimates, by application group, of current levels of compliance with the respirator program provision of the proposed rule.

The four other major costs of respiratory protection are the per-employee costs for all aspects of respirator use: equipment, training, fit-testing, and cleaning. Table V–12 of Chapter V in the PEA breaks out OSHA's estimate of the unit costs for the two types of respirators needed: A half-mask respirator and a full-face powered air-purifying respirator. As derived in the PEA, the annualized per-employee cost for a half-mask respirator would be $524 and the annualized per-employee cost for a full-face powered air-purifying respirator would be $1,017.

Table V–13 in Chapter V of the PEA presents the number of additional employees, by application group and NAICS code, that would need to wear respirators to comply with the proposed standard and the cost to industry to comply with the respirator protection provisions in the proposed rule. OSHA judges that only workers in Beryllium Production work with processes that would require a full-face respirator and estimates that there are 23 of those workers. Three hundred and eighteen workers in other assorted application groups are estimated to need half-mask respirators. A total of 341 employees would need to wear some type of respirator, resulting in a total annualized cost of $249,684 for affected industries to comply with the respiratory protection requirements of the proposed standard. Table IX–7 at the end of this section breaks out the costs of respiratory protection by application group and NAICS code.

2. Ancillary Provisions

This section presents OSHA's estimated costs for ancillary beryllium control programs required under the proposed rule. Based on the program requirements contained in the proposed standard, OSHA considered the following cost elements in the following employer duties: (a) Assess employees' exposure to airborne beryllium, (b) establish regulated areas, (c) develop a written exposure control plan, (d) provide protective work clothing, (e) establish hygiene areas and practices, (f) implement housekeeping measures, (g) provide medical surveillance, (h) provide medical removal for employees who have developed CBD or been confirmed positive for beryllium sensitization, and (i) provide appropriate training.

The worker population affected by each program element varies by several criteria discussed in detail in each subsection below. In general, some elements would apply to all workers exposed to beryllium at or above the action level. Other elements would apply to a smaller set of workers who are exposed above the PEL. The training requirements would apply to all employees who work in a beryllium work area (*e.g.,* an area with any level of exposure to airborne beryllium). The regulated area program elements triggered by exposures exceeding the proposed PEL of 0.2 μg/m³ would apply to those workers for whom feasible controls are not adequate. In the earlier discussion of respiratory protection, OSHA estimated that 10 percent of all affected workers with current exposures above the proposed PEL would fall in this category.

Costs for each program requirement are aggregated by employment and by industry. For the most part, unit costs do not vary by industry, and any variations are specifically noted. The estimated compliance rate for each provision of the proposed standard by application group is presented in Table V–15 of the PEA.

a. Exposure Assessment

Most establishments wishing to perform exposure monitoring would require the assistance of an outside consulting industrial hygienist (IH) to obtain accurate results. While some firms might already employ or train qualified staff, OSHA judged that the testing protocols are fairly challenging and that few firms have sufficiently skilled staff to eliminate the need for outside consultants.

The proposed standard requires that, after receiving the results of any exposure monitoring where exposures exceed the TWA PEL or STEL, the employer notify each such affected employee in writing of suspected or known sources of exposure, and the corrective action(s) being taken to reduce exposure to or below the PEL. Those workers exposed at or above the action level and at or below the PEL must have their exposure levels monitored annually.

For costing purposes, OSHA estimates that, on average, there are four workers per work area. OSHA interpreted the initial exposure assessment as requiring first-year testing of at least one worker in each distinct job classification and work area who is, or may reasonably be expected to be, exposed to airborne concentrations of beryllium at or above the action level.

The proposed standard requires that whenever there is a change in the production, process, control equipment, personnel, or work practices that may result in new or additional exposures, or when the employer has any reason to suspect that a change may result in new or additional exposures, the employer must conduct additional monitoring. The Agency has estimated that this provision would require an annual sampling of 10 percent of the affected workers.

OSHA estimates that an industrial hygienist (IH) would spend 1 day each year to sample 2 workers, for a per worker IH fee of $257. This exposure monitoring requires that three samples be taken per worker: One TWA and two STEL for an annual IH fee per sample of $86. Based on the 2000 EMSL Laboratory Testing Catalog (ERG, 2007b), OSHA estimated that analysis of each sample would cost $137 in lab fees. When combined with the IH fee, OSHA estimated the annual cost to obtain a TWA sample to be $223 per sampled worker and the annual cost to obtain the two STEL samples to be $445 per sampled worker. The direct exposure monitoring unit costs are summarized in Table V–16 in Chapter V of the PEA.

The cost of the sample also incorporates a productivity loss due to the additional time for the worker to participate in the sampling (30 minutes per worker sampled) as well as for the associated recordkeeping time incurred by a manager (15 minutes per worker sampled). The STEL samples are assumed to be taken along with the TWA sample and, thus, labor costs were not added to both unit costs. Including the costs related to lost productivity, OSHA estimates the total annual cost of a TWA sample to be $251, and 2 STEL samples, $445. The total annual cost per worker for all sampling taken is then $696. OSHA estimates the total annualized cost of this provision to be $2,208,950 for all affected industries. The annualized cost of this provision for each affected NAICS industry is shown in Table IX–6.

b. Beryllium Work Areas and Regulated Areas

The proposed beryllium standard requires the employer to establish and maintain a regulated area wherever employees are, or can reasonably expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. Regulated areas require specific provisions that both limit employee exposure within its boundaries and curb the migration of beryllium outside the area. The Agency judged, based on the preliminary findings of the technological feasibility analysis, that companies can reduce establishment-wide exposure by ensuring that only authorized employees wearing proper protective equipment have access to areas of the establishment where such higher concentrations of beryllium exist, or can be reasonably expected to exist. Workers in other parts of the establishment are also likely to see a reduction in beryllium exposures due to these measures since fewer employees would be traveling through regulated areas and subsequently carrying beryllium residue to other work areas on their clothes and shoes.

Requirements in the proposed rule for a regulated area include: Demarcating the boundaries of the regulated area as separate from the rest of the workplace, limiting access to the regulated area, providing an appropriate respirator to each person entering the regulated area and other protective clothing and equipment as required by paragraph (g) and paragraph (h), respectively.

OSHA estimated that the total annualized cost per regulated area, including set-up costs ($76), respirators ($1,768) and protective clothing ($4,500), is $6,344.

When establishments are in full compliance with the standard, regulated areas would be required only for those workers for whom controls could not feasibly reduce their exposures to or below the 0.2 μg/m³ TWA PEL and the 2 μg/m³ STEL. Based on the findings of the technological feasibility analysis, OSHA estimated that 10 percent of the affected workers would be exposed above the TWA PEL or STEL after implementation of engineering controls and thus would require regulated areas (with one regulated area, on average, for every four workers exposed above the proposed TWA PEL or STEL).

The proposed standard requires that all beryllium work areas are adequately established and demarcated. ERG estimated that one work area would need to be established for every 12 at-risk workers. OSHA estimates that the annualized cost would be $33 per work area.

OSHA estimates the total annualized cost of the regulated areas and work areas is $629,031 for all affected industries. The cost for each affected application group and NAICS code is shown in Table IX–6.

c. Written Exposure Control Plan

The proposed standard requires that employers must establish and maintain a written exposure control plan for beryllium work areas. The written program must contain:

1. An inventory of operations and job titles reasonably expected to have exposure.
2. An inventory of operations and job titles reasonably expected to have exposure at or above the action level.
3. An inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL.
4. Procedures for minimizing cross-contamination, including but not limited to preventing the transfer of beryllium between surfaces, equipment, clothing, materials and articles within beryllium work areas.
5. Procedures for keeping surfaces in the beryllium work area free as practicable of beryllium.
6. Procedures for minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace.
7. An inventory of engineering and work practice controls required by paragraph (f)(2) of this standard.
8. Procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators.

The unit cost estimates take into account the judgment that (1) most establishments have an awareness of beryllium risks and, thus, should be able to develop or modify existing safeguards in an expeditious fashion, and (2) many operations have limited beryllium activities and these establishments need to make only modest changes in procedures to create the necessary exposure control plan. ERG's experts estimated that managers would spend eight hours per establishment to develop and implement such a written exposure control plan, yielding a total cost per establishment to develop and implement the written control plan of $563.53 and an annualized cost of $66. In addition, because larger firms with more affected workers will need to develop more complicated written control plans, the development of a plan would require an extra thirty minutes of a manager's time per affected employee, for a cost of $35 per affected employee and an annualized cost of $4 per employee. Managers would also need 12 minutes (0.2 hours) per affected employee per quarter, or 48 minutes per affected employee per year to review and update the plan, for a recurring cost of $56 per affected employee per year to maintain and update the plan. Five minutes of clerical time would also be needed per employee for providing each employee with a copy of the written exposure control plan—yielding an annualized cost of $2 per employee. The total annual per-employee cost for development, implementation, review, and update of a written exposure control plan is then $62. The Agency estimates the total annualized cost of this provision to be $1,769,506 for all affected establishments. The breakdown of these costs by application group and NAICS code is presented in Table IX–6.

d. Personal Protective Clothing and Equipment

The proposed standard requires personal protective clothing and equipment for workers:

1. Whose exposure can reasonably be expected to exceed the TWA PEL or STEL.
2. When work clothing or skin may become visibly contaminated with beryllium, including during maintenance and repair activities or during non-routine tasks.
3. Where employees' skin can reasonably be expected to be exposed to soluble beryllium compounds.

OSHA has determined that it would be necessary for employers to provide reusable overalls and/or lab coats at a cost of $284 and $86, respectively, for operations in the following application groups:

Beryllium Production
Beryllium Oxide, Ceramics & Composites
Nonferrous Foundries
Fabrication of Beryllium Alloy Products
Copper Rolling, Drawing & Extruding
Secondary Smelting, Refining and Alloying
Precision Turned Products
Dental Laboratories

Chemical process operators in the spring and stamping application group would require chemical resistant protective clothing at an annual cost of $849. Gloves and/or shoe covers would be required when performing operations in several different application groups, depending on the process being performed, at an annual cost of $50 and $78, respectively.

The proposed standard requires that all reusable protective clothing and equipment be cleaned, laundered, repaired, and replaced as needed to maintain their effectiveness. This includes such safeguards as transporting contaminated clothing in sealed and labeled impermeable bags and informing any third party businesses coming in contact with such materials of the risks associated with beryllium exposure. OSHA estimates that the lowest cost alternative to satisfy this provision is for an employer to rent and launder reusable protective clothing—at an estimated annual cost per employee of $49. Ten minutes of clerical time would also be needed per establishment with laundry needs to notify the cleaners in writing of the potentially harmful effects of beryllium exposure and how the protective clothing and equipment must be handled in accordance with this standard—at a per establishment cost of $3.

The Agency estimates the total annualized cost of this provision to be $1,407,365 for all affected establishments. The breakdown of these costs by application group and NAICS code is shown in Table IX–6.

e. Hygiene Areas and Practices

The proposed standard requires employers to provide readily accessible washing facilities to remove beryllium from the hands, face, and neck of each employee working in a beryllium work area and also to provide a designated change room in workplaces where employees would have to remove their personal clothing and don the employer-provided protective clothing. The proposed standard also requires that employees shower at the end of the work shift or work activity if the employee reasonably could have been exposed to beryllium at levels above the PEL or STEL, and if those exposures could reasonably be expected to have caused contamination of the employee's hair or body parts other than hands, face, and neck.

In addition to other forms of PPE costed previously, for processes where hair may become contaminated, head coverings can be purchased at an annual cost of $28 per employee. This could satisfy the requirement to avoid contaminated hair. If workers are covered by protective clothing such that no body parts (including their hair where necessary, but not including their hands, face, and neck) could reasonably be expected to have been contaminated by beryllium, and they could not reasonably be expected to be exposed to beryllium while removing their protective clothing, they would not need to shower at the end of a work shift or work activity. OSHA notes that some facilities already have showers, and the Agency judges that all employers either already have showers where needed or will have sufficient measures in place to ensure that employees could not reasonably be expected to be exposed to beryllium while removing protective clothing. Therefore, OSHA has preliminarily determined that employers will not need to provide any new shower facilities to comply with the standard.

The Agency estimated the costs for the addition of a change room and segregated lockers based on the costs for acquisition of portable structures. The change room is presumed to be used in providing a transition zone from general working areas into beryllium-using regulated areas. OSHA estimated that portable building, adequate for 10 workers per establishment can be rented annually for $3,251, and that lockers could be procured for a capital cost of $407—or $48 annualized—per establishment. This results in an annualized cost of $3,299 per facility to rent a portable change room with lockers. OSHA estimates that the 10 percent of affected establishments unable to meet the proposed TWA PEL would require change rooms. The Agency estimated that a worker using a change room would need 2 minutes per day to change clothes. Assuming 250 days per year, this annual time cost for changing clothes is $185 per employee.

The Agency estimates the total annualized cost of the provision on hygiene areas and practices to be $389,241 for all affected establishments. The breakdown of these costs by application group and NAICS code can be seen in Table IX–6.

f. Housekeeping

The proposed rule specifies requirements for cleaning and disposing of beryllium-contaminated wastes. The employer shall maintain all surfaces in beryllium work areas as free as practicable of accumulations of beryllium and shall ensure that all spills and emergency releases of beryllium are cleaned up promptly, in accordance with the employer's written exposure control plan and using a HEPA-filtered vacuum or other methods that minimize the likelihood and level of exposure. The employer shall not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of exposure have been tried and were not effective.

ERG's experts estimated that each facility would need to purchase a single vacuum at a cost of $2,900 for every five affected employees in order to successfully integrate housekeeping into their daily routine. The per-employee cost would be $580, resulting in an annualized cost of $68 per worker. ERG's experts also estimated that all affected workers would require an additional five minutes per work day (.083 hours) to complete vacuuming tasks and to label and dispose of beryllium-contaminated waste. While this allotment is modest, OSHA judged that the steady application of this incremental additional cleaning, when combined with currently conducted cleaning, would be sufficient in average establishments to address dust or surface contamination hazards. Assuming that these affected workers would be working 250 days per year, OSHA estimates that the annual labor cost per employee for additional time spent cleaning in order to comply with this provision is $462.

The proposed standard requires each disposal bag with contaminated materials to be properly labeled. ERG estimated a cost of 10 cents per label with one label needed per day for every five workers. With the disposal of one labeled bag each day and 250 working days, the per-employee annual cost would be $5. The annualized cost of a HEPA-filtered vacuum, combined with the additional time needed to perform housekeeping and the labeling of disposal bags, results in a total annualized cost of $535 per employee.

The Agency estimates the total annualized cost of this provision to be $12,574,921 for all affected establishments. The breakdown of these costs by application group and NAICS code is shown in Table IX–6.

g. Medical Surveillance

The proposed standard requires the employer to make medical surveillance available at no cost to the employee, and at a reasonable time and place, for the following employees:

1. Employees who have worked in a regulated area for more than 30 days in the last 12 months
2. Employees showing signs or symptoms of chronic beryllium disease (CBD)
3. Employees exposed to beryllium during an emergency; and
4. Employees exposed to airborne beryllium above 0.2 $\mu g/m^3$ for more than 30 days in a 12-month period for 5 years or more.

As discussed in the regulated areas section of this analysis of program costs, the Agency estimates that approximately 10 percent of affected employees would have exposure in excess of the PEL after the standard goes into effect and would therefore be placed in regulated areas. The Agency further estimates that a very small number of employees will be affected by emergencies in a given year, likely less than 0.1 percent of the affected population, representing a small additional cost. The number of workers who would suffer signs and symptoms of CBD after the rule takes effect is difficult to estimate, but would likely substantially exceed those with actual cases of CBD.

While the symptoms of CBD vary greatly, the first to appear are usually chronic dry cough (generally defined as a nonproductive cough, without phlegm or sputum, lasting two months or more) and shortness of breath during exertion. Ideally, in developing these costs estimates, OSHA would first estimate the percent of affected workers who might be presenting with a chronic cough and/or experiencing shortness of breath.

Studies have found the prevalence of a chronic cough ranging from 10 to 38 percent across various community populations, with smoking accounting for up to 18 percent of cough prevalence (Irwin, 1990; Barbee, 1991). However, these studies are over 20 years old, and the number of smokers has decreased substantially since then. It's also not clear whether the various segments of the U.S. population studied are similar enough to the population of workers exposed to beryllium such that results of these studies could be generalized to the affected worker population.

A more recent study from a plant in Cullman, Alabama that works with beryllium alloy found that about five percent of employees said they were current smokers, with roughly 52 percent saying they were previous smokers and approximately 43 percent stating they had never smoked (Newman et al., 2001). This study does not, however, report on the prevalence of chronic cough in this workplace.

OSHA was unable to identify any studies on the general prevalence of the other common early symptom of CBD, shortness of breath. Lacking any better data to base an estimate on, the Agency used the studies cited above (Irwin, 1990; Barbee, 1991) showing the prevalence of chronic cough in the general population, adjusted to account for the long term decrease in smoking prevalence (and hence, the amount of overall cases of chronic cough), and estimated that 15 percent of the worker population with beryllium exposure would exhibit a chronic cough or other sign or symptom of CBD that would trigger medical surveillance. The Agency welcomes comment and further data on this question.

According to the proposed rule, the initial (baseline) medical examination would consist of the following:

1. A medical and work history, with emphasis on past and present exposure, smoking history and any history of respiratory system dysfunction;
2. A physical examination with emphasis on the respiratory tract;
3. A physical examination for skin breaks and wounds;
4. A pulmonary function test;
5. A standardized beryllium lymphocyte proliferation test (BeLPT) upon the first examination and within every two years from the date of the first examination until the employee is confirmed positive for beryllium sensitization;
6. A CT scan, offered every two years for the duration of the employee's employment, if the employee was exposed to airborne beryllium at levels above 0.2 $\mu g/m^3$ for more than 30 days in a 12-month period for at least 5 years. This obligation begins on the start-up date of this standard, or on the 15th year after the employee's first exposure above for more than 30 days in a 12-month period, whichever is later; and
7. Any other test deemed appropriate by the Physician or other Licensed Health Care Professional (PLHCP).

Table V–17 in Chapter V of the PEA lists the direct unit costs for initial medical surveillance activities including: Work and medical history, physical examination, pulmonary function test, BeLPT, CT scan, and costs of additional tests. In OSHA's cost model, all of the activities will take place during an employee's initial visit and on an annual basis thereafter and involve a single set of travel costs, except that: (1) The BeLPT tests will only be performed at two-year intervals after the initial test, but will be conducted in conjunction with the annual general examination (no additional travel costs); and (2) the CT scans will typically involve different specialists and are therefore treated as separate visits not encompassed by the general exams (therefore requiring separate travel costs). Not all employees would require CT scans, and employers would only be required to offer them every other year.

In addition to the fees for the annual medical exam, employers may also incur costs for lost work time when their employees are unavailable to perform their jobs. This includes time for traveling, a health history review, the physical exam, and the pulmonary function test. Each examination would require 15 minutes (or 0.25 hours) of a human resource manager's time for recording the results of the exam and tests and the PLHCP's written opinion for each employee and any necessary post-exam consultation with the employee. There is also a cost of 15 minutes of supervisor time to provide information to the physician, five minutes of supervisor time to process a licensed physician's written medical opinion, and five minutes for an employee to receive a licensed physician's written medical opinion. The total unit annual cost for the medical examinations and tests, excluding the BeLPT test, and the time required for both the employee and the supervisor is $297.

The estimated fee for the BeLPT is $259. With the addition of the time incurred by the worker to undergo the test, the total cost for a BeLPT is $261. The standard requires a biennial BeLPT for each employee covered by the medical surveillance provision, so most workers would receive between two and five BeLPT tests over a ten year period (including the BeLPT performed during the initial examination), depending on whether the results of these tests were positive. OSHA therefore estimates a net present value (NPV) of $1,417 for all five tests. This NPV annualized over a ten year period is $166.

Together, the annualized net present value of the BeLPT and the annualized cost of the remaining medical surveillance produce an annual cost of $436 per employee.

The proposed standard requires that a helical tomography (CT scan) be offered to employees exposed to airborne beryllium above 0.2 $\mu g/m^3$ for more than 30 days in a 12-month period, for a period of 5 years or more. The five years do not need to be consecutive, and the exposure does not need to occur after the effective date of the standard. The CT scan shall be offered every 2 years starting on the 15th year after the first year the employee was exposed above 0.2 μg/m³ for more than 30 days in a 12-month period, for the duration of their employment. The total yearly cost for biennial CT scans consists of medical costs totaling $1,020, comprised of a $770 fee for the scan and the cost of a specialist to review the results, which OSHA estimates would cost $250. The Agency estimates an additional cost of $110 for lost work time, for a total of $1,131. The annualized yearly cost for biennial CT scans is $574.

Based on OSHA's estimates explained earlier in this section, all workers in regulated areas, workers exposed in emergencies, and an estimated 15 percent of workers not in regulated areas who exhibit signs and symptoms of CBD will be eligible for medical surveillance other than CT scans. The estimate for the number of workers eligible to receive CT scans is 25 percent of workers who are exposed above 0.2 in the exposure profile. The estimate of 25 percent is based on the facts that roughly this percentage of workers have 15-plus years of job tenure in the durable manufacturing sector and the estimate that all those with 15-plus years of job tenure and current exposure over 0.2 would have had at least 5 years of such exposure in the past.

The costs estimated for this provision are likely to be significantly overestimated, since not all affected employees offered medical surveillance would necessarily accept the offer. At Department of Energy facilities, only about 50 percent of eligible employees participate in the voluntary medical surveillance tests, and a report on an initial medical surveillance program at four aluminum manufacture facilities found participation rates to be around 57 percent (Taiwo et al., 2008). Where employers already offer equivalent health surveillance screening, no new costs are attributable to the proposed standard.

Within 30 days after an employer learns that an employee has been confirmed positive for beryllium sensitization, the employer's designated licensed physician shall consult with the employee to discuss referral to a CBD diagnostic center that is mutually agreed upon by the employer and the employee. If, after this consultation, the employee wishes to obtain a clinical evaluation at a CBD diagnostic center, the employer must provide the evaluation at no cost to the employee. OSHA estimates this consultation will take 15 minutes, with an estimated total cost of $33.

Table V–18 in Chapter V of the PEA lists the direct unit costs for a clinical evaluation with a specialist at a CBD diagnostic center. To estimate these costs, ERG contacted a healthcare provider who commonly treats patients with beryllium-related disease, and asked them to provide both the typical tests given and associated costs of an initial examination for a patient with a positive BeLPT test, presented in Table V–18 in Chapter V of the PEA. Their typical evaluation includes bronchoscopy with lung biopsy, a pulmonary stress test, and a chest CAT scan. The total cost for the entire suite of tests is $6,305.

In addition, there are costs for lost productivity and travel. The Agency has estimated the clinical evaluation would take three days of paid time for the worker to travel to and from one of two locations: Penn Lung Center at the Cleveland Clinic Foundation in Cleveland, Ohio or National Jewish Medical Center in Denver, Colorado. OSHA estimates lost work time is 24 hours, yielding total cost for the 3 days of $532.

OSHA estimates that roundtrip air-fare would be available for most facilities at $400, and the cost of a hotel room would be approximately $100 per night, for a total cost of $200 for the hotel room. OSHA estimates a per diem cost of $50 for three days, for a total of $150. The total cost per trip for traveling expenses is therefore $750.

The total cost of a clinical evaluation with a specialist at a CBD diagnostic center is equal to the cost of the examination plus the cost of lost work-time and the cost for the employee to travel to the CBD diagnostic center, or $7,620.

Based on the data from the exposure profile and the prevalence of beryllium sensitization observed at various levels of cumulative exposure,[18] OSHA estimated the number of workers eligible for BeLPT testing (4,181) and the percentage of workers who will be confirmed positive for sensitization (two positive BeLPT tests, as specified in the proposed standard) and referred to a CBD diagnostic center. During the first year that the medical surveillance provisions are in effect, OSHA estimates that 9.4 percent of the workers who are tested for beryllium sensitization will be identified as sensitized. This percentage is an average based on: (1) The number of employees in the baseline exposure profile that are in a given cumulative exposure range; (2) the expected prevalence for a given cumulative exposure range (from Table VI–6 in Section VI of the preamble); and (3) an assumed even distribution of employees by cumulative years of exposure at a given level—20 percent having exposures at a given level for 5 years, 20 percent for 15 years, 20 percent for 25 years, 20 percent for 30 years, and 20 percent for 40 years.

[18] See Table VI–6 in Section VI of the preamble, Preliminary Risk Assessment.

OSHA did not assume that all workers with confirmed sensitization would choose to undergo evaluation at a CBD diagnostic center, which may involve invasive procedures and/or travel. For purposes of this cost analysis, OSHA estimates that approximately two-thirds of workers who are confirmed positive for beryllium sensitization will choose to undergo evaluation for CBD. OSHA requests comment on the CBD evaluation participation rate. OSHA estimates that about 264 of all non-dental lab workers will go to a diagnostic center for CBD evaluation in the first year.

The calculation method described above applies to all workers except dental technicians, who were analyzed with one modification. The rates for dental technicians are calculated differently due to the estimated 75 percent beryllium-substitution rate at dental labs, where the 75 percent of labs that eliminate all beryllium use are those at higher exposure levels. None of the remaining labs affected by this standard had exposures above 0.1 μg/m³. For the dental labs, the same calculation was done as presented in the previous paragraph, but only the remaining 25 percent of employees (2,314) who would still face beryllium exposures were included in the baseline cumulative exposure profile. With that one change, and all other elements of the calculation the same, OSHA estimates that 9 percent of dental lab workers tested for beryllium sensitization will be identified as sensitized. The predicted prevalence of sensitization among those dental lab workers tested in the first year after the standard takes effect is slightly lower than the predicted prevalence among all other tested workers combined. This slightly lower rate is not surprising because only dental lab workers with exposures below 0.1 μg/m³ are included (after adjusting for substitution), and OSHA's exposure profile indicates that the vast majority of non-dental workers exposed to beryllium are also exposed at 0.1 μg/m³ or lower. OSHA estimates that 20 dental lab workers (out of 347 tested for sensitization) would go to a diagnostic center for CBD evaluation in the first year.

In each year after the first year, OSHA relied on a 10 percent worker turnover rate in a steady state (as discussed in Chapter VII of the PEA) to estimate that the annual sensitization incidence rate is 10 percent of the first year's incidence rate. Based on that rate and the number of workers in the medical surveillance program, the CBD evaluation rate for workers other than those in dental labs would drop to 0.63 percent (.063 × .10). The evaluation rate for dental labs technicians is similarly estimated to drop to 0.58 percent (.058 × .10).

Based on these unit costs and the number of employees requiring medical surveillance estimated above, OSHA estimates that the medical surveillance and referral provisions would result in an annualized total cost of $2,882,706. These costs are presented by application group and NAICS code in Table IX–7.

h. Medical Removal Provision

Once a licensed physician diagnoses an employee with CBD or the employee is confirmed positive for sensitization to beryllium, that employee is eligible for medical removal and has two choices:

(a) Removal from current job, or

(b) Remain in a job with exposure above the action level while wearing a respirator pursuant to 29 CFR 1910.134.

To be eligible for removal, the employee must accept comparable work if such is available, but if not available the employer would be required to place the employee on paid leave for six months or until such time as comparable work becomes available, whichever comes first. During that six-month period, whether the employee is re-assigned or placed on paid leave, the employer must continue to maintain the employee's base earnings, seniority and other rights, and benefits that existed at the time of the first test.

For purposes of this analysis, OSHA has conservatively estimated the costs as if all employees will choose removal, rather than remaining in the current job while wearing a respirator. In practice, many workers may prefer to continue working at their current job while wearing a respirator, and the employer would only incur the respirator costs identified earlier in this chapter. The removal costs are significantly higher over the same six-month period, so this analysis likely overestimates the total costs for this provision.

OSHA estimated that the majority of firms would be able to reassign the worker to a job at least at the clerical level. The employer will often incur a cost for re-assigning the worker because this provision requires that, regardless of the comparable work the medically removed worker is performing, the employee must be paid the full base earnings for the previous position for six months. The cost per hour of reassigning a worker to a clerical job is based on the wage difference of a production worker of $22.16 and a clerical worker of $19.97, for a difference of $2.19. Over the six-month period, the incremental cost of reassigning a worker to a clerical position would be $2,190 per employee. This estimate is based on the employee remaining in a clerical position for the entire 6-month period, but the actual cost would be lower if there is turnover or if the employee is placed in any alternative position (for any part of the six-month period) that is compensated at a wage closer to the employee's previous wage.

Some firms may not have the ability to place the worker in an alternate job. If the employee chooses not to remain in the current position, the additional cost to the employer would be at most the cost of equipping that employee with a respirator, which would be required if the employee would continue to face exposures at or above the action level. Based on the earlier discussion of respirator costs, that option would be significantly cheaper than the alternative of providing the employee with six months of paid leave. Therefore, in order to estimate the maximum potential economic cost of the remaining alternatives, the Agency has conservatively estimated the cost per worker based on the cost of 6 months paid leave.

Using the wage rate of a production worker of $22.16 for 6 months (or 8 hours a day for 125 days), the total per-worker cost for this provision when a firm cannot place a worker in an alternate job is $22,161.

OSHA has estimated an average medical removal cost per worker assuming 75 percent of firms are able to find the employee an alternate job, and the remaining 25 percent of firms would not. The weighted average of these costs is $7,183. Based on these unit costs, OSHA estimates that the medical removal provision would result in an annualized total cost of $148,826. The breakdown of these costs by application group and NAICS code is shown in Table IX–6.

i. Training

As specified in the proposed standard and existing OSHA standard 29 CFR 1910.1200 on hazard communication, training is required for all employees where there is potential exposure to beryllium. In addition, newly hired employees would require training before starting work.

OSHA anticipates that training in accordance with the requirements of the proposed rule, which includes hazard communication training, would be conducted by in-house safety or supervisory staff with the use of training modules or videos. ERG estimated that this training would last, on average, eight hours. (Note that this estimate does not include the time taken for hazard communication training that is already required by 29 CFR 1910.1200.) The Agency judged that establishments could purchase sufficient training materials at an average cost of $2 per worker, encompassing the cost of handouts, video presentations, and training manuals and exercises. For initial and periodic training, ERG estimated an average class size of five workers with one instructor over an eight hour period. The per-worker cost of initial training totals to $239.

Annual retraining of workers is also required by the standard. OSHA estimates the same unit costs as for initial training, so retraining would require the same per-worker cost of $239.

Finally, to calculate training costs, the Agency needs the turnover rate of affected workers to know how many workers are receiving initial training versus retraining. Based on a 26.3 percent new hire rate in manufacturing, OSHA calculated a total net present value (NPV) of ten years of initial and annual retraining of $2,101 per employee. Annualizing this NPV gives a total annual cost for training of $246.

Based on these unit costs, OSHA estimates that the training requirements in the standard would result in an annualized total cost of $5,797,535. The breakdown of these costs by application group and NAICS code is presented in Table IX–6.

Table IX-6

Annualized Cost of Program Requirements for Industries Affected by the Proposed Beryllium Standard by Application Group and Six-Digit NAICS Industry (in 2010 dollars)

NAICS Code	Industry	Exposure Assessment	Regulated Areas and Beryllium Work Areas	Medical Surveillance	Medical Removal Provision	Written Exposure Control Plan	Protective Work Clothing & Equipment	Hygiene Areas and Practices	House-keeping	Training	Total Program Costs
Beryllium Production											
331419	Primary smelting and refining of nonferrous metals	$0	$1,683	$11,121	$6,359	$0	$17,801	$8,112	$0	$0	$45,075
Beryllium Oxide Ceramics and Composites											
327113a	Porcelain electrical supply manufacturing (primary)	$6,959	$4,162	$9,205	$1,912	$2,645	$2,761	$2,432	$22,189	$10,230	$62,495
327113b	Porcelain electrical supply manufacturing (secondary)	$17,311	$5,303	$20,307	$1,276	$11,365	$4,938	$1,959	$67,370	$31,060	$160,889
334220	Cellular telephones manufacturing	$12,365	$3,788	$14,505	$911	$8,118	$8,526	$1,399	$48,122	$22,186	$119,920
334310	Compact disc players manufacturing	$6,183	$1,894	$7,252	$456	$4,059	$830	$864	$24,061	$11,093	$56,692
334411	Electron tube manufacturing	$25,967	$7,955	$30,460	$1,914	$17,048	$11,252	$2,938	$101,055	$46,590	$245,179
334415	Electronic resistor manufacturing	$14,838	$4,545	$17,406	$1,094	$9,742	$6,346	$1,679	$57,746	$26,623	$140,019
334419	Other electronic component manufacturing	$11,129	$3,409	$13,054	$820	$7,306	$3,227	$1,292	$43,309	$19,967	$103,514
334510	Electromedical equipment manufacturing	$11,129	$3,409	$13,054	$820	$7,306	$8,193	$1,292	$43,309	$19,967	$108,480
336322b	Other motor vehicle electrical and electronic equipment manufacturing	$12,365	$3,788	$14,505	$911	$8,118	$5,243	$1,399	$48,122	$22,186	$116,637
Aluminum and Copper Foundries											
331521	Aluminum die-casting foundries	$18,965	$11,764	$22,386	$2,948	$6,580	$14,421	$3,882	$39,473	$18,199	$138,616
331522	Nonferrous (except aluminum) die-casting foundries	$102,953	$63,860	$121,522	$16,003	$35,718	$50,165	$20,536	$214,281	$98,792	$723,831
331524	Aluminum foundries (except die-casting)	$18,965	$11,764	$22,386	$2,948	$6,580	$7,835	$3,882	$39,473	$18,199	$132,030
331525a	Copper foundries (except die-casting) (non-sand casting foundries)	$54,186	$33,610	$63,959	$8,423	$18,799	$14,318	$10,808	$112,780	$51,996	$368,879
331525b	Copper foundries (except die-casting) (sand casting foundries)	$75,706	$48,627	$91,350	$11,940	$26,047	$31,197	$15,520	$157,416	$72,575	$530,377
Secondary Smelting, Refining, and Alloying											
331314	Secondary smelting & alloying of aluminum	$1,687	$984	$1,926	$251	$625	$284	$294	$3,609	$1,664	$11,325
331421b	Copper rolling, drawing, and extruding	$1,687	$984	$1,926	$251	$625	$733	$294	$3,609	$1,664	$11,774
331423	Secondary smelting, refining, & alloying of copper	$5,062	$2,953	$5,779	$752	$1,876	$706	$882	$10,827	$4,992	$33,829
331492	Secondary smelting, refining, & alloying of nonferrous metal (except copper & aluminum)	$38,355	$15,256	$40,496	$4,129	$18,761	$9,889	$4,411	$108,274	$49,918	$289,489
Precision Turned Products											
332721a	Precision turned product manufacturing (high beryllium content)	$19,773	$20,306	$39,419	$6,022	$11,265	$22,809	$8,725	$59,373	$27,373	$215,066
332721b	Precision turned product manufacturing (low beryllium content)	$339,855	$93,938	$406,491	$22,244	$239,550	$363,790	$35,735	$1,420,434	$654,876	$3,576,912
Copper Rolling, Drawing and Extruding											
331422	Copper wire (except mechanical) drawing	$330,266	$77,096	$426,151	$23,234	$240,458	$349,147	$27,975	$2,043,664	$942,210	$4,460,202
331421a	Copper rolling, drawing, and extruding	$77,074	$7,662	$109,469	$1,983	$72,471	$105,427	$1,919	$617,121	$284,517	$1,277,644

Table IX-6, continued

Annualized Cost of Program Requirements for Industries Affected by the Proposed Beryllium Standard by Application Group and Six-Digit NAICS Industry (in 2010 dollars)

NAICS Code	Industry	Exposure Assessment	Regulated Areas and Beryllium Work Areas	Medical Surveillance	Medical Removal Provision	Written Exposure Control Plan	Protective Work Clothing & Equipment	Hygiene Areas and Practices	House-keeping	Training	Total Program Costs
Fabrication of Beryllium Alloy Products											
332612	Light gauge spring manufacturing	$147,766	$22,281	$192,128	$4,170	$150,032	$80,612	$3,613	$1,107,234	$510,479	$2,218,314
332116	Metal stamping	$37,074	$9,640	$51,382	$1,355	$35,726	$11,246	$2,229	$265,310	$122,318	$536,280
334417	Electronic connector manufacturing	$23,146	$6,018	$32,079	$846	$22,304	$18,014	$1,392	$165,639	$76,366	$345,805
336322a	Other motor vehicle electrical & electronic equipment	$79,660	$20,712	$110,402	$2,911	$76,762	$44,357	$4,789	$570,058	$262,819	$1,172,471
Arc and Gas Welding											
331111	Iron and steel mills	$3,167	$1,467	$3,792	$295	$2,085	$0	$3,685	$14,171	$6,533	$35,195
331221	Rolled steel shape manufacturing	$658	$305	$788	$61	$433	$0	$3,379	$2,945	$1,358	$9,926
331513	Steel foundries (except investment)	$647	$300	$775	$60	$426	$0	$3,378	$2,897	$1,336	$9,819
332117	Powder metallurgy part manufacturing	$435	$201	$521	$41	$286	$0	$3,352	$1,946	$897	$7,679
332212	Hand and edge tool manufacturing	$1,394	$646	$1,669	$130	$918	$0	$3,469	$6,239	$2,876	$17,341
332312	Fabricated structural metal manufacturing	$26,737	$12,383	$32,010	$2,493	$17,601	$0	$21,713	$119,636	$55,157	$287,730
332313	Plate work manufacturing	$10,108	$4,681	$12,101	$942	$6,654	$0	$8,208	$45,228	$20,852	$108,775
332322	Sheet metal work manufacturing	$32,749	$15,168	$39,207	$3,053	$21,558	$0	$26,594	$146,534	$67,558	$352,421
332323	Ornamental and architectural metal work manufacturing	$18,474	$8,556	$22,117	$1,722	$12,161	$0	$15,002	$82,660	$38,110	$198,802
332439	Other metal container manufacturing	$3,206	$1,485	$3,838	$299	$2,111	$0	$3,690	$14,346	$6,614	$35,589
332919	Other metal valve and pipe fitting manufacturing	$1,300	$602	$1,556	$121	$856	$0	$3,457	$5,816	$2,681	$16,389
332999	All other miscellaneous fabricated metal product manufacturing	$16,000	$7,410	$19,155	$1,492	$10,532	$0	$12,993	$71,590	$33,006	$172,178
333111	Farm machinery and equipment manufacturing	$9,531	$4,414	$11,411	$889	$6,274	$0	$7,740	$42,647	$19,662	$102,568
333414a	Heating equipment (except warm air furnaces) manufacturing	$2,858	$1,324	$3,421	$266	$1,881	$0	$3,647	$12,788	$5,896	$32,081
333911	Pump and pumping equipment manufacturing	$3,174	$1,470	$3,800	$296	$2,089	$0	$3,686	$14,202	$6,548	$35,266
333922	Conveyor and conveying equipment manufacturing	$4,314	$1,998	$5,164	$402	$2,840	$0	$3,825	$19,301	$8,899	$46,743
333924	Industrial truck, tractor, trailer, and stacker machinery manufacturing	$2,079	$963	$2,489	$194	$1,369	$0	$3,552	$9,303	$4,289	$24,237
333999	All other miscellaneous general purpose machinery manufacturing	$8,472	$3,924	$10,142	$790	$5,577	$0	$6,880	$37,906	$17,476	$91,167
336211	Motor vehicle body manufacturing	$7,157	$3,315	$8,569	$667	$4,712	$0	$5,812	$32,026	$14,765	$77,024
336214	Travel trailer and camper manufacturing	$6,588	$3,051	$7,888	$614	$4,337	$0	$5,350	$29,480	$13,591	$70,900
336399a	All other motor vehicle parts manufacturing	$3,531	$1,636	$4,228	$329	$2,325	$0	$3,729	$15,802	$7,285	$38,865
336510	Railroad rolling stock	$1,293	$599	$1,548	$121	$851	$0	$3,456	$5,787	$2,668	$16,323
336999	All other transportation equipment manufacturing	$1,712	$793	$2,050	$160	$1,127	$0	$3,508	$7,661	$3,532	$20,542
337215	Showcase, partition, shelving, and locker manufacturing	$1,562	$723	$1,870	$146	$1,028	$0	$3,489	$6,988	$3,222	$19,027
811310	Commercial and industrial machinery and equipment repair	$68,217	$31,594	$81,669	$6,360	$44,906	$0	$55,397	$305,236	$140,726	$734,105

Table IX-6, continued

Annualized Cost of Program Requirements for Industries Affected by the Proposed Beryllium Standard by Application Group and Six-Digit NAICS Industry (in 2010 dollars)

NAICS Code	Industry	Exposure Assessment	Regulated Areas and Beryllium Work Areas	Medical Surveillance	Medical Removal Provision	Written Exposure Control Plan	Protective Work Clothing & Equipment	Hygiene Areas and Practices	House-keeping	Training	Total Program Costs
Resistance Welding											
333411	Air purification equipment manufacturing	$22,068	$1,036	$32,575	$0	$25,212	$0	$0	$202,669	$93,438	$376,997
333412	Industrial and commercial fan and blower manufacturing	$9,308	$437	$13,740	$0	$10,634	$0	$0	$85,483	$39,411	$159,013
333414b	Heating equipment (except warm air furnaces) manufacturing	$28,356	$1,331	$41,856	$0	$32,395	$0	$0	$260,413	$120,061	$484,410
333415	Air-conditioning, warm air heating, and industrial refrigeration equipment manufacturing	$51,965	$2,439	$76,705	$0	$59,367	$0	$0	$477,235	$220,024	$887,734
335211	Electric housewares and household fan manufacturing	$4,667	$219	$6,889	$0	$5,332	$0	$0	$42,863	$19,762	$79,732
335212	Household vacuum cleaner manufacturing	$1,497	$70	$2,210	$0	$1,710	$0	$0	$13,748	$6,339	$25,574
335221	Household cooking appliance manufacturing	$4,227	$198	$6,239	$0	$4,829	$0	$0	$38,819	$17,897	$72,210
335222	Household refrigerator and home freezer manufacturing	$969	$45	$1,430	$0	$1,107	$0	$0	$8,896	$4,101	$16,548
335224	Household laundry equipment manufacturing	$484	$23	$715	$0	$553	$0	$0	$4,448	$2,051	$8,274
335228	Other major household appliance manufacturing	$1,673	$79	$2,470	$0	$1,912	$0	$0	$15,366	$7,084	$28,583
336311	Carburetor, piston, piston ring, and valve manufacturing	$4,799	$225	$7,084	$0	$5,483	$0	$0	$44,076	$20,321	$81,989
336312	Gasoline engine and engine parts manufacturing	$32,671	$1,533	$48,225	$0	$37,325	$0	$0	$300,041	$138,331	$558,125
336321	Vehicular lighting equipment manufacturing	$4,095	$192	$6,044	$0	$4,678	$0	$0	$37,606	$17,338	$69,954
336322c	Other motor vehicle electrical and electronic equipment manufacturing	$28,004	$1,314	$41,336	$0	$31,993	$0	$0	$257,178	$118,569	$478,393
336330	Motor vehicle steering and suspension components (except spring) manufacturing	$10,832	$508	$15,988	$0	$12,374	$0	$0	$99,474	$45,862	$185,039
336340	Motor vehicle brake system manufacturing	$8,762	$411	$12,934	$0	$10,010	$0	$0	$80,469	$37,099	$149,686
336350	Motor vehicle transmission and power train parts manufacturing	$20,959	$984	$30,937	$0	$23,944	$0	$0	$192,479	$88,740	$358,042
336360	Motor vehicle seating and interior trim manufacturing	$17,744	$833	$26,192	$0	$20,272	$0	$0	$162,960	$75,131	$303,132
336370	Motor vehicle metal stamping	$32,407	$1,521	$47,835	$0	$37,023	$0	$0	$297,614	$137,212	$553,612
336391	Motor vehicle air-conditioning manufacturing	$3,522	$165	$5,199	$0	$4,024	$0	$0	$32,349	$14,914	$60,175
336399b	All other motor vehicle parts manufacturing	$59,441	$2,789	$87,741	$0	$67,909	$0	$0	$545,896	$251,680	$1,015,456
Dental Laboratories											
339116	Dental laboratories	$118,601	$14,334	$172,420	$0	$155,480	$187,007	$0	$816,900	$376,623	$1,841,363
621210	Offices of dentists	$16,107	$1,947	$23,417	$0	$21,116	$26,293	$0	$110,944	$51,150	$250,973
	Total	**$2,208,950**	**$629,031**	**$2,882,076**	**$148,826**	**$1,769,506**	**$1,407,365**	**$389,241**	**$12,574,921**	**$5,797,535**	**$27,807,451**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Total Annualized Cost

As shown in Table IX–7, the total annualized cost of the proposed rule is estimated to be about $37.6 million. As shown, at $27.8 million, the program costs represent about 74 percent of the total annualized costs of the proposed rule. The annualized cost of complying with the PEL accounts for the remaining 26 percent, almost all of which is for engineering controls and work practices. Respiratory protection, at about $237,600, represents only 3 percent of the annualized cost of complying with the PEL and less than 1 percent of the annualized cost of the proposed rule.

Table IX-7

Annualized Costs to Industries Affected by the Proposed Beryllium Standard, by Application Group and Six-Digit NAICS

NAICS code	Industry	Engineering Controls and Work Practices	Respirator Costs	Program Costs	Total Costs
Beryllium Production					
331419	Primary smelting and refining of nonferrous metals	$1,188,758	$23,381	$45,075	$1,257,214
Beryllium Oxide Ceramics and Composites					
327113a	Porcelain electrical supply manufacturing (primary)	$175,546	$2,702	$62,495	$240,744
327113b	Porcelain electrical supply manufacturing (secondary)	$72,102	$1,744	$160,889	$234,736
334220	Cellular telephones manufacturing	$51,502	$1,246	$119,920	$172,668
334310	Compact disc players manufacturing	$25,751	$675	$56,692	$83,118
334411	Electron tube manufacturing	$108,154	$2,617	$245,179	$355,950
334415	Electronic resistor manufacturing	$61,802	$1,495	$140,019	$203,316
334419	Other electronic component manufacturing	$46,352	$1,132	$103,514	$150,998
334510	Electromedical equipment manufacturing	$46,352	$1,132	$108,480	$155,964
336322b	Other motor vehicle electrical and electronic equipment manufacturing	$51,502	$1,246	$116,637	$169,385
Nonferrous Foundries					
331521	Aluminum die-casting foundries	$182,887	$3,899	$138,616	$325,402
331522	Nonferrous (except aluminum) die-casting foundries	$992,813	$20,999	$723,831	$1,737,643
331524	Aluminum foundries (except die-casting)	$182,887	$3,899	$132,030	$318,816
331525a	Copper foundries (except die-casting) (non-sand casting foundries)	$522,533	$11,052	$368,879	$902,464
331525b	Copper foundries (except die-casting) (sand casting foundries)	$682,229	$15,962	$530,377	$1,228,568
Secondary Smelting, Refining, and Alloying					
331314	Secondary smelting & alloying of aluminum	$19,186	$3,246	$11,325	$33,757
331421b	Copper rolling, drawing, and extruding	$19,186	$3,246	$11,775	$34,207
331423	Secondary smelting, refining, & alloying of copper	$57,558	$9,820	$33,831	$101,209
331492	Secondary smelting, refining, & alloying of nonferrous metal (except copper & aluminum)	$287,789	$5,024	$289,489	$582,301
Precision Turned Products					
332721a	Precision turned product manufacturing (high beryllium content)	$162,739	$8,864	$215,066	$386,669
332721b	Precision turned product manufacturing (low beryllium content)	$888,502	$30,866	$3,576,912	$4,496,280
Copper Rolling, Drawing and Extruding					
331421a	Copper rolling, drawing, and extruding	$23,656	$1,677	$1,277,644	$1,302,977
331422	Copper wire (except mechanical) drawing	$96,231	$28,425	$4,460,202	$4,584,858
Fabrication of Beryllium Alloy Products					
332612	Light gauge spring manufacturing	$588,200	$8,874	$2,218,314	$2,815,387
332116	Metal stamping	$134,748	$3,531	$536,280	$674,558
334417	Electronic connector manufacturing	$84,126	$2,204	$345,805	$432,136
336322a	Other motor vehicle electrical & electronic equipment	$289,526	$7,586	$1,172,471	$1,469,583
Arc and Gas Welding					
331111	Iron and steel mills	$18,123	$679	$35,195	$53,997
331221	Rolled steel shape manufacturing	$3,766	$679	$9,926	$14,371
331513	Steel foundries (except investment)	$3,705	$679	$9,819	$14,203
332117	Powder metallurgy part manufacturing	$2,489	$679	$7,679	$10,846
332212	Hand and edge tool manufacturing	$7,979	$679	$17,341	$25,998
332312	Fabricated structural metal manufacturing	$153,001	$4,352	$287,730	$445,083
332313	Plate work manufacturing	$57,841	$1,645	$108,775	$168,261
332322	Sheet metal work manufacturing	$187,400	$5,330	$352,421	$545,151
332323	Ornamental and architectural metal work manufacturing	$105,713	$3,007	$198,802	$307,521
332439	Other metal container manufacturing	$18,347	$679	$35,589	$54,614
332919	Other metal valve and pipe fitting manufacturing	$7,438	$679	$16,389	$24,506
332999	All other miscellaneous fabricated metal product manufacturing	$91,556	$2,604	$172,178	$266,338
333111	Farm machinery and equipment manufacturing	$54,540	$1,551	$102,568	$158,660

IX-7, continued

Annualized Costs to Industries Affected by the Proposed Beryllium Standard, by Application Group and Six-Digit NAICS

NAICS code	Industry	Engineering Controls and Work Practices	Respirator Costs	Program Costs	Total Costs
Arc and Gas Welding					
333414a	Heating equipment (except warm air furnaces) manufacturing	$16,354	$679	$32,081	$49,114
333911	Pump and pumping equipment manufacturing	$18,163	$679	$35,266	$54,108
333922	Conveyor and conveying equipment manufacturing	$24,684	$717	$47,006	$72,407
333924	Industrial truck, tractor, trailer, and stacker machinery	$11,897	$679	$24,237	$36,813
333999	All other miscellaneous general purpose machinery manufacturing	$48,478	$1,379	$91,167	$141,023
336211	Motor vehicle body manufacturing	$40,958	$1,165	$77,024	$119,147
336214	Travel trailer and camper manufacturing	$37,701	$1,072	$70,900	$109,673
336399a	All other motor vehicle parts manufacturing	$20,208	$679	$38,865	$59,753
336510	Railroad rolling stock	$7,400	$679	$16,323	$24,403
336999	All other transportation equipment manufacturing	$9,797	$679	$20,542	$31,018
337215	Showcase, partition, shelving, and locker manufacturing	$8,937	$679	$19,027	$28,643
811310	Commercial and industrial machinery and equipment repair	$390,361	$11,103	$734,105	$1,135,568
Resistance Welding					
333411	Air purification equipment manufacturing	$0	$0	$376,997	$376,997
333412	Industrial and commercial fan and blower manufacturing	$0	$0	$159,013	$159,013
333414b	Heating equipment (except warm air furnaces) manufacturing	$0	$0	$484,410	$484,410
333415	Air-conditioning, warm air heating, and industrial refrigeration equipment manufacturing	$0	$0	$887,734	$887,734
335211	Electric housewares and household fan manufacturing	$0	$0	$79,732	$79,732
335212	Household vacuum cleaner manufacturing	$0	$0	$25,574	$25,574
335221	Household cooking appliance manufacturing	$0	$0	$72,210	$72,210
335222	Household refrigerator and home freezer manufacturing	$0	$0	$16,548	$16,548
335224	Household laundry equipment manufacturing	$0	$0	$8,274	$8,274
335228	Other major household appliance manufacturing	$0	$0	$28,583	$28,583
336311	Carburetor, piston, piston ring, and valve manufacturing	$0	$0	$81,989	$81,989
336312	Gasoline engine and engine parts manufacturing	$0	$0	$558,125	$558,125
336321	Vehicular lighting equipment manufacturing	$0	$0	$69,954	$69,954
336322c	Other motor vehicle electrical and electronic equipment	$0	$0	$478,393	$478,393
336330	Motor vehicle steering and suspension components (except spring) manufacturing	$0	$0	$185,039	$185,039
336340	Motor vehicle brake system manufacturing	$0	$0	$149,686	$149,686
336350	Motor vehicle transmission and power train parts manufacturing	$0	$0	$358,042	$358,042
336360	Motor vehicle seating and interior trim manufacturing	$0	$0	$303,132	$303,132
336370	Motor vehicle metal stamping	$0	$0	$553,612	$553,612
336391	Motor vehicle air-conditioning manufacturing	$0	$0	$60,175	$60,175
336399b	All other motor vehicle parts manufacturing	$0	$0	$1,015,456	$1,015,456
Dental Laboratories					
339116	Dental laboratories	$1,013,143	$0	$1,841,363	$2,854,507
621210	Offices of dentists	$137,596	$0	$250,973	$388,569
	Total	**$9,487,239**	**$237,571**	**$27,807,451**	**$37,597,325**

Note-For Dental Laboratories, "Engineering Controls and Work Practices" represents the substituion costs of switching to non-Beryllium alloys.
Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

F. Economic Feasibility Analysis and Regulatory Flexibility Determination

Chapter VI of the PEA, summarized here, investigates the economic impacts of the proposed beryllium rule on affected employers. This impact investigation has two overriding objectives: (1) To establish whether the proposed rule is economically feasible for all affected application groups/industries, and (2) to determine if the Agency can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

In the discussion below, OSHA first presents its approach for achieving these objectives and next applies this approach to industries with affected employers. The Agency invites comment on any aspect of the methods, data, or preliminary findings presented here or in Chapter VI of the PEA.

1. Analytic Approach

a. Economic Feasibility

Section 6(b)(5) of the OSH Act directs the Secretary of Labor to set standards based on the available evidence where no employee, over his/her working life time, will suffer from material impairment of health or functional capacity, even if such employee has regular exposure to the hazard, ''to the exent feasible'' (29 U.S.C. 655(b)(5)). OSHA interpreted the phrase ''to the extent feasible'' to encompass economic feasibility and was supported in this view by the U.S. Court of Appeals for the D.C. Circuit, which has long held that OSHA standards would satisfy the economic feasibility criterion even if they imposed significant costs on regulated industries and forced some marginal firms out of business, so long as they did not cause massive economic dislocations within a particular industry or imperil the existence of that industry. *Am. Iron and Steel Inst.* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991); *United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1265 (D.C. Cir. 1980); *Indus. Union Dep't* v. *Hodgson,* 499 F.2d 467 (D.C. Cir. 1974).

b. The Price Elasticity of Demand and Its Relationship to Economic Feasibility

In practice, the economic burden of an OSHA standard on an industry—and whether the standard is economically feasible for that industry—depends on the magnitude of compliance costs incurred by establishments in that industry and the extent to which they are able to pass those costs on to their customers. That, in turn, depends, to a significant degree, on the price elasticity of demand for the products sold by establishments in that industry.

The price elasticity of demand refers to the relationship between the price charged for a product and the demand for that product: The more elastic the relationship, the less an establishment's compliance costs can be passed through to customers in the form of a price increase and the more the establishment has to absorb compliance costs in the form of reduced profits. When demand is inelastic, establishments can recover most of the costs of compliance by raising the prices they charge; under this scenario, profit rates are largely unchanged and the industry remains largely unaffected. Any impacts are primarily on those customers using the relevant product. On the other hand, when demand is elastic, establishments cannot recover all compliance costs simply by passing the cost increase through in the form of a price increase; instead, they must absorb some of the increase from their profits. Commonly, this will mean reductions both in the quantity of goods and services produced and in total profits, though the profit rate may remain unchanged. In general, ''[w]hen an industry is subjected to a higher cost, it does not simply swallow it; it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers,'' in the words of the court in *Am. Dental Ass'n* v. *Sec'y of Labor* (984 F.2d 823, 829 (7th Cir. 1993)).

The court's summary is in accord with microeconomic theory. In the long run, firms can remain in business only if their profits are adequate to provide a return on investment that ensures that investment in the industry will continue. Over time, because of rising real incomes and productivity increases, firms in most industries are able to ensure an adequate profit. As technology and costs change, however, the long-run demand for some products naturally increases and the long-run demand for other products naturally decreases. In the face of additional compliance costs (or other external costs), firms that otherwise have a profitable line of business may have to increase prices to stay viable. Increases in prices typically result in reduced quantity demanded, but rarely eliminate all demand for the product. Whether this decrease in the total production of goods and services results in smaller output for each establishment within the industry or the closure of some plants within the industry, or a combination of the two, is dependent on the cost and profit structure of individual firms within the industry.

If demand is perfectly inelastic (*i.e.,* the price elasticity of demand is zero), then the impact of compliance costs that are one percent of revenues for each firm in the industry would be a one percent increase in the price of the product, with no decline in quantity demanded. Such a situation represents an extreme case, but might be observed in situations in which there were few, if any, substitutes for the product in question, or if the products of the affected sector account for only a very small portion of the revenue or income of its customers.

If the demand is perfectly elastic (*i.e.,* the price elasticity of demand is infinitely large), then no increase in price is possible and before-tax profits would be reduced by an amount equal to the costs of compliance (net of any cost savings—such as reduced workers' compensation insurance premiums—resulting from the proposed standard) if the industry attempted to maintain production at the same level as previously. Under this scenario, if the costs of compliance are such a large percentage of profits that some or all plants in the industry could no longer operate in the industry with hope of an adequate return on investment, then some or all of the firms in the industry would close. This scenario is highly unlikely to occur, however, because it can only arise when there are other products—unaffected by the proposed rule—that are, in the eyes of their customers, perfect substitutes for the products the affected establishments make.

A commonly-discussed intermediate case would be a price elasticity of demand of one (in absolute terms). In this situation, if the costs of compliance amount to one percent of revenues, then production would decline by one percent and prices would rise by one percent. As a result, industry revenues would remain the same, with somewhat lower production, but with similar profit rates per unit of output (in most situations where the marginal costs of production net of regulatory costs would fall as well). Customers would, however, receive less of the product for their (same) expenditures, and firms would have lower total profits; this, as the court described in *Am. Dental Ass'n* v. *Sec'y of Labor,* is the more typical case.

c. Variable Costs Versus Fixed Costs

A decline in output as a result of an increase in price may occur in a variety of ways: individual establishments could each reduce their levels of production; some marginal plants could close; or, in the case of an expanding industry, new entry may be delayed until demand equals supply. In some situations, there could be a combination of these three effects. Which possibility is most likely depends on the form that the costs of the regulation take. If the costs are variable costs (*i.e.,* costs that vary with the level of production at a facility), then economic theory suggests that any reductions in overall output will be the result of reductions in output at each affected facility, with few, if any, plant closures. If, on the other hand, the costs of a regulation primarily take the form of fixed costs (*i.e.,* costs that do not vary with the level of production at a facility), then reductions in overall output are more likely to take the form of plant closures or delays in new entry.

Most of the costs of this regulation, as estimated in Chapter V of the PEA, are variable costs in the sense that they will tend to vary by production levels and/or employment levels. Almost all of the major costs of program elements, such as medical surveillance and training, will vary in proportion to the number of employees (which is a rough proxy for the amount of production). Exposure monitoring costs will vary with the number of employees, but do have some economies of scale to the extent that a larger firm need only conduct representative sampling rather than sample every employee. Finally, the costs of operating and maintaining engineering controls tend to vary by usage—which typically closely tracks the level of production and are not fixed costs in the strictest sense.

This leaves two kinds of costs that are, in some sense, fixed costs—capital costs of engineering controls and certain initial costs. The capital costs of engineering controls due to the standard—many of which are scaled to production and/or employment levels—constitute a relatively small share of the total costs, representing 10 percent of total annualized costs (or approximately $870 per year per affected establishment).

Some ancillary provisions require initial costs that are fixed in the sense that they do not vary by production activity or the number of employees. Some examples are the costs to develop a training plan for general training not currently required and to develop a written exposure control plan.

As a result of these considerations, OSHA expects it to be quite likely that any reductions in total industry output would be due to reductions in output at each affected facility rather than as a result of plant closures. However, closures of some marginal plants or poorly performing facilities are always possible.

d. Economic Feasibility Screening Analysis

To determine whether a rule is economically feasible, OSHA begins with two screening tests to consider minimum threshold effects of the rule under two extreme cases: (1) All costs are passed through to customers in the form of higher prices (consistent with a price elasticity of demand of zero), and (2) all costs are absorbed by the firm in the form of reduced profits (consistent with an infinite price elasticity of demand).

In the former case, the immediate impact of the rule would be observed in increased industry revenues. While there is no hard and fast rule, in the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of one percent of annual revenues. Retrospective studies of previous OSHA regulations have shown that potential impacts of such a small magnitude are unlikely to eliminate an industry or significantly alter its competitive structure,[19] particularly since most industries have at least some ability to raise prices to reflect increased costs, and normal price variations for products typically exceed three percent a year.

In the latter case, the immediate impact of the rule would be observed in reduced industry profits. OSHA uses the ratio of annualized costs to annual profits as a second check on economic feasibility. Again, while there is no hard and fast rule, in the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of ten percent of annual profits. In the context of economic feasibility, the Agency believes this threshold level to be fairly modest, given that normal year-to-year variations in profit rates in an industry can exceed 40 percent or more. OSHA also considered whether this threshold would be adequate to assure that upfront costs would not create major credit problems for affected employers. To do this, OSHA examined a worst case scenario in which annualized costs were ten percent of profits and all of the annualized costs were the result of upfront costs. In this scenario, assuming a three percent discount rate and a ten year life of equipment, total costs would be 85 percent of profits[20] in the year in which these upfront costs were incurred. Because upfront costs would be less than one year's profits in the year they were incurred, this means that an employer could pay for all of these costs from that year's profits and would not necessarily have to incur any new borrowing. As a result, it is unlikely that these costs would create a credit crunch or other major credit problems. It would be true, however, that paying regulatory costs from profits might reduce investment from profits in that year. OSHA's choice of a threshold level of ten percent of annual profits is low enough that even if, in a hypothetical worst case, all compliance costs were upfront costs, then upfront costs—assuming a three percent discount rate and a ten-year time period—would be no more than 85 percent of first-year profits and thus would be affordable from profits without resort to credit markets. If the threshold level were *first-year* costs of ten percent of annual profits, firms could even more easily expect to cover first-year costs at the threshold level out of current profits without having to access capital markets and otherwise being threatened with short-term insolvency.

In general, because it is usually the case that firms would be able to pass on to their customers some or all of the costs of the proposed rule in the form of higher prices, OSHA will tend to give much more weight to the ratio of industry costs to industry revenues than to the ratio of industry costs to industry profits. However, if costs exceed either the threshold percentage of revenue or the threshold percentage of profits for an industry, or if there is other evidence of a threat to the viability of an industry because of the proposed standard, OSHA will examine the effect of the rule on that industry more closely. Such an examination would include market factors specific to the industry, such as normal variations in prices and profits, and any special circumstances, such as close domestic substitutes of equal cost, which might make the industry particularly vulnerable to a regulatory cost increase.

The preceding discussion focused on the economic viability of the affected industries in their entirety. However, even if OSHA found that a proposed standard did not threaten the survival of affected industries, there is still the question of whether the industries' competitive structure would be significantly altered. For example, if the annualized costs of an OSHA standard were equal to 10 percent of an industry's annual profits, and the price elasticity of demand for the products in that industry were equal to one, then OSHA would not expect the industry to go out of business. However, if the increase in costs were such that most or all small firms in that industry would have to close, it might reasonably be concluded that the competitive structure of the industry had been altered. For this reason, OSHA also calculates compliance costs by size of firm and conducts its economic feasibility screening analysis for small and very small entities.

e. Regulatory Flexibility Screening Analysis

The Regulatory Flexibility Act (RFA), Public Law 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601), requires Federal agencies to consider the economic impact that a proposed rulemaking will have on small entities. The RFA states that whenever a Federal agency is required to publish general notice of proposed rulemaking for any proposed rule, the agency must prepare and make available for public comment an initial regulatory flexibility analysis (IRFA). 5 U.S.C. 603(a). Pursuant to section 605(b), in lieu of an IRFA, the head of an agency may certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. A certification must be supported by a factual basis. If the head of an agency makes a certification, the agency shall publish such certification in the **Federal Register** at the time of publication of general notice of proposed rulemaking or at the time of publication of the final rule. 5 U.S.C. 605(b).

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed beryllium rule will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the proposed rule on

[19] See OSHA's Web page, *http://www.osha.gov/dea/lookback.html#Completed*, for a link to all completed OSHA lookback reviews.

[20] At a discount rate of 3 percent over a life of investment of 10 years, the present value of that stream of annualized costs would be 8.53 times a single year's annualized costs. Hence, if yearly annualized costs are 10 percent of profits, upfront costs would be 85 percent of the profits in that first year. As a simple example, assume annualized costs are $1 for each of the 10 years. If annualized costs are 10 percent of profits, this translates to a yearly profit of $10. The present value of that stream of $1 for each year is $8.53. (The formula for this calculation is ($1*(1.03∧10) − 1)/((.03)×(1.03)∧10).

small entities. These screening tests do not constitute hard and fast rules and are similar in concept to those OSHA developed above to identify minimum threshold effects for purposes of demonstrating economic feasibility.

There are, however, two differences. First, for each affected industry, the screening tests are applied, not to all establishments, but to small entities (defined as ''small business concerns'' by SBA) and also to very small entities (as defined by OSHA as businesses with fewer than 20 employees). Second, although OSHA's regulatory flexibility screening test for revenues also uses a minimum threshold level of annualized costs equal to one percent of annual revenues, OSHA has established a minimum threshold level of annualized costs equal to five percent of annual profits for the average small entity or very small entity. The Agency has chosen a lower minimum threshold level for the profitability screening analysis and has applied its screening tests to both small entities and very small entities in order to ensure that certification will be made, and an IRFA will not be prepared, only if OSHA can be highly confident that a proposed rule will not have a significant economic impact on a substantial number of small entities or very small entities in any affected industry.

Furthermore, certification will not be made, and an IRFA will be prepared, if OSHA believes the proposed rule might otherwise have a significant economic impact on a substantial number of small entities, even if the minimum threshold levels are not exceeded for revenues or profitability for small entities or very small entities in all affected industries.

2. Impacts on Affected Industries

In this section, OSHA applies its screening criteria and other analytic methods, as needed, to determine (1) whether the proposed rule is economically feasible for all affected industries within the scope of this proposed rule, and (2) whether the Agency can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

a. Economic Feasibility Screening Analysis: All Establishments

To determine whether the proposed rule's projected costs of compliance would threaten the economic viability of affected industries, OSHA first compared, for each affected industry, annualized compliance costs to annual revenues and profits per (average) affected establishment. The results for all affected establishments in all affected industries are presented in Table IX–8. Shown in the table for each affected industry are the total number of establishments, the total number of affected establishments, annualized costs per affected establishment, annual revenues per establishment, the profit rate, annual profits per establishment, annualized compliance costs as a percentage of annual revenues, and annualized compliance costs as a percentage of annual profits.

The annualized costs per affected establishment for each affected industry were calculated by distributing the industry-level (incremental) annualized compliance costs among all affected establishments in the industry, where annualized compliance costs reflect a 3 percent discount rate. The annualized cost of the proposed rule for the average affected establishment is estimated at $9,197 in 2010 dollars. It is clear from Table IX–8 that the estimates of the annualized costs per affected establishment vary widely from industry to industry. These estimates range from $1,257,214 for NAICS 331419 (Beryllium Production) and $120,372 for NAICS 327113a (Porcelain Electrical Supply Manufacturing (primary)) to $1,636 for NAICS 621210 (Offices of Dentists) and $1,632 for NAICS 339116 (Dental Laboratories).

Table IX-8
Screening Analysis for Establishments Affected by the Proposed Beryllium Standard
With Costs Calculated Using a Three Percent Discount Rate

				Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment ($)	Rate	Per Establishment ($)	Per Establishment ($)	As a Percent of Revenues	As a Percent of Profits
Beryllium Production										
331419	Primary smelting and refining of nonferrous metals	161	1	$8,524,863	--	--	--	$1,257,214	--	--
Beryllium Oxide Ceramics and Composites										
327113a	Porcelain electrical supply manufacturing (primary)	106	2	$789,731	--	--	--	$120,372	--	--
327113b	Porcelain electrical supply manufacturing (secondary)	106	14	$789,731	7,450,295	5.01%	373,542	$16,767	0.23%	4.49%
334220	Cellular telephones manufacturing	810	10	$35,475,343	43,796,720	6.08%	2,663,922	$17,267	0.04%	0.65%
334310	Compact disc players manufacturing	464	5	$3,975,351	8,567,567	4.39%	376,456	$16,624	0.19%	4.42%
334411	Electron tube manufacturing	79	21	$1,220,476	15,449,068	7.85%	1,212,421	$16,950	0.11%	1.40%
334415	Electronic resistor manufacturing	61	12	$560,967	9,196,181	7.85%	721,703	$16,943	0.18%	2.35%
334419	Other electronic component manufacturing	1,133	9	$10,013,730	8,838,244	7.85%	693,613	$16,778	0.19%	2.42%
334510	Electromedical equipment manufacturing	629	9	$27,480,966	43,689,930	6.75%	2,947,904	$17,329	0.04%	0.59%
336322b	Other motor vehicle electrical and electronic equipment manufacturing	636	10	$12,152,053	19,107,002	1.83%	348,832	$16,939	0.09%	4.86%
Nonferrous Foundries										
331521	Aluminum die-casting foundries	254	7	$4,310,021	16,968,585	5.22%	885,603	$46,486	0.27%	5.25%
331522	Nonferrous (except aluminum) die-casting foundries	140	38	$1,510,799	10,791,418	5.22%	563,212	$45,727	0.42%	8.12%
331524	Aluminum foundries (except die-casting)	394	7	$2,518,097	6,391,108	5.22%	333,557	$45,545	0.71%	13.65%
331525a	Copper foundries (except die-casting) (non-sand casting foundries)	208	20	$1,205,574	5,796,031	5.22%	302,499	$45,123	0.78%	14.92%
331525b	Copper foundries (except die-casting) (sand casting foundries)	208	25	$1,205,574	5,796,031	5.22%	302,499	$49,143	0.85%	16.25%
Secondary Smelting, Refining, and Alloying										
331314	Secondary smelting & alloying of aluminum	122	1	$4,837,129	39,648,599	4.54%	1,802,008	$33,757	0.09%	1.87%
331421b	Copper rolling, drawing, and extruding	96	1	$12,513,425	130,348,178	4.79%	6,248,900	$34,206	0.03%	0.55%
331423	Secondary smelting, refining, & alloying of copper	24	3	$723,759	30,156,619	4.79%	1,445,710	$33,639	0.11%	2.33%
331492	Secondary smelting, refining, & alloying of nonferrous metal (except copper & aluminum)	248	30	$8,195,807	33,047,610	4.79%	1,584,305	$19,410	0.06%	1.23%
Precision Turned Products										
332721a	Precision turned product manufacturing (high beryllium content)	3,124	18	$13,262,706	4,245,425	5.82%	247,032	$20,979	0.49%	8.49%
332721b	Precision turned product manufacturing (low beryllium content)	3,124	294	$13,262,706	4,245,425	5.82%	247,032	$15,295	0.36%	6.19%
Copper Rolling, Drawing and Extruding										
331421a	Copper rolling, drawing, and extruding	96	15	$12,513,425	130,348,178	4.79%	6,248,900	$86,865	0.07%	1.39%
331422	Copper wire (except mechanical) drawing	114	59	$6,471,491	56,767,462	4.79%	2,721,436	$77,709	0.14%	2.86%
Fabrication of Beryllium Alloy Products										
332612	Light gauge spring manufacturing	323	323	$2,167,977	6,712,003	5.61%	376,763	$8,716	0.13%	2.31%
332116	Metal stamping	1,484	74	$9,749,800	6,569,946	5.12%	336,300	$9,116	0.14%	2.71%
334417	Electronic connector manufacturing	231	46	$5,029,508	21,772,761	7.85%	1,708,696	$9,354	0.04%	0.55%
336322a	Other motor vehicle electrical & electronic equipment	636	159	$12,152,053	19,107,002	1.83%	348,832	$9,243	0.05%	2.65%
Arc and Gas Welding										
331111	Iron and steel mills	587	7	$92,726,004	157,965,934	5.41%	8,542,604	$8,149	0.01%	0.10%
331221	Rolled steel shape manufacturing	161	1	$8,376,271	52,026,531	5.41%	2,813,531	$10,438	0.02%	0.37%
331513	Steel foundries (except investment)	220	1	$4,251,852	19,326,599	5.22%	1,008,670	$10,486	0.05%	1.04%
332117	Powder metallurgy part manufacturing	133	1	$1,414,108	10,632,394	5.12%	544,246	$11,921	0.11%	2.19%
332212	Hand and edge tool manufacturing	1,066	3	$5,077,868	4,763,479	5.61%	267,387	$8,913	0.19%	3.33%
332312	Fabricated structural metal manufacturing	3,407	56	$26,119,614	7,666,455	4.74%	363,273	$7,957	0.10%	2.19%
332313	Plate work manufacturing	1,288	21	$6,023,356	4,676,519	4.74%	221,596	$7,957	0.17%	3.59%
332322	Sheet metal work manufacturing	4,173	69	$17,988,908	4,310,786	4.74%	204,266	$7,957	0.18%	3.90%
332323	Ornamental and architectural metal work manufacturing	2,354	39	$5,708,707	2,425,109	4.74%	114,913	$7,957	0.33%	6.92%
332439	Other metal container manufacturing	370	7	$3,565,875	9,637,500	4.30%	414,839	$8,142	0.08%	1.96%
332919	Other metal valve and pipe fitting manufacturing	265	3	$4,584,082	17,298,424	7.00%	1,211,086	$9,012	0.05%	0.74%
332999	All other miscellaneous fabricated metal product manufacturing	3,262	33	$13,963,184	4,280,559	7.00%	299,688	$7,957	0.19%	2.66%
333111	Farm machinery and equipment manufacturing	1,041	20	$24,067,145	23,119,255	6.36%	1,471,196	$7,957	0.03%	0.54%

Table IX-8, continued

Screening Analysis for Establishments Affected by the Proposed Beryllium Standard

With Costs Calculated Using a Three Percent Discount Rate

				Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment ($)	Rate	Per Establishment ($)	Per Establishment ($)	As a Percent of Revenues	As a Percent of Profits
333414a	Heating equipment (except warm air furnaces) manufacturing	460	6	$4,781,561	10,394,697	4.68%	486,402	$8,214	0.08%	1.69%
333911	Pump and pumping equipment manufacturing	571	7	$12,395,387	21,708,209	5.36%	1,163,538	$8,148	0.04%	0.70%
333922	Conveyor and conveying equipment manufacturing	776	9	$6,569,120	8,465,361	5.36%	453,735	$7,994	0.09%	1.76%
333924	Industrial truck, tractor, trailer, and stacker machinery manufacturing	374	4	$7,444,451	19,904,948	5.36%	1,066,885	$8,464	0.04%	0.79%
333999	All other miscellaneous general purpose machinery manufacturing	1,524	18	$10,972,258	7,199,644	5.36%	385,894	$7,957	0.11%	2.06%
336211	Motor vehicle body manufacturing	742	15	$9,877,558	13,312,072	1.83%	243,036	$7,957	0.06%	3.27%
336214	Travel trailer and camper manufacturing	683	14	$7,465,024	10,929,757	1.83%	199,542	$7,957	0.07%	3.99%
336399a	All other motor vehicle parts manufacturing	1,350	7	$32,279,766	23,910,938	1.83%	436,537	$8,087	0.03%	1.85%
336510	Railroad rolling stock	226	3	$11,927,191	52,775,180	5.47%	2,887,552	$9,019	0.02%	0.31%
336999	All other transportation equipment manufacturing	374	4	$5,250,368	14,038,417	6.56%	921,324	$8,660	0.06%	0.94%
337215	Showcase, partition, shelving, and locker manufacturing	1,194	3	$5,815,404	4,870,523	4.26%	207,405	$8,766	0.18%	4.23%
811310	Commercial and industrial machinery and equipment repair	21,960	143	$31,650,469	1,441,278	5.42%	78,080	$7,957	0.55%	10.19%
Resistance Welding										
333411	Air purification equipment manufacturing	358	25	$3,060,744	8,549,565	4.68%	400,062	$15,044	0.18%	3.76%
333412	Industrial and commercial fan and blower manufacturing	151	11	$1,681,585	11,136,327	4.68%	521,106	$15,044	0.14%	2.89%
333414b	Heating equipment (except warm air furnaces) manufacturing	460	32	$4,781,561	10,394,697	4.68%	486,402	$15,044	0.14%	3.09%
333415	Air-conditioning, warm air heating, and industrial refrigeration equipment manufacturing	843	59	$25,454,383	30,194,998	4.68%	1,412,924	$15,044	0.05%	1.06%
335211	Electric housewares and household fan manufacturing	106	5	$2,209,657	20,845,825	4.03%	840,119	$15,044	0.07%	1.79%
335212	Household vacuum cleaner manufacturing	34	2	$891,600	26,223,543	4.03%	1,056,849	$15,044	0.06%	1.42%
335221	Household cooking appliance manufacturing	96	5	$3,757,849	39,144,257	4.03%	1,577,573	$15,044	0.04%	0.95%
335222	Household refrigerator and home freezer manufacturing	22	1	$4,489,845	204,083,854	4.03%	8,224,892	$15,044	0.01%	0.18%
335224	Household laundry equipment manufacturing	11	1	$3,720,514	338,228,505	4.03%	13,631,126	$15,044	0.00%	0.11%
335228	Other major household appliance manufacturing	38	2	$3,499,273	92,086,126	4.03%	3,711,212	$15,044	0.02%	0.41%
336311	Carburetor, piston, piston ring, and valve manufacturing	109	5	$1,715,429	15,737,881	1.83%	287,323	$15,044	0.10%	5.24%
336312	Gasoline engine and engine parts manufacturing	742	37	$20,000,705	26,955,128	1.83%	492,114	$15,044	0.06%	3.06%
336321	Vehicular lighting equipment manufacturing	93	5	$2,322,610	24,974,299	1.83%	455,950	$15,044	0.06%	3.30%
336322c	Other motor vehicle electrical and electronic equipment manufacturing	636	32	$12,152,053	19,107,002	1.83%	348,832	$15,044	0.08%	4.31%
336330	Motor vehicle steering and suspension components (except spring) manufacturing	246	12	$8,856,584	36,002,374	1.83%	657,287	$15,044	0.04%	2.29%
336340	Motor vehicle brake system manufacturing	199	10	$8,147,826	40,943,850	1.83%	747,503	$15,044	0.04%	2.01%
336350	Motor vehicle transmission and power train parts manufacturing	476	24	$21,862,014	45,928,600	1.83%	838,508	$15,044	0.03%	1.79%
336360	Motor vehicle seating and interior trim manufacturing	403	20	$15,168,862	37,639,856	1.83%	687,183	$15,044	0.04%	2.19%
336370	Motor vehicle metal stamping	736	37	$19,809,238	26,914,725	1.83%	491,376	$15,044	0.06%	3.06%
336391	Motor vehicle air-conditioning manufacturing	80	4	$3,798,464	47,480,804	1.83%	866,847	$15,044	0.03%	1.74%
336399b	All other motor vehicle parts manufacturing	1,350	68	$32,279,766	23,910,938	1.83%	436,537	$15,044	0.06%	3.45%
Dental Laboratories										
339116	Dental laboratories	6,995	1,749	$4,100,626	586,222	10.55%	61,873	$1,632	0.28%	2.64%
621210	Offices of dentists	129,830	238	$100,431,324	773,560	8.47%	65,557	$1,636	0.21%	2.50%
	Totals / Averages	207,586	4,088	$877,101,106	8,145,219	7.42%	604,340	$9,197	0.11%	1.52%

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 331419) and Beryllium Oxide (NAICS 327113a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

As previously discussed, OSHA has established a minimum threshold level of annualized costs equal to one percent of annual revenues—and, secondarily, annualized costs equal to 10 percent of annual profits—below which the

Agency has concluded that costs are unlikely to threaten the economic viability of an affected industry. The results of OSHA's threshold tests for all affected establishments are displayed in Table IX–8. For all affected establishments, the estimated annualized cost of the proposed rule is, on average, equal to 0.11 percent of annual revenue and 1.52 percent of annual profit.

As Table IX–8 shows, there are no industries in which the annualized costs of the proposed rule exceed one percent of annual revenues. However there are three six-digit NAICS industries where annualized costs exceed ten percent of annual profits.

NAICS 331525 (Copper foundries except die-casting) has the highest cost impact as a percentage of profits. NAICS 331525 is made up of two types of copper foundries: sand casting foundries and non-sand casting foundries, incurring an annualized cost as a percent of profit of 16.25 percent and 14.92 percent, respectively. The other two six-digit NAICS industries where annualized costs exceed ten percent of annual profits are NAICS 331534: Aluminum foundries (except die-casting), 13.65 percent; and NAICS 811310: Commercial and industrial machinery and equipment repair, 10.19 percent.

OSHA believes that the beryllium-containing inputs used by these industries have a relatively inelastic demand for three reasons. First, beryllium has rare and unique characteristics, including low mass, high melting temperature, dimensional stability over a wide temperature range, strength, stiffness, light weight, and high elasticity (''springiness'') that can significantly improve the performance of various alloys. These characteristics cannot easily be replicated by other materials. In economic terms, this means that the elasticity of substitution between beryllium and non-beryllium inputs will be low. Second, products which contain beryllium or beryllium-alloy components typically have high-performance applications (whose performance depends on the use of higher-cost beryllium). The lack of available competing products with these performance characteristics suggests that the price elasticity of demand for products containing beryllium or beryllium-alloy components will be low. Third, components made of beryllium or beryllium-containing alloys typically account for only a small portion of the overall cost of the finished goods that these parts are used to make. For example, the cost of brakes made of a beryllium-alloy used in the production of a jet airplane represents a trivial percentage of the overall cost to produce that airplane. As economic theory indicates, the elasticity of derived demand for a factor of production (such as beryllium) varies directly with the elasticity of substitution between the input in question and other inputs; the price elasticity of demand for the final product that the input is used to produce; and, in general, the share of the cost of the final product that the input accounts for. Applying these three conditions to beryllium points to the relative inelastic derived demand for this factor of production and the likelihood that cost increases resulting from the proposed rule would be passed on to the consumer in the form of higher prices.

A secondary point is that the establishments in an industry that use beryllium may be more profitable than those that don't. This follows from the prior arguments about beryllium's rare and desirable characteristics and its valuable applications. For example, of the 208 establishments that make up NAICS 331525, OSHA estimated that 45 establishments (or 21 percent) work with beryllium. Of the 394 establishments that make up NAICS 331524, OSHA estimated that only 7 establishments (less than 2 percent) work with beryllium. Of the 21,960 establishments that make up NAICS 811310, OSHA estimated that 143 (0.7 percent) work with beryllium. However, when OSHA calculated the cost-to-profit ratio, it used the average profit per firm for the entire NAICs industry, not the average profit per firm for firms working with beryllium.

(1) Normal Year-to-Year Variations in Prices and Profit Rates

The United States has a dynamic and constantly changing economy in which an annual percentage increase in industry revenues or prices of one percent or more are common. Examples of year-to-year changes in an industry that could cause such an increase in revenues or prices include increases in fuel, material, real estate, or other costs; tax increases; and shifts in demand.

To demonstrate the normal year-to-year variation in prices for all the manufacturers in general industry affected by the proposed rule, OSHA developed in the PEA year-to-year producer price indices and year-to-year percentage changes in producer prices, by industry, for the years 1999–2010. For all of the industries estimated to be affected by this proposed standard over the 12-year period, the average change in producer prices was 4.4 percent a year—which is over 4 times as high as OSHA's 1 percent cost-to-revenue threshold. For the industries found to have the largest estimated potential annual cost impact as a percentage of revenue shown in Chapter VI of the PEA are—NAICS 331524: Aluminum Foundries (except Die-Casting), (0.71 percent); NAICS 331525(a and b): Copper Foundries (except Die-Casting) (average of 0.81 percent); NAICS 332721a: Precision Turned Product Manufacturing of high content beryllium (0.49 percent); [21] and NAICS 811310: Commercial and Industrial Machinery and Equipment (Except Automotive and Electronic) Repair and Maintenance (0.55 percent)—the average annual changes in producer prices in these industries over the 12-year period analyzed were 3.1 percent, 8.2 percent, 3.6 percent and 2.3 percent, respectively.

Based on these data, it is clear that the potential price impacts of the proposed rule in affected industries are all well within normal year-to-year variations in prices in those industries. The maximum cost impact of the proposed rule as a percentage of revenue in any affected industry is 0.84 percent, while, as just noted, the average annual change in producer prices for affected industries was 4.4 percent for the period 1999–2010. In fact, Chapter VI of the PEA shows two of the industries within the secondary smelting, refining, and alloying group, for example, the prices rose over 60 percent in one year without imperiling the existence of those industries. Thus, OSHA preliminarily concludes that the potential price impacts of the proposal would not threaten the economic viability of any industries affected by this proposed standard.

Profit rates are also subject to the dynamics of the U.S. economy. A recession, a downturn in a particular industry, foreign competition, or the increased competitiveness of producers of close domestic substitutes are all easily capable of causing a decline in profit rates in an industry of well in excess of ten percent in one year or for several years in succession.

To demonstrate the normal year-to-year variation in profit rates for all the manufacturers affected by the proposed rule, OSHA presented data in the PEA on year-to-year profit rates and year-to-year percentage changes in profit rates, by industry, for the years 2002–2009. For the industries that OSHA has estimated will be affected by this

[21] By contrast, NAICS 332721b: Precision Turned Product Manufacturing of low content beryllium alloys has a cost to revenue ratio below 0.4 percent.

proposed standard over the 8-year period, the average change in profit rates is calculated to be 39 percent per year. For the industries with the largest estimated potential annual cost impacts as a percentage of profit—NAICS 331524: Aluminum foundries (except die-casting), (14 percent); NAICS 331525(a and b): Copper foundries (except die-casting) (16 percent); NAICS 332721a: Precision Turned Product Manufacturing of high content beryllium (8 percent); [22] and NAICS 811310 Commercial and Industrial Machinery and Equipment (Except Automotive and Electronic) Repair and Maintenance (10 percent)—the average annual changes in profit rates in these industries over the eight-year period were 35 percent, 35 percent, 11 percent, and 5 percent, respectively.

A longer-term loss of profits in excess of 10 percent a year could be more problematic for some affected industries and might conceivably, under sufficiently adverse circumstances, threaten an industry's economic viability. However, as previously discussed, OSHA's analysis indicates that affected industries would generally *not* absorb the costs of the proposed rule in reduced profits but, instead, would be able to pass on most or all of those costs in the form of higher prices (due to the relative price inelasticity of demand for beryllium and beryllium-containing inputs). It is possible that such price increases will result in some reduction in output, and the reduction in output might be met through the closure of a small percentage of the plants in the industry. The only realistic circumstance where an entire industry would be significantly affected by small potential price increases would be where there is a very close or perfect substitute product available not subject to OSHA regulation. In most cases where beryllium is used, there is no substitute product that could be used in place of beryllium and achieve the same level of performance. The main potential concern would be substitution by foreign competition, but the following discussion reveals why such competition is not likely.

(2) International Trade Effects

World production of beryllium is a thin market, with only a handful of countries known to process beryllium ores and concentrates into beryllium products, and characterized by a high degree of variation and uncertainty. The United States accounts for approximately 65 percent of world beryllium deposits and 90 percent of world production, but there is also a significant stockpiling of beryllium materials in Kazakhstan, Russia, China, and possibly other countries (USGS, 2013a). For the individual years 2008–2012, the United States' net import reliance as a percentage of apparent consumption (that is, imports minus exports net of industry and government stock adjustments) ranged from 10 percent to 61 percent (USGS, 2013b). To assure an adequate stockpile of beryllium materials to support national defense interests, the U.S. Department of Defense, in 2005, under the Defense Production Act, Title III, invested in a public-private partnership with the leading U.S. beryllium producer to build a new $90.4 million primary beryllium facility in Elmore, Ohio. Construction of that facility was completed in 2011 (USGS, 2013b).

One factor of importance to firms working with beryllium and beryllium alloys is to have a reliable supply of beryllium materials. U.S. manufacturers can have a relatively high confidence in the availability of beryllium materials relative to manufacturers in many foreign countries, particularly those that do not have economic or national security partnerships with the United States.

Firms using beryllium in production must consider not just the cost of the chemical itself but also the various regulatory costs associated with the use, transport, and disposal of the material. For example, for marine transport, metallic beryllium powder and beryllium compounds are classified by the International Maritime Organization (IMO) as poisonous substances, presenting medical danger. Beryllium is also classified as flammable. The United Nations classification of beryllium and beryllium compounds for the transport of dangerous goods is ''poisonous substance'' and, for packing, a ''substance presenting medium danger'' (WHO, 1990). Because of beryllium's toxicity, the material is subject to various workplace restrictions as well as international, national, and State requirements and guidelines regarding beryllium content in environmental media (USGS, 2013a).

As the previous discussion indicates, the production and use of beryllium and beryllium alloys in the United States and foreign markets appears to depend on the availability of production facilities; beryllium stockpiles; national defense and political considerations; regulations limiting the shipping of beryllium and beryllium products; international, national, and State regulations and guidelines regarding beryllium content in environmental media; and, of course, the special performance properties of beryllium and beryllium alloys in various applications. Relatively small changes in the price of beryllium would seem to have a minor effect on the location of beryllium production and use. In particular, as a result of this proposed rule, OSHA would expect that, if all compliance costs were passed through in the form of higher prices, a price increase of 0.11 percent, on average, for firms manufacturing or using beryllium in the United States—and not exceeding 1 percent in any affected industry—would have a negligible effect on foreign competition and would therefore not threaten the economic viability of any affected domestic industries.

(b) Economic Feasibility Screening Analysis: Small and Very Small Businesses

The preceding discussion focused on the economic viability of the affected industries in their entirety. Even though OSHA found that the proposed standard did not threaten the survival of these industries, there is still the possibility that the competitive structure of these industries could be significantly altered such as by small entities exiting from the industry as a result of the proposed standard.

To address this possibility, OSHA examined the annualized costs of the proposed standard per affected small entity, and per affected very small entity, for each affected industry. Again, OSHA used a minimum threshold level of annualized compliance costs equal to one percent of annual revenues—and, secondarily, annualized compliance costs equal to ten percent of annual profits—below which the Agency has concluded that the costs are unlikely to threaten the survival of small entities or very small entities or, consequently, to alter the competitive structure of the affected industries.

Based on the results presented in Table IX–9, the annualized cost of compliance with the proposed rule for the average affected small entity is estimated to be $8,108 in 2010 dollars. Based on the results presented in Table IX–10, the annualized cost of compliance with the proposed rule for the average affected very small entity is estimated to be $1,955 in 2010 dollars. These tables also show that there are no industries in which the annualized costs of the proposed rule for small entities or very small entities exceed one percent of annual revenues. NAICS 331525b: Sand Copper Foundries (except die-casting) has the highest estimated cost

[22] By contrast, NAICS 332721b: Precision Turned Product Manufacturing of low content beryllium alloys has a cost to profit ratio of 6 percent.

impact as a percentage of revenues for small entities, 0.95 percent, and NAICS 336322b: Other motor vehicle electrical and electronic equipment has the highest estimated cost impact as a percentage of revenues for very small entities, 0.70 percent.

Small entities in four industries—NAICS 331525: Sand and non-sand foundries (except die-casting); NAICS 331524(a and b): Aluminum foundries (except die-casting); NAICS 811310: Commercial and Industrial Machinery and Equipment; and NAICS 331522: Nonferrous (except aluminum) die-casting foundries—have annualized costs in excess of 10 percent of annual profits (17.45 percent, 16.12 percent, 11.68 percent, and 10.64 percent, respectively). Very small entities in 7 industries are estimated to have annualized costs in excess of 10 percent of annual profit; NAICS 336322b: Other motor vehicle electrical and electronic equipment (38.49 percent); [23] NAICS 336322a: Other motor vehicle electrical and electronic equipment, (18.18 percent); NAICS 327113: Porcelain electrical Supply Manufacturing (13.82 percent); NAICS 811310: Commercial and Industrial Machinery and Equipment (Except Automotive and Electronic) Repair and Maintenance (12.76 percent); NAICS 332721a: Precision turned product manufacturing (10.50 percent); NAICS 336214: Travel trailer and camper manufacturing (10.75 percent); and NAICS 336399: All other motor vehicle parts manufacturing (10.38 percent).

In general, cost impacts for affected small entities or very small entities will tend to be somewhat higher, on average, than the cost impacts for the average business in those affected industries. That is to be expected. After all, smaller businesses typically suffer from diseconomies of scale in many aspects of their business, leading to less revenue per dollar of cost and higher unit costs. Small businesses are able to overcome these obstacles by providing specialized products and services, offering local service and better service, or otherwise creating a market niche for themselves. The higher cost impacts for smaller businesses estimated for this rule—other than very small entities in NAICS 336322b: Other motor vehicle electrical and electronic equipment—generally fall within the range observed in other OSHA regulations and, as verified by OSHA's lookback reviews, have not been of such a magnitude to lead to the economic failure of regulated small businesses.

The ratio of annualized costs to annual profit is a sizable 38.49 percent in NAICS 336322b: Other motor vehicle electrical and electronic equipment. However, OSHA believes that the actual ratio is significantly lower. There are 386 very small entities in NAICS 336322, of which only 6, or 1.5 percent, are affected entities using beryllium. When OSHA calculated the cost-to-profit ratio, it used the average profit per firm for the entire NAICs industry, not the average profit rate for firms working with beryllium. The profit rate for all establishments in NAICS 336322b was estimated at 1.83 percent. If, for example, the average profit rate for a very small entity in NAICS 336322b were equal to 5.95 percent, the average profit rate for its application group, Beryllium Oxide Ceramics and Composites, then the ratio of the very small entity's annualized cost of the proposed rule to its annual profit would actually be 11.77 percent. OSHA tentatively concludes the 6 establishments in the NAICS specializing in beryllium production will have a higher than average profit rate and will be able to pass much of the cost onto the consumer for three main reasons: (1) The absence of substitutes containing the rare performance characteristics of beryllium; (2) the relative price insensitivity of (other) motor vehicles containing the special performance characteristics of beryllium and beryllium alloys; and (3) the fact that electrical and electronic components made of beryllium or beryllium-containing alloys typically account for only a small portion of the overall cost of the finished (other) motor vehicles. The annualized compliance cost to annual revenue ratio for NAICS 336332b is 0.70 percent, 0.30 percent below the 1 percent threshold. Based on OSHA's experience, price increases of this magnitude have not historically been associated with the economic failure of small businesses.

[23] NAICS 336322 contains entities that fall into three separate application groups. NAICS 336322b is in the Beryllium Oxide Ceramics and Composites application group. NAICS 336322a (which follows in the text) is in the Fabrication of Beryllium Alloy Products application group.

Table IX-9

Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Beryllium Standard
With Costs Calculated Using a Three Percent Discount Rate

				Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Small Entities	Total Affected Small Entities	Total for SBA Entitities ($1,000)	Per Entity ($s)	Rate	Per Entity ($s)	Per Entity ($s)	As a Percent of Revenues	As a Percent of Profits
Beryllium Production										
331419	Primary smelting and refining of nonferrous me	--	--	--	--	--	--	--	--	--
Beryllium Oxide Ceramics and Composites										
327113a	Porcelain electrical supply manufacturing (prin	85	1	$326,127	--	--	--	--	--	--
327113b	Porcelain electrical supply manufacturing (sec	85	11	$326,127	$3,836,783	5.01%	$192,368	$12,979	0.34%	6.75%
334220	Cellular telephones manufacturing	724	9	$35,475,343	$48,999,093	6.08%	$2,980,355	$19,318	0.04%	0.65%
334310	Compact disc players manufacturing	460	5	$3,975,351	$8,642,068	4.39%	$379,730	$16,768	0.19%	4.42%
334411	Electron tube manufacturing	62	16	$1,220,476	19,685,102	7.85%	1,544,859	$21,598	0.11%	1.40%
334415	Electronic resistor manufacturing	46	9	$385,781	8,386,547	7.85%	658,164	$15,052	0.18%	2.29%
334419	Other electronic component manufacturing	990	8	$4,796,313	4,844,761	7.85%	380,210	$12,982	0.27%	3.41%
334510	Electromedical equipment manufacturing	494	7	$3,752,243	7,595,634	6.75%	512,503	$8,812	0.12%	1.72%
336322b	Other motor vehicle electrical and electronic eq	585	9	$12,152,053	20,772,740	1.83%	379,243	$18,415	0.09%	4.86%
Nonferrous Foundries										
331521	Aluminum die-casting foundries	209	6	$2,070,759	9,907,938	5.22%	517,103	$38,396	0.39%	7.43%
331522	Nonferrous (except aluminum) die-casting four	129	35	$813,444	6,305,771	5.22%	329,103	$35,014	0.56%	10.64%
331524	Aluminum foundries (except die-casting)	351	6	$1,690,008	4,814,839	5.22%	251,290	$40,517	0.84%	16.12%
331525a	Copper foundries (except die-casting) (non-sar	195	19	$925,667	4,747,008	5.22%	247,750	$41,295	0.87%	16.67%
331525b	Copper foundries (except die-casting) (sand ca	195	23	$925,667	4,747,008	5.22%	247,750	$45,131	0.95%	18.22%
Secondary Smelting, Refining, and Alloying										
331314	Secondary smelting & alloying of aluminum	98	1	$4,837,129	49,358,460	4.54%	2,243,316	$33,757	0.07%	1.50%
331421b	Copper rolling, drawing, and extruding	70	1	$12,513,425	178,763,215	4.79%	8,569,920	$34,206	0.02%	0.40%
331423	Secondary smelting, refining, & alloying of co	23	3	$723,759	31,467,777	4.79%	1,508,567	$35,101	0.11%	2.33%
331492	Secondary smelting, refining, & alloying of no	217	26	$8,195,807	37,768,697	4.79%	1,810,634	$22,183	0.06%	1.23%
Precision Turned Products										
332721a	Precision turned product manufacturing (high	3,006	18	$11,393,081	3,790,113	5.82%	220,539	$19,481	0.51%	8.83%
332721b	Precision turned product manufacturing (low b	3,006	283	$11,393,081	3,790,113	5.82%	220,539	$14,207	0.37%	6.44%
Copper Rolling, Drawing and Extruding										
331421a	Copper rolling, drawing, and extruding	70	11	$12,513,425	178,763,215	4.79%	8,569,920	$119,129	0.07%	1.39%
331422	Copper wire (except mechanical) drawing	84	43	$6,471,491	77,041,555	4.79%	3,693,377	$105,463	0.14%	2.86%
Fabrication of Beryllium Alloy Products										
332612	Light gauge spring manufacturing	262	262	$1,030,905	3,934,752	5.61%	220,868	$7,277	0.18%	3.29%
332116	Metal stamping	1,367	68	$7,693,541	5,628,048	5.12%	288,086	$8,395	0.15%	2.91%
334417	Electronic connector manufacturing	176	35	$1,556,871	8,845,860	7.85%	694,211	$5,765	0.07%	0.83%
336322a	Other motor vehicle electrical & electronic equ	585	146	$12,152,053	20,772,740	1.83%	379,243	$10,048	0.05%	2.65%

Table IX-9, continued

Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Beryllium Standard
With Costs Calculated Using a Three Percent Discount Rate

				Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment ($s)	Rate	Per Establishment ($s)	Per Establishment ($s)	As a Percent of Revenues	As a Percent of Profits
Arc and Gas Welding										
331111	Iron and steel mills	461	5	$92,726,004	201,141,005	5.41%	10,877,459	$10,377	0.01%	0.10%
331221	Rolled steel shape manufacturing	134	1	$8,376,271	62,509,488	5.41%	3,380,437	$12,541	0.02%	0.37%
331513	Steel foundries (except investment)	188	1	$2,739,158	14,569,989	5.22%	760,419	$8,657	0.06%	1.14%
332117	Powder metallurgy part manufacturing	106	1	$841,084	7,934,752	5.12%	406,161	$8,278	0.10%	2.04%
332212	Hand and edge tool manufacturing	975	3	$3,072,300	3,151,077	5.61%	176,878	$7,037	0.22%	3.98%
332312	Fabricated structural metal manufacturing	3,001	49	$15,405,728	5,133,531	4.74%	243,251	$6,076	0.12%	2.50%
332313	Plate work manufacturing	1,220	20	$4,900,364	4,016,692	4.74%	190,330	$7,379	0.18%	3.88%
332322	Sheet metal work manufacturing	3,835	63	$12,607,305	3,287,433	4.74%	155,774	$7,010	0.21%	4.50%
332323	Ornamental and architectural metal work manu	2,287	38	$4,118,512	1,800,836	4.74%	85,332	$6,548	0.36%	7.67%
332439	Other metal container manufacturing	302	5	$1,698,117	5,622,904	4.30%	242,034	$5,858	0.10%	2.42%
332919	Other metal valve and pipe fitting manufacturir	207	2	$2,028,451	9,799,278	7.00%	686,061	$6,301	0.06%	0.92%
332999	All other miscellaneous fabricated metal produ	3,111	32	$10,202,505	3,279,494	7.00%	229,602	$6,782	0.21%	2.95%
333111	Farm machinery and equipment manufacturing	941	18	$5,132,720	5,454,538	6.36%	347,100	$3,899	0.07%	1.12%
333414a	Heating equipment (except warm air furnaces)	410	5	$2,583,472	6,301,151	4.68%	294,852	$5,769	0.09%	1.96%
333911	Pump and pumping equipment manufacturing	399	5	$3,348,262	8,391,635	5.36%	449,783	$4,457	0.05%	0.99%
333922	Conveyor and conveying equipment manufact	707	8	$4,768,668	6,744,933	5.36%	361,522	$6,809	0.10%	1.88%
333924	Industrial truck, tractor, trailer, and stacker mac	347	4	$7,444,451	21,453,748	5.36%	1,149,899	$9,122	0.04%	0.79%
333999	All other miscellaneous general purpose machi	1,385	16	$5,601,674	4,044,530	5.36%	216,783	$5,282	0.13%	2.44%
336211	Motor vehicle body manufacturing	652	13	$9,877,558	15,149,628	1.83%	276,583	$9,055	0.06%	3.27%
336214	Travel trailer and camper manufacturing	585	12	$2,513,608	4,296,766	1.83%	78,445	$4,404	0.10%	5.61%
336399a	All other motor vehicle parts manufacturing	1,156	6	$32,279,766	27,923,673	1.83%	509,796	$9,445	0.03%	1.85%
336510	Railroad rolling stock	157	2	$11,927,191	75,969,367	5.47%	4,156,603	$12,983	0.02%	0.31%
336999	All other transportation equipment manufactur	349	3	$941,637	2,698,100	6.56%	177,073	$4,339	0.16%	2.45%
337215	Showcase, partition, shelving, and locker manu	1,120	3	$3,688,129	3,292,972	4.26%	140,227	$6,966	0.21%	4.97%
811310	Commercial and industrial machinery and equi	19,857	129	$17,088,964	860,601	5.42%	46,622	$5,445	0.63%	11.68%
Resistance Welding										
333411	Air purification equipment manufacturing	283	20	$1,327,014	4,689,095	4.68%	219,418	$8,363	0.18%	3.81%
333412	Industrial and commercial fan and blower manu	118	8	$1,001,835	8,490,124	4.68%	397,281	$11,780	0.14%	2.97%
333414b	Heating equipment (except warm air furnaces)	410	29	$2,583,472	6,301,151	4.68%	294,852	$10,186	0.16%	3.45%
333415	Air-conditioning, warm air heating, and industi	695	49	$25,454,383	36,625,012	4.68%	1,713,806	$18,247	0.05%	1.06%
335211	Electric housewares and household fan manuf	101	5	$2,209,657	21,877,797	4.03%	881,709	$15,789	0.07%	1.79%
335212	Household vacuum cleaner manufacturing	29	1	$891,600	30,744,844	4.03%	1,239,064	$17,638	0.06%	1.42%
335221	Household cooking appliance manufacturing	91	5	$3,757,849	41,295,040	4.03%	1,664,253	$15,870	0.04%	0.95%
335222	Household refrigerator and home freezer manu	16	1	$4,489,845	280,615,299	4.03%	11,309,226	$16,548	0.01%	0.15%
335224	Household laundry equipment manufacturing	9	1	$3,720,514	413,390,395	4.03%	16,660,266	$8,274	0.00%	0.05%
335228	Other major household appliance manufacturin	24	1	$185,373	7,723,871	4.03%	311,284	$1,740	0.02%	0.56%

Table IX-9, continued

Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Beryllium Standard
With Costs Calculated Using a Three Percent Discount Rate

				Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment ($s)	Rate	Per Establishment ($s)	Per Establishment ($s)	As a Percent of Revenues	As a Percent of Profits
Resistance Welding										
336311	Carburetor, piston, piston ring, and valve manu	89	4	$499,977	5,617,722	1.83%	102,562	$5,227	0.09%	5.10%
336312	Gasoline engine and engine parts manufacturin	697	35	$20,000,705	28,695,417	1.83%	523,886	$16,015	0.06%	3.06%
336321	Vehicular lighting equipment manufacturing	75	4	$671,947	8,959,292	1.83%	163,568	$6,084	0.07%	3.72%
336322c	Other motor vehicle electrical and electronic eq	585	29	$12,152,053	20,772,740	1.83%	379,243	$16,355	0.08%	4.31%
336330	Motor vehicle steering and suspension compo	209	10	$8,856,584	42,376,000	1.83%	773,649	$17,707	0.04%	2.29%
336340	Motor vehicle brake system manufacturing	159	8	$8,147,826	51,244,189	1.83%	935,554	$18,828	0.04%	2.01%
336350	Motor vehicle transmission and power train pa	397	20	$21,862,014	55,068,044	1.83%	1,005,365	$18,037	0.03%	1.79%
336360	Motor vehicle seating and interior trim manufa	273	14	$3,482,677	12,757,060	1.83%	232,903	$6,586	0.05%	2.83%
336370	Motor vehicle metal stamping	540	27	$7,262,381	13,448,854	1.83%	245,533	$8,894	0.07%	3.62%
336391	Motor vehicle air-conditioning manufacturing	72	4	$3,798,464	52,756,449	1.83%	963,163	$16,715	0.03%	1.74%
336399b	All other motor vehicle parts manufacturing	1,156	58	$32,279,766	27,923,673	1.83%	509,796	$17,568	0.06%	3.45%
Dental Laboratories										
339116	Dental laboratories	6,703	1,676	$3,156,130	470,853	10.55%	49,696	$1,394	0.30%	2.81%
621210	Offices of dentists	123,077	225	$94,120,777	764,731	8.47%	64,809	$1,630	0.21%	2.51%
	Total/Average	**193,274**	**3,741**	**$687,134,666**	**7,300,515**	**7.55%**	**550,848**	**$8,108**	**0.11%**	**1.47%**

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 331419) and Beryllium Oxide (NAICS 327113a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Table IX-10

Screening Analysis for Very Small Entities (with fewer than 20 employees) Affected by the Proposed Beryllium Standard
With Costs Calculated Using a Three Percent Discount Rate

				Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Small Entities	Total Affected Small Entities	Total for Very Small Entitities ($1,000)	Per Entity ($s)	Rate	Per Entity ($s)	Per Entity ($s)	As a Percent of Revenues	As a Percent of Profits
Beryllium Production										
331419	Primary smelting and refining of nonferrous metals	--	--	--	--	--	--	--	--	--
Beryllium Oxide Ceramics and Composites										
327113a	Porcelain electrical supply manufacturing (primary)	53	0	52,358	--	--	--	--	--	--
327113b	Porcelain electrical supply manufacturing (secondary)	53	7	52,358	$987,892	5.01%	$192,368	$6,846	0.69%	13.82%
334220	Cellular telephones manufacturing	445	4	576,956	$1,296,530	6.08%	$2,980,355	$6,273	0.48%	7.95%
334310	Compact disc players manufacturing	373	4	1,128,513	$3,025,503	4.39%	$379,730	$8,383	0.28%	6.31%
334411	Electron tube manufacturing	38	10	45,454	$1,196,149	7.85%	$1,544,859	$6,430	0.54%	6.85%
334415	Electronic resistor manufacturing	17	3	25,647	$1,508,662	7.85%	$658,164	$6,848	0.45%	5.78%
334419	Other electronic component manufacturing	624	5	639,599	$1,024,999	7.85%	$380,210	$6,962	0.68%	8.65%
334510	Electromedical equipment manufacturing	324	3	420,245	$1,297,053	6.75%	$512,503	$6,271	0.48%	7.17%
336322b	Other motor vehicle electrical and electronic equipment manufa	386	6	349,811	$906,246	1.83%	$379,243	$6,368	0.70%	38.49%
Nonferrous Foundries										
331521	Aluminum die-casting foundries	107	0	153,274	--	5.22%	$517,103	--	--	--
331522	Nonferrous (except aluminum) die-casting foundries	84	0	92,703	--	5.22%	$329,103	--	--	--
331524	Aluminum foundries (except die-casting)	217	0	204,397	--	5.22%	$251,290	--	--	--
331525a	Copper foundries (except die-casting) (non-sand casting found	131	0	139,372	--	5.22%	$247,750	--	--	--
331525b	Copper foundries (except die-casting) (sand casting foundries)	131	0	139,372	--	5.22%	$247,750	--	--	--
Secondary Smelting, Refining, and Alloying										
331314	Secondary smelting & alloying of aluminum	45	0	306,390	--	4.54%	$2,243,316	--	--	--
331421b	Copper rolling, drawing, and extruding	26	0	48,421	--	4.79%	$8,569,920	--	--	--
331423	Secondary smelting, refining, & alloying of copper	11	1	85,353	$7,759,405	4.79%	$1,508,567	$21,589	0.28%	5.80%
331492	Secondary smelting, refining, & alloying of nonferrous metal (e	121	15	388,603	$3,211,598	4.79%	$1,810,634	$11,055	0.34%	7.18%
Precision Turned Products										
332721a	Precision turned product manufacturing (high beryllium conten	1,970	12	2,219,340	$1,126,568	5.82%	$220,539	$6,881	0.61%	10.50%
332721b	Precision turned product manufacturing (low beryllium content	1,970	185	2,219,340	$1,126,568	5.82%	$220,539	$5,045	0.45%	7.70%
Copper Rolling, Drawing and Extruding										
331421a	Copper rolling, drawing, and extruding	26	4	48,421	$1,862,347	4.79%	$8,569,920	$5,684	0.31%	6.37%
331422	Copper wire (except mechanical) drawing	35	18	254,426	$7,269,304	4.79%	$3,693,377	$7,682	0.11%	2.20%
Fabrication of Beryllium Alloy Products										
332612	Light gauge spring manufacturing	164	164	156,603	$954,897	5.61%	$220,868	$3,310	0.35%	6.18%
332116	Metal stamping	807	40	1,033,657	$1,280,864	5.12%	$288,086	$3,543	0.28%	5.40%
334417	Electronic connector manufacturing	106	11	129,405	$1,220,804	7.85%	$694,211	$3,014	0.25%	3.15%
336322a	Other motor vehicle electrical & electronic equipment	386	60	349,811	$906,246	1.83%	$379,243	$3,007	0.33%	18.18%

Table IX-10, continued

Screening Analysis for Very Small Entities (with fewer than 20 employees) Affected by the Proposed Beryllium Standard

With Costs Calculated Using a Three Percent Discount Rate

				Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Small Entities	Total Affected Small Entities	Total for Very Small Entitities ($1,000)	Per Entity ($s)	Rate	Per Entity ($s)	Per Entity ($s)	As a Percent of Revenues	As a Percent of Profits
Arc and Gas Welding										
331111	Iron and steel mills	268	0	1,018,914	--	5.41%	$10,877,459	--	--	--
331221	Rolled steel shape manufacturing	50	0	208,799	--	5.41%	$3,380,437	--	--	--
331513	Steel foundries (except investment)	94	0	$112,227	--	5.22%	760,419	--	--	--
332117	Powder metallurgy part manufacturing	55	0	$100,643	--	5.12%	406,161	--	--	--
332212	Hand and edge tool manufacturing	751	2	$681,375	907,290	5.61%	176,878	$3,171	0.35%	6.23%
332312	Fabricated structural metal manufacturing	2,159	35	$3,182,459	1,474,043	4.74%	243,251	$2,299	0.16%	3.29%
332313	Plate work manufacturing	845	14	$1,007,308	1,192,080	4.74%	190,330	$2,891	0.24%	5.12%
332322	Sheet metal work manufacturing	2,778	46	$2,631,155	947,140	4.74%	155,774	$2,620	0.28%	5.84%
332323	Ornamental and architectural metal work manufacturing	1,957	32	$1,342,443	685,970	4.74%	85,332	$3,153	0.46%	9.70%
332439	Other metal container manufacturing	203	2	$187,607	924,174	4.30%	242,034	$2,471	0.27%	6.21%
332919	Other metal valve and pipe fitting manufacturing	115	1	$181,192	1,575,580	7.00%	686,061	$4,302	0.27%	3.90%
332999	All other miscellaneous fabricated metal product manufacturing	2,353	24	$2,117,303	899,831	7.00%	229,602	$2,560	0.28%	4.06%
333111	Farm machinery and equipment manufacturing	673	7	$785,460	1,167,103	6.36%	347,100	$2,299	0.20%	3.10%
333414a	Heating equipment (except warm air furnaces) manufacturing	283	2	$365,551	1,291,699	4.68%	294,852	$2,536	0.20%	4.20%
333911	Pump and pumping equipment manufacturing	251	1	$497,397	1,981,660	5.36%	449,783	$2,477	0.12%	2.33%
333922	Conveyor and conveying equipment manufacturing	407	4	$541,532	1,330,547	5.36%	361,522	$2,335	0.18%	3.27%
333924	Industrial truck, tractor, trailer, and stacker machinery manufact	195	1	$213,335	1,094,026	5.36%	1,149,899	$2,761	0.25%	4.71%
333999	All other miscellaneous general purpose machinery manufactur	975	10	$1,151,152	1,180,669	5.36%	216,783	$2,298	0.19%	3.63%
336211	Motor vehicle body manufacturing	400	4	$535,923	1,339,807	1.83%	276,583	$2,298	0.17%	9.39%
336214	Travel trailer and camper manufacturing	410	5	$480,503	1,171,958	1.83%	78,445	$2,300	0.20%	10.75%
336399a	All other motor vehicle parts manufacturing	653	1	$835,261	1,279,114	1.83%	509,796	$2,424	0.19%	10.38%
336510	Railroad rolling stock	83	0	$189,164	--	5.47%	4,156,603	--	--	--
336999	All other transportation equipment manufacturing	307	2	$253,916	827,087	6.56%	177,073	$2,938	0.36%	5.41%
337215	Showcase, partition, shelving, and locker manufacturing	814	2	$582,654	715,791	4.26%	140,227	$3,035	0.42%	9.96%
811310	Commercial and industrial machinery and equipment repair	18,714	122	$10,692,921	571,386	5.42%	46,622	$3,949	0.69%	12.76%
Resistance Welding										
333411	Air purification equipment manufacturing	189	13	$283,628	1,500,678	4.68%	219,418	$2,506	0.17%	3.57%
333412	Industrial and commercial fan and blower manufacturing	60	4	$78,644	1,310,729	4.68%	397,281	$2,401	0.18%	3.92%
333414b	Heating equipment (except warm air furnaces) manufacturing	283	20	$365,551	1,291,699	4.68%	294,852	$2,321	0.18%	3.84%
333415	Air-conditioning, warm air heating, and industrial refrigeration e	395	28	$806,994	2,043,023	4.68%	1,713,806	$1,094	0.05%	1.14%
335211	Electric housewares and household fan manufacturing	70	4	$99,219	1,417,419	4.03%	881,709	$1,151	0.08%	2.01%
335212	Household vacuum cleaner manufacturing	18	0	$21,745	--	4.03%	1,239,064	--	--	--
335221	Household cooking appliance manufacturing	57	2	$66,863	1,173,037	4.03%	1,664,253	$1,056	0.09%	2.23%
335222	Household refrigerator and home freezer manufacturing	6	0	$8,833	--	4.03%	11,309,226	--	--	--
335224	Household laundry equipment manufacturing	4	0	$1,837	--	4.03%	16,660,266	--	--	--
335228	Other major household appliance manufacturing	15	0	$24,856	--	4.03%	311,284	--	--	--

Table IX-10, continued

Screening Analysis for Very Small Entities (with fewer than 20 employees) Affected by the Proposed Beryllium Standard
With Costs Calculated Using a Three Percent Discount Rate

				Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Small Entities	Total Affected Small Entities	Total for Very Small Entitities ($1,000)	Per Entity ($s)	Rate	Per Entity ($s)	Per Entity ($s)	As a Percent of Revenues	As a Percent of Profits
Resistance Welding										
336311	Carburetor, piston, piston ring, and valve manufacturing	59	3	$54,436	922,644	1.83%	102,562	$1,395	0.15%	8.28%
336312	Gasoline engine and engine parts manufacturing	545	27	$883,783	1,621,620	1.83%	523,886	$1,331	0.08%	4.49%
336321	Vehicular lighting equipment manufacturing	45	2	$59,894	1,330,971	1.83%	163,568	$1,056	0.08%	4.35%
336322c	Other motor vehicle electrical and electronic equipment manufa	386	19	$349,811	906,246	1.83%	379,243	$1,452	0.16%	8.78%
336330	Motor vehicle steering and suspension components (except sp	116	5	$998,968	8,611,797	1.83%	773,649	$1,056	0.01%	0.67%
336340	Motor vehicle brake system manufacturing	82	3	$96,867	1,181,305	1.83%	935,554	$1,056	0.09%	4.90%
336350	Motor vehicle transmission and power train parts manufacturin	240	9	$304,951	1,270,628	1.83%	1,005,365	$1,056	0.08%	4.55%
336360	Motor vehicle seating and interior trim manufacturing	167	7	$310,566	1,859,677	1.83%	232,903	$1,056	0.06%	3.11%
336370	Motor vehicle metal stamping	225	11	$478,984	2,128,816	1.83%	245,533	$1,329	0.06%	3.42%
336391	Motor vehicle air-conditioning manufacturing	34	1	$80,741	2,374,734	1.83%	963,163	$1,056	0.04%	2.44%
336399b	All other motor vehicle parts manufacturing	653	33	$835,261	1,279,114	1.83%	509,796	$1,267	0.10%	5.43%
Dental Laboratories										
339116	Dental laboratories	6,379	1,595	1,807,075	$283,285	10.55%	$49,696	$922	0.33%	3.09%
621210	Offices of dentists	119,544	219	81,995,117	$685,899	8.47%	$64,809	$1,464	0.21%	2.52%
	Total/Average	172,628	2,875	128,347,342	$679,421	8.27%	$56,189	$1,955	0.29%	3.48%

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 331419) and Beryllium Oxide (NAICS 327113a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

(c) Regulatory Flexibility Screening Analysis

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed beryllium standard will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the proposed standard on small entities. The minimum threshold effects for this purpose are annualized costs equal to one percent of annual revenues, and annualized costs equal to five percent of annual profits, applied to each affected industry. OSHA has applied these screening tests both to small entities and to very small entities. For purposes of certification, the threshold level cannot be exceeded for affected small entities or very small entities in any affected industry.

Tables IX–9 and Table IX–10, presented above, show that the annualized costs of the proposed standard do not exceed one percent of annual revenues for affected small entities or affected very small entities in any affected industry. These tables also show that the annualized costs of the proposed standard exceed five percent of annual profits for affected small entities in 12 industries and for affected very small entities in 30 industries. OSHA is therefore unable to certify that the proposed standard will not have a significant economic impact on a substantial number of small entities and must prepare an Initial Regulatory Flexibility Analysis (IRFA). The IRFA is presented in Chapter IX of the PEA and is reproduced in Section IX.I of this preamble.

G. Benefits and Net Benefits

In this section, OSHA presents a summary of the estimated benefits and net benefits of the proposed beryllium rule. This section proceeds in five steps. The first step estimates the numbers of diseases and deaths prevented by comparing the current (baseline) situation to a world in which the proposed PEL is adopted in a final standard to a world in which employees are exposed at the level of the proposed PEL throughout their working lives. The second step also assumes that the proposed PEL is adopted, but uses the results from the first step to estimate what would happen under a more realistic scenario in which employees have been exposed for varying periods of time to the baseline situation and will thereafter be exposed to the new PEL.

The third step covers the monetization of benefits. Then, in the fourth step, OSHA estimates the net benefits and incremental benefits of the proposed rule by comparing the monetized benefits to the costs presented in Chapter V of the PEA. The models underlying each step inevitably need to make a variety of assumptions based on limited data. In the fifth step, OSHA provides a sensitivity analysis to explore the robustness of the estimates of net benefits with respect to many of the assumptions made in developing and applying the underlying models. A full explanation of the derivation of the estimates presented here is provided in Chapter VII of the PEA for the proposed rule. OSHA invites comments on any aspect of the data and methods used to estimate the benefits and net benefits of this proposed rule. Because dental labs constitute a significant source of both costs and benefits to the rule (over 40 percent), OSHA is particularly interested in comments regarding the appropriateness of the model, assumptions, and data to estimating the benefits to workers in that industry.

OSHA has added to the docket the spreadsheets used to calculate the estimates of benefits outlined below (OSHA, 2015a). Those interested in exploring the details and methodology of OSHA's benefits analysis, such as how the life table referred to below was developed and applied, should consult those spreadsheets.

Step 1—Estimation of the Steady-State Number of Beryllium-Related Diseases Avoided

Methods of Estimation

The first step in OSHA's development of the benefits analysis compares the situation in which employees continue to be at baseline exposure levels for their entire working lives to the situation in which all employees have been exposed at a given PEL for their entire working lives. This is a comparison of two steady-state situations. To do this, OSHA must estimate both the risk associated with the baseline exposure levels and the risk following the promulgation of a new beryllium standard. OSHA's approach assumes for inputs such as the turnover rate and the exposure response function that they are similar across all workers exposed to beryllium, regardless of industry.

An exposure-response model, discussed below, is used to estimate a worker's risk of beryllium-related disease based on the worker's cumulative beryllium exposure. The Agency used a lifetime risk model to estimate the baseline risk and the associated number of cases for the various disease endpoints. A lifetime risk model explicitly follows a worker each year, from work commencement onwards, accumulating the worker's beryllium exposure in the workplace and estimating outcomes each year for the competing risks that can occur. To go from exposure to number of cases, the Agency needs to estimate an exposure-response relationship, and this is discussed below. The possible outcomes are no change, or the various health endpoints OSHA has considered (beryllium sensitization, CBD, lung cancer, and the mortality associated with these endpoints). As part of the estimation discussion, OSHA will mention specific parameters used in some of the estimation methods, but will further discuss how these parameters were derived later in this section.

The baseline lifetime risk model is the most complicated part of the analysis. The Agency only needs to make relatively simple adjustments to this model to reflect changes in activities and conditions due to the standard, which, working through the model, then lead to changes in relevant health outcomes. There are three channels by which the standard generates benefits. First are estimated benefits due to the lowering of the PEL. Second are estimated benefits with further exposure reductions from the substitution of non-beryllium for beryllium-containing materials, ending workers' beryllium exposures entirely. This potential source of benefits is particularly significant with respect to OSHA's assumptions for how dental labs are likely to reduce exposures (see below). Finally, the model estimates benefits due to the ancillary programs that are required by the proposed standard. The last channel affects CBD and sensitization, endpoints which may be mitigated or prevented with the help of ancillary provisions such as dermal protection and medical surveillance for early detection, and for which the Agency has some information on the effects on risk of ancillary provisions. The benefits of ancillary provisions are not estimated for lung cancer because the benefits from reducing lung cancer are considered to be the result of reducing airborne exposure only and thus the ancillary provisions will have no separable effect on airborne exposures. The discussion here will concentrate on CBD as being the most important and complex endpoint, and most illustrative of other endpoints: The structure for other endpoints is the same; only the exposure response functions are different. Here OSHA will discuss first the exposure-response model, then the structure of the year-to-year changes for a worker, then the estimated exposure distribution in the affected population and the risk model with the lowering of the PEL, and, last, the other adjustments for the ancillary benefits and the substitution benefits.

The exposure response model is designed to translate beryllium exposure to risk of adverse health endpoints. In the case of beryllium sensitization and CBD, the Agency uses the cumulative exposure data from a beryllium manufacturing facility. Specifically, OSHA uses the quartile data from the Cullman plant that is presented in Table VI–7 of the Preliminary Risk Assessment in the preamble. The raw data from this study show cases of CBD with cumulative exposures that would represent an average exposure level of less than 0.1 μg/m^3 if exposed for 10 years; show cases of CBD with exposures lasting less than one year; and show cases of CBD with actual average exposure of less than 0.1 μg/m^3.

Prevalence is defined as the percentage of persons with a condition in a population at a given point in time. The quartile data in Table VI–7 of the Preliminary Risk Assessment are prevalence percentages (the number of cases of illness documented over several years in the 319 person cohort from the Cullman plant) at different cumulative exposure levels. The Cullman data do not cover persons who left the work force or what happened to persons who remained in the workforce after the study was completed. For the lifetime risk model, the prevalence percentages will be translated into incidence percentages—the estimated number of new cases predicted to occur each year. For this purpose OSHA assumed that the incidence for any given cumulative exposure level is constant from year to year and continues after exposure ceases.

To calculate incidence from prevalence, OSHA assumed a steady state in which both the size of the beryllium-exposed affected population, exposure concentrations during employment and prevalence are constant over time. If these conditions are met, and turnover among workers with a condition is equal to turnover for workers without a condition, then the incidence rate will be equal to the turnover rate multiplied by the prevalence rate. If the turnover rate among persons with a condition is higher than the turnover rate for workers without the condition, then this assumption will underestimate incidence. This might happen if, in addition to other reasons for leaving work, persons with a condition leave a place of employment more frequently because their disabilities cause them to have difficulty continuing to do the work. If the turnover rate among persons with a condition is lower than the turnover rate for workers without the condition, then this assumption will overestimate incidence. This could happen if an employer provides special benefits to workers with the condition, and the employer would cease to provide these benefits if the employee left work.

To illustrate, if 10 percent of the work force (including 10 percent of those with the condition) leave each year and if the overall prevalence is at 20 percent, then a 2 percent (10 percent times 20 percent) incidence rate will be needed in order to keep a steady 20 percent group prevalence rate each year. OSHA's model assumes a constant 10 percent turnover rate (see later in this section for the rationale for this particular turnover rate). While turnover rates are not available for the specific set of employees in question, for manufacturing as a whole, the turnover rates are greater than 20 percent, and greater than 30 percent for the economy as a whole (BLS, 2013). For this analysis, OSHA assumed an effective turnover rate of 10 percent. Different turnover rates will result in different incidence rates. The lower the turnover rate the lower the estimated incidence rate. This is a conservative assumption for the industries where turnover rates may be higher. However, some occupations/industries, such as dental lab technicians, may have lower turnover rates than manufacturing workers. Additionally, the typical dental technician even if leaving one workplace, has significant likelihood of continuing to work as a dental technician and going to another workplace that uses beryllium. OSHA welcomes comments on its turnover estimates and on sectors, such as dental laboratories, where turnover may be lower than ten percent.

Using Table VI–7 of the Preliminary Risk Assessment, when a worker's cumulative exposure is below 0.147 (μg/m^3-years), the prevalence of CBD is 2.5 percent and so the derived annual risk would be 0.25 percent (0.10×2.5 percent). It will stay at this level until the worker has reached a cumulative exposure of 1.468, where it will rise to 0.80 percent.

The model assumes a maximum 45-year (250 days per year) working life (ages 20 through 65 or age of death or onset of CBD, whichever is earlier) and follows workers after retirement through age 80. The 45-year working life is based on OSHA's legal requirements and is longer than the working lives of most exposed workers. A shorter working life will be examined later in this section. While employed, the worker accumulates beryllium exposure at a rate depending on where the worker is in the empirical exposure profile presented in Chapter IV of the PEA (*i.e.,* OSHA calculates a general risk model which depends on the exposure level and then plug in our empirical exposure distribution to estimate the final number of cases of various health outcomes). Following a worker's retirement, there is no increased exposure, just a constant annual risk resulting from the worker's final cumulative exposure.

OSHA's model follows the population of workers each year, keeping track of cumulative exposure and various health outcomes. Explicitly, each year the model calculates: The increased cumulative exposure level for each worker versus last year, the incidence at the new exposure level, the survival rate for this age bracket, and the percentage of workers who have not previously developed CBD in earlier years.

For any individual year, the equation for predicting new cases of CBD for workers at age t is:

New CBD cases rate(t) = modeled incidence rate(t) * survival rate(t) * (1-currently have CBD rate(t)), where the variables used are:

New CBD cases rate(t) is the output variable to be calculated;

cumulative exposure(t) = cumulative exposure(t-1) + current exposure;

modeled incidence rate(t) is a function of cumulative exposure; and

survival rate(t) is the background survival rate from mortality due to other causes in the national population.

Then for the next year the model updates the survival rate (due to an increase in the worker's age), incidence rate (due to any increased cumulative exposure), and the rate of those currently having CBD, which increases due to the new CBD case rate of the year before. This process then repeats for all 60 years.

It is important to note that this model is based on the assumption that prevalence is explained by an underlying constant incidence, and as a result, prevalence will be different depending on the average number of years of exposure in the population examined and (though a sensitivity analysis is provided later) on the assumption of a maximum of 45 years of exposure. OSHA also examined (OSHA 2015c) a model in which prevalence is constant at the levels shown in Table VI–7 of the preliminary risk assessment, with a population age (and thus exposure) distribution estimated based on an assumed constant turnover rate. OSHA solicits comment on this and other alternative approaches to using the available prevalence data to develop an exposure-response function for this benefits analysis.

In the next step, OSHA uses its model to take into account the adoption of the lower proposed PEL. OSHA uses the exposure profile for workers as estimated in Chapter IV of the PEA for each of the various application groups. These exposure profiles estimate the number of workers at various exposure levels, specifically the ranges less than 0.1 μg/m³, 0.1 to 0.2, 0.2 to 0.5, 0.5 to 1.0, 1.0 to 2.0, and greater than 2.0 μg/m³. Translating these ranges into exposure levels for the risk model, the model assumes an average exposure equal to the midpoint of the range, except for the lower end, where it was assumed to be equal to 0.1 μg/m³, and the upper end, where it was assumed to be equal to 2.0 μg/m³.

The model increases the workers' cumulative exposure each year by these midpoints and then plugs these new values into the new case equation. This alters the incidence rate as cumulative exposure crosses a threshold of the quartile data. So then using the exposure profiles by application group from Chapter IV of the PEA, the baseline exposure flows through the life time risk model to give us a baseline number of cases. Next OSHA calculated the number of cases estimated to occur after the implementation of the proposed PEL of 0.2 μg/m³. Here OSHA simply takes the number of workers with current average exposure above 0.2 μg/m³ and set their exposure level at 0.2 μg/m³; all exposures for workers exposed below 0.2 μg/m³ stay the same. After adjusting the worker exposure profile in this way, OSHA goes through all the same calculations and obtains a post-standard number of CBD cases. Subtracting estimated post-standard CBD cases from estimated pre-standard CBD cases gives us the number of CBD cases that would be averted due to the proposed change in the PEL.

Based on these methods, OSHA's estimate of benefits associated with the proposed rule does not include benefits associated with current compliance that have already been achieved with regard to the new requirements, or benefits obtained from future compliance with existing beryllium requirements. However, available exposure data indicate that few employees are currently exposed above the existing standard's PEL of 2.0 μg/m³. To achieve consistency with the cost estimation method in chapter V, all employees in the exposure profile that are above 2.0 μg/m³ are assumed to be at the 2.0 μg/m³ level.

There is also a component that applies only to dental labs. OSHA has preliminarily assumed, based on the estimates of higher costs for engineering controls than using substitutes presented in the cost chapter, that rather than incur the costs of compliance with the proposed standard, many dental labs are likely to stop using beryllium-containing materials after the promulgation of the proposed standard.[24] OSHA estimated earlier in this PEA that, for the baseline, only 25 percent of dental lab workers still work with beryllium. OSHA estimates that, if OSHA adopts the proposed rule, 75 percent of the 25 percent still using beryllium will stop working with beryllium; their beryllium exposure level will therefore drop to zero. OSHA estimates that the 75 percent of workers will not be a random sample of the dental lab exposure profile but instead will concentrate among workers who are currently at the highest exposure levels because it would cost more to reduce those higher exposures into compliance with the proposed PEL. Under this judgment OSHA is estimating that the rule would eliminate all cases of CBD in the 75 percent of dental lab workers with the highest exposure levels. As discussed in the sensitivity analysis below, dental labs constitute a significant source of both costs and benefits to the rule (over 40 percent), and the extent to which dental laboratories substitute other materials for beryllium has significant effects on the benefits and costs of the rule. To derive its baseline estimate of cases of CBD in dental laboratories, OSHA (1) estimated baseline cases of CBD using the existing rate of beryllium use in dental labs without a projection of further substitution; (2) estimated cases of CBD with the proposed regulation using an estimate that 75 percent of the dental labs with higher exposure would switch to other materials and thus eliminate exposure to beryllium; and (3) estimated that the turnover rate in the industry is 10 percent. OSHA welcomes comments on all aspects of the analysis of substitution away from beryllium in the dental laboratories sector.

Estimation results for both dental labs and non-dental workplaces appear in the table below.

CBD CASE ESTIMATES, 45-YEAR TOTALS, BASELINE AND WITH PEL OF 0.2 μg/m³

		Current beryllium exposure (μg/m³)						Total
		< 0.1	0.1–0.2	0.2–0.5	0.5–1.0	1.0–2.0	> 2.0	
Baseline	Dental labs	827	636	432	608	155	466	3,124
	Non-dental	5,912	631	738	287	112	214	7,893
	Total	6,739	1,267	1,171	895	267	679	11,017
PEL = 0.2 μg/m³	Dental labs	679	0	0	0	0	0	679
	Non-dental	5,912	631	693	255	98	186	7,774
	Total	6,591	631	693	255	98	186	8,454
Prevented by PEL reduction.	Dental labs	148	636	432	608	155	466	2,444
	Non-dental	0	0	45	32	14	27	119
	Total	148	636	478	640	169	493	2,563

[24] In Chapter V (Costs) of the PEA, OSHA explored the cost of putting in LEV instead of substitution. The Agency costed an enclosure for 2 technicians: The Powder Safe Type A Enclosure, 32 inch wide with HEPA filter, AirClean Systems (2011), which including operating and maintenance, was annualized at $411 per worker. This is significantly higher than the annual cost for substitution of $166 per worker, shown later in this section.

In contrast to this PEL component of the benefits, both the ancillary program benefits calculation and the substitution benefits calculation are relatively simple. Both are percentages of the lifetime-risk-model CBD cases that still occur in the post-standard world. OSHA notes that in the context of existing CBD prevention programs, some ancillary-provision programs similar to those included in OSHA's proposal have eliminated a significant percentage of the remaining CBD cases (discussed later in this chapter). If the ancillary provisions reduce remaining CBD cases by 90 percent for example, and if the estimated baseline contains 120 cases of CBD, and post-standard compliance with a lower PEL reduces the total to 100 cases of CBD, then 90 of those remaining 100 cases of CBD would be averted due to the ancillary programs.

OSHA assumed, based on the clinical experience discussed further below, that approximately 65 percent of CBD cases ultimately result in death. Later in this chapter, OSHA provides a sensitivity analysis of the effects of different values for assuming this percentage at 50 percent and 80 percent on the number of CBD deaths prevented. OSHA welcomes comment on this assumption. OSHA's exposure-response model for lung cancer is based on lung cancer mortality data. Thus, all of the estimated cases of lung cancer in the benefits analysis are cases of premature death from beryllium-related lung cancer.

Finally, in recognition of the uncertainty in this aspect of these models, OSHA presents a ''high'' estimate, a ''low'' estimate, and uses the midpoint of these two as our ''primary'' estimate. The low estimate is simply those CBD fatalities prevented due to everything except the ancillary provisions, *i.e.,* both the reduction in the PEL and the substitution by dental labs. The high estimate includes both of these factors plus all the ancillary benefits calculated at an effectiveness rate of 90 percent in preventing cases of CBD not averted by the reduction of the PEL. The midpoint is the combination of reductions attributed to adopting the proposed PEL, substitution by dental labs, and the ancillary provisions calculated at an effectiveness rate of only 45 percent.

a. Chronic Beryllium Disease

CBD is a respiratory disease in which the body's immune system reacts to the presence of beryllium in the lung, causing a progression of pathological changes including chronic inflammation and tissue scarring. Immunological sensitization to beryllium (BeS) is a precursor that occurs before early-stage CBD. Only sensitized individuals can go on to develop CBD. In early, asymptomatic stages of CBD, small granulomatous lesions and mild inflammation occur in the lungs. As CBD progresses, the capacity and function of the lungs decrease, which eventually affects other organs and bodily functions as well. Over time the spread of lung fibrosis (scarring) and loss of pulmonary function cause symptoms such as: A persistent dry cough, shortness of breath, fatigue, night sweats, chest and join pain, clubbing of fingers due to impaired oxygen exchange, and loss of appetite. In these later stages CBD can also impair the liver, spleen, and kidneys, and cause health effects such as granulomas of the skin and lymph nodes, and *cor pulmonale* (enlargement of the heart). The speed and extent of disease progression may be influenced by the level and duration of exposure, treatment with corticosteroids, and genetics, but these effects are not fully understood.

Corticosteroid therapy, in workers whose beryllium exposure has ceased, has been shown to control inflammation, ease symptoms, and in some cases prevent the development of fibrosis. However, corticosteroid use can have adverse effects, including increased risk of infections; accelerated bone loss or osteoporosis; psychiatric effects such as depression, sleep disturbances, and psychosis; adrenal suppression; ocular effects; glucose intolerance; excessive weight gain; increased risk of cardiovascular disease; and poor wound healing. The effects of CBD, and of common treatments for CBD, are discussed in detail in this preamble at Section V, Health Effects, and Section VIII, Significance of Risk.

OSHA's review of the literature on CBD suggests three broad types of CBD progression (see this preamble at Section V, Health Effects). In the first, individuals progress relatively directly toward death related to CBD. They suffer rapidly advancing disability and their death is significantly premature. Medical intervention is not applied, or if it is, does little to slow the progression of disease. In the second type, individuals live with CBD for an extended period of time. The progression of CBD in these individuals is naturally slow, or may be medically stabilized. They may suffer significant disability, in terms of loss of lung function—and quality of life—and require medical oversight their remaining years. They would be expected to lose some years of normal lifespan. As discussed previously, advanced CBD can involve organs and systems beyond the respiratory system; thus, CBD can contribute to premature death from other causes. Finally, individuals with the third type of CBD progression do not die prematurely from causes related to CBD. The disease is stabilized and may never progress to a debilitating state. These individuals nevertheless may experience some disability or loss of lung function, as well as side effects from medical treatment, and may be affected by the disease in many areas of their lives: Work, recreation, family, etc.[25]

In the analysis that follows, OSHA assumes, based on the clinical experience discussed below, that 35 percent of workers who develop CBD experience the third type of progression and do not die prematurely from CBD. The remaining 65 percent were estimated to die prematurely, whether from rapid disease progression (type 1) or slow (type 2). Although the proportion of CBD patients who die prematurely as a result of the disease is not well understood or documented at this time, OSHA believes this assumption is consistent with the information submitted in response to the RFI. Newman et al. (2003) presented a scenario for what they considered to be the ''typical'' CBD patient:

> We have included an example of a life care plan for a typical clinical case of CBD. In this example, the hypothetical case is diagnosed at age 40 and assumed to live an additional 33.7 years (approximately 5% reduced life expectancy in this model). In this hypothetical example, this individual would be considered to have moderate severity of chronic beryllium disease at the time of initial diagnosis. They require treatment with prednisone and treatment for early cor pulmonale secondary to CBD. They have experienced some, but not all, of the side effects of treatment and only the most common CBD-related health effects.

In short, *most* workers diagnosed with CBD are expected to have shortened life expectancy, even if they do not progress rapidly and directly to death. It should be emphasized that this represents the Agency's best estimate of the mortality related to CBD based upon the current available evidence. As described in Section V, Health Effects, there is a substantial degree of uncertainty as to the prognosis for those contracting CBD, particularly as the relatively less severe

[25] As indicated in the Health Effects section of this preamble: ''It should be noted, however, that treatment with corticosteroids has side-effects of their own that need to be measured against the possibility of progression of disease (Gibson *et al.,* 1996; Zaki *et al.,* 1987). Alternative treatments such as azathiopurine and infliximab, while successful at treating symptoms of CBD, have been demonstrated to have side-effects as well (Pallavicino *et al.,* 2013; Freeman, 2012)''.

cases are likely not to be studied closely for the remainder of their lives.

As mentioned previously, OSHA used the Cullman data set for empirical estimates of beryllium sensitization and CBD prevalence in its exposure response model, which translates beryllium exposure to risk of adverse health endpoints for the purpose of determining the benefits that could be achieved by preventing those adverse health endpoints.

OSHA chose the cumulative exposure quartile data as the basis for this benefits analysis. The choice of cumulative quartiles was based in part on the need to use the cumulative exposure forecast developed in the model, and in part on the fact that in statistically fitted models for CBD, the cumulative exposure tended to fit the CBD data better than other exposure variables. OSHA also chose the quartile model because the outside expert who examined the logistic and proportional hazards models believed statistical modeling of the data set to be unreliable due to its small size. In addition, the proportional hazards model with its dummy variables by year of detection is difficult to interpret for purposes of this section. Of course regression analyses are often useful in empirical analysis. They can be a useful compact representation of a set of data, allow investigations of various variable interactions and possible causal relationships, have added flexibility due to covariate transformations, and under certain conditions can be shown to be statistically ''optimal.'' However, they are only useful when used in the proper setting. The possibility of misspecification of functional form, endogeneity, or incorrect distributional assumptions are just three reasons to be cautious about using regression analyses.

On the other hand, the use of results produced by a quartile analysis as inputs in a benefits assessment implies that the analytic results are being interpreted as evidence of an exposure-response causal relationship. Regression analysis is a more sophisticated approach to estimating causal relationships (or even correlations) than quartile or other quantile analysis, and any data limitations that may apply to a particular regression-based exposure-response estimation also apply to exposure-response estimation conducted with a quartile analysis using the same data set. In this case, OSHA adopted the quartile analysis because the logistic regression analysis yielded extremely high prevalence rates for higher level of exposure over long time periods that some might not find credible. Use of the quartile analysis serves to show that there are significant benefits even without using an extremely high estimate of prevalence for long periods of exposure at high levels. As a check on the quartile model, the Agency performed the same benefits calculation using the logit model estimated by the Agency's outside expert, and these benefit results are presented in a separate OSHA background document (OSHA, 2015b). The difference in benefits between the two models is slight, and there is no qualitative change in final outcomes. The Agency solicits comment on these issues.

(1) Number of CBD Cases Prevented by the Proposed PEL

To examine the effect of simply changing the PEL, including the effect of the standard on some dental labs to discontinue their use of beryllium, OSHA compared the number of CBD-related deaths (mortality) and cases of non-fatal CBD (morbidity) that would occur if workers were exposed for a 45-year working life to PELs of 0.1, 0.2, or 0.5 μg/m³ to the number of cases that would occur at levels of exposure at or below the current PEL. The number of avoided cases over a hypothetical working life of exposure for the current population at a lower PEL is then equal to the difference between the number of cases at levels of exposure at or below the current PEL for that population minus the number of cases at the lower PEL. This approach represents a steady-state comparison based on what would hypothetically happen to workers who received a specific average level of occupational exposure to beryllium during an entire working life. (Chapter VII in the PEA modifies this approach by introducing a model that takes into account the timing of benefits before steady state is reached.)

As indicated in Table IX–11, the Agency estimates that there would be 16,240 cases of beryllium sensitization, from which there would be 11,017, or about 70 percent, progressing to CBD. The Agency arrived at these estimates by using the CBD and BeS prevalence values from the Agency's preliminary risk analysis, the exposure profile at current exposure levels (under an assumption of full, or fixed, compliance with the existing beryllium PEL), and the model outlined in the previous methods of estimation section after a working lifetime of exposure. Applying the prior midpoint estimate, as explained above, that 65 percent of CBD cases cause or contribute to premature death, the Agency predicts a total of 7,161 cases of mortality and 3,856 cases of morbidity from exposure at current levels; this translates, annually, to 165 cases of mortality and 86 cases of morbidity. At the proposed PEL, OSHA's base model estimates that, due to the airborne factor only, a total of 2,563 CBD cases would be avoided from exposure at current levels, including 1,666 cases of mortality and 897 cases of morbidity—or an average of 37 cases of mortality and 20 cases of morbidity annually. OSHA has not estimated the quantitative benefits of sensitization cases avoided.

OSHA requests comment on this analysis, including feedback on the data relied on and the approach and assumptions used. As discussed earlier, based on information submitted in response to the RFI, the Agency estimates that most of the workers with CBD will progress to an early death, even if it comes after retirement, and has quantified those cases prevented. However, given the evolving nature of science and medicine, the Agency invites public comment on the current state of CBD-related mortality.

The proposed standard also includes provisions for medical surveillance and removal. The Agency believes that to the extent the proposal provides medical surveillance sooner and to more workers than would have been the case in the absence of the proposed standard, workers will be more likely to receive appropriate treatment and, where necessary, removal from beryllium exposure. These interventions may lessen the severity of beryllium-related illnesses, and possibly prevent premature death. The Agency requests public comment on this issue.

(2) CBD Cases Prevented by the Ancillary Provisions of the Proposed Standard

The nature of the chronic beryllium disease process should be emphasized. As discussed in this preamble at Section V, Heath Effects, the chronic beryllium disease process involves two steps. First, workers become sensitized to beryllium. In most epidemiological studies of CBD conducted to date, a large percentage of sensitized workers have progressed to CBD. A certain percentage of the population has an elevated risk of this occurring, even at very low exposure levels, and sensitization can occur from dermal as well as inhalation exposure to beryllium. For this reason, the threat of beryllium sensitization and CBD persist to a substantial degree, even at very low levels of airborne beryllium exposure. It is therefore desirable not only to significantly reduce airborne beryllium exposure, but to avoid nearly any source of beryllium exposure, so as to prevent beryllium sensitization.

The analysis presented above accounted only for CBD-prevention benefits associated with the proposed reduction of the PEL, from 2 ug/m³ to 0.2 ug/m³. However, the proposed standard also includes a variety of ancillary provisions—including requirements for respiratory protection, personal protective equipment (PPE), housekeeping procedures, hygiene areas, medical surveillance, medical removal, and training—that the Agency believes would further reduce workers' risk of disease from beryllium exposure. These provisions were described in Chapter I of the PEA and discussed extensively in Section XVIII of this preamble, Summary and Explanation of the Proposed Standard.

The leading manufacturer of beryllium in the U.S., Materion Corporation (Materion), has implemented programs including these types of provisions in several of its plants and has worked with NIOSH to publish peer-reviewed studies of their effectiveness in reducing workers' risk of sensitization and CBD. The Agency used the results of these studies to estimate the health benefits associated with a comprehensive standard for beryllium.

The best available evidence on comprehensive beryllium programs comes from studies of programs introduced at Materion plants in Reading, PA; Tucson, AZ; and Elmore, OH. These studies are discussed in detail in this preamble at Section VI, Preliminary Risk Assessment, and Section VIII, Significance of Risk. All three facilities were in compliance with the current PEL prior to instituting comprehensive programs, and had taken steps to reduce airborne levels of beryllium below the PEL, but their medical surveillance programs continued to identify cases of sensitization and CBD among their workers. Beginning around 2000, these facilities introduced comprehensive beryllium programs that used a combination of engineering controls, dermal and respiratory PPE, and stringent housekeeping measures to reduce workers' dermal exposures and airborne exposures. These comprehensive beryllium programs have substantially lowered the risk of sensitization among workers. At the times that studies of the programs were published, insufficient follow-up time had elapsed to report directly on the results for CBD. However, since only sensitized workers can develop CBD, reduction of sensitization risk necessarily reduces CBD risk as well.

In the Reading, PA copper beryllium plant, full-shift airborne exposures in all jobs were reduced to a median of 0.1 ug/m³ or below, and dermal protection was required for production-area workers, beginning in 2000–2001 (Thomas et al., 2009). In 2002, the process with the highest exposures (with a median of 0.1 ug/m³) was enclosed, and workers involved in that process were required to use respiratory protection. Among 45 workers hired after the enclosure was built and respiratory protection instituted, one was found to be sensitized (2.2 percent). This is more than an 80 percent reduction in sensitization from a previous group of 43 workers hired after 1992, 11.5 percent of whom had been sensitized by the time of testing in 2000.

In the Tucson beryllium ceramics plant, respiratory and skin protection was instituted for all workers in production areas in 2000 (Cummings *et al.,* 2007). BeLPT testing in 2000–2004 showed that only 1 (1 percent) of 97 workers hired during that time period was sensitized to beryllium. This is a 90 percent reduction from the prevalence of sensitization in a 1998 BeLPT screening, which found that 6 (9 percent) of 69 workers hired after 1992 were sensitized.

In the Elmore, OH beryllium production and processing facility, all new workers were required to wear loose-fitting powered air-purifying respirators (PAPRs) in manufacturing buildings, beginning in 1999 (Bailey *et al.,* 2010). Skin protection became part of the protection program for new workers in 2000, and glove use was required in production areas and for handling work boots, beginning in 2001. Bailey *et al.* (2010) found that 23 (8.9 percent) of 258 workers hired between 1993 and 1999, before institution of respiratory and dermal protection, were sensitized to beryllium. The prevalence of sensitization among the 290 workers who were hired after the respiratory protection and PPE measures were put in place was about 2 percent, close to an 80 percent reduction in beryllium sensitization.

In a response to OSHA's 2002 Request for Information (RFI), Lee Newman *et al.* from National Jewish Medical and Research Center (NJMRC) summarized results of beryllium program effectiveness from several sources. Said Dr. Newman (in response to Question #33):

Q. 33. What are the potential impacts of reducing occupational exposures to beryllium in terms of costs of controls, costs for training, benefits from reduction in the number or severity of illnesses, effects on revenue and profit, changes in worker productivity, or any other impact measures than you can identify?

A: From experience in [the Tucson, AZ facility discussed above], one can infer that approximately 90 percent of beryllium sensitization can be eliminated. Furthermore, the preliminary data would suggest that potentially 100 percent of CBD can be eliminated with appropriate workplace control measures.

In a study by Kelleher 2001, Martyny 2000, Newman, JOEM 2001) in a plant that previously had rates of sensitization as high as 9.7 percent, the data suggests that when lifetime weighted average exposures were below 0.02 µg per cu meter that the rate of sensitization fell to zero and the rate of CBD fell to zero as well.

In an unpublished study, we have been conducting serial surveillance including testing new hires in a precision machining shop that handles beryllium and beryllium alloys in the Southeast United States. At the time of the first screening with the blood BeLPT of people tested within the first year of hire, we had a rate of 6.7 percent (4/60) sensitization and with 50 percent of these individuals showing CBD at the time of initial clinical evaluation. At that time, the median exposures in the machining areas of the plant was 0.47 µg per cu meter. Subsequently, efforts were made to reduce exposures, further educate the workforce, and increase monitoring of exposure in the plant. Ongoing testing of newly hired workers within the first year of hire demonstrated an incremental decline in the rate of sensitization and in the rate of CBD. For example, at the time of most recent testing when the median airborne exposures in the machining shop were 0.13 µg per cu meter, the percentage of newly hired workers found to have beryllium sensitization or CBD was now 0 percent (0/55). Notably, we also saw an incremental decline in the percentage of longer term workers being detected with sensitization and disease across this time period of exposure reduction and improved hygiene practices.

Thus, in calculating the potential economic benefit, it's reasonable to work with the assumption that with appropriate efforts to control exposures in the work place, rates of sensitization can be reduced by over 90 percent. (NJMRC, RFI Ex. 6–20)

OSHA has reviewed these papers and is in agreement with Dr. Newman's testimony. OSHA judges Dr. Newman's estimate to be an upper bound of the effectiveness of ancillary programs and examined the results of using Dr. Newman's estimate that beryllium ancillary programs can reduce BeS by 90 percent, and potentially eliminate CBD where sensitization is reduced, because CBD can only occur where there is sensitization. OSHA applied this 90 percent reduction factor to all cases of CBD remaining after application of the reductions due to lowering the PEL alone. OSHA applied this reduction broadly because the proposed standard would require housekeeping and PPE related to skin exposure (18,000 of

28,000 employees will need PPE because of possible skin exposure) to apply to all or most employees likely to come in contact with beryllium and not just those with exposure above the action level. Table IX–11 shows that there are 11,017 baseline cases of CBD and that the proposed PEL of 0.2 μg/m^3 would prevent 2,563 cases through airborne prevention alone. The remaining number of cases of CBD is then 8,454 (11,017 minus 2,563). If OSHA applies the full ninety percent reduction factor to account for prevention of skin exposure (''non-airborne'' protections), then 7,609 (90 percent of 8,454 cases) additional cases of CBD would be prevented.

The Agency recognizes that there are significant differences between the comprehensive programs discussed above and the proposed standard. While the proposed standard includes many of the same elements, it is generally less stringent. For example, the proposed standard's requirements for respiratory protection and PPE are narrower, and many provisions of the standard apply only to workers exposed above the proposed TWA PEL or STEL. However, many provisions, such as housekeeping and beryllium work areas, apply to all employers covered by the proposed standard. To account for these differences, OSHA has provided a range of benefits estimates (shown in Table IX–11), first, assuming that there are no ancillary provisions to the standard, and, second, assuming that the comprehensive standard achieves the full 90-percent reduction in risk documented in existing programs. The Agency is taking the midpoint of these two numbers as its main estimate of the benefits of avoided CBD due to the ancillary provisions of the proposed standard. The results in Table IX–11 suggest that approximately 60 percent of the beryllium sensitization cases and the CBD cases avoided would be attributable to the ancillary provisions of the standard. OSHA solicits comment on all aspects of this approach to analyzing ancillary provisions and solicits additional data that might serve to make more accurate estimates of the effects of ancillary provisions. OSHA is interested in the extent of the effects of ancillary provisions and whether these apply to all exposed employees or only those exposed above or below a given exposure level.

(3) Morbidity Only Cases

As previously indicated, the Agency does not believe that all CBD cases will ultimately result in premature death. While currently strong empirical data on this are lacking, the Agency estimates that approximately 35 percent of cases would not ultimately be fatal, but would result in some pain and suffering related to having CBD, and possible side effects from steroid treatment, as well as the dread of not knowing whether the disease will ultimately lead to premature death. These would be described as ''mild'' cases of CBD relative to the others. These are the residual cases of CBD after cases with premature mortality have been counted. As indicated in Table IX–11, the Agency estimates the standard will prevent 2,228 such cases (midpoint) over 45 years, or an estimated 50 cases annually.

b. Lung Cancer

In addition to the Agency's determinations with respect to the risk of chronic beryllium disease, the Agency has preliminarily determined that chronic beryllium exposure at the current PEL can lead to a significantly elevated risk of (fatal) lung cancer. OSHA used the estimation methodology outlined at the beginning of this section. However, unlike with chronic beryllium disease, the underlying data were based on incidence of lung cancer and thus there was no need to address the possible limitations of prevalence data. The Agency also used lifetime excess risk estimates of lung cancer mortality, presented in Table VI–20 in Section VI of this preamble, Preliminary Risk Assessment, to estimate the benefits of avoided lung cancer mortality. The lung cancer risk estimates are derived from one of the best-fitting models in a recent, high-quality NIOSH lung cancer study, and are based on average exposure levels. The estimates of excess lifetime risk of lung cancer were taken from the line in Table VI–20 in the risk assessment labeled PWL (piecewise log-linear) not including professional and asbestos workers. This model avoids possible confounding from asbestos exposure and reduces the potential for confounding due to smoking, as smoking rates and beryllium exposures can be correlated via professional worker status. Of the three estimates in the NIOSH study that excluded professional workers and those with asbestos exposure, this model was chosen because it was at the midpoint of risk results.

Table IX–11 shows the number of avoided fatal lung cancers for PELs of 0.2 μg/m^3, 0.1 μg/m^3, and 0.5 μg/m^3. At the proposed PEL of 0.2 μg/m^3, an estimated 180 lung cancers would be prevented over the lifetime of the current worker population. This is the equivalent of 4.0 cases avoided annually, given a 45-year working life of exposure.

Combining the two major fatal health endpoints—for lung cancer and CBD-related mortality—OSHA estimates that the proposed PEL would prevent between 1,846 and 6,791 premature fatalities over the lifetime of the current worker population, with a midpoint estimate of 4,318 fatalities prevented. This is the equivalent of between 41 and 151 premature fatalities avoided annually, with a midpoint estimate of 96 premature fatalities avoided annually, given a 45-year working life of exposure.

Note that the Agency based its estimates of reductions in the number of beryllium-related diseases over a working life of constant exposure for workers who are employed in a beryllium-exposed occupation for their entire working lives, from ages 20 to 65. In other words, workers are assumed not to enter or exit jobs with beryllium exposure mid-career or to switch to other exposure groups during their working lives. While the Agency is legally obligated to examine the effect of exposures from a working lifetime of exposure and set its standard accordingly,[26] in an alternative analysis purely for informational purposes, using the same underlying risk model for CBD, the Agency examined, in Chapter VII of the PEA, the effect of assuming that workers are exposed for a maximum of only 25 working years, as opposed to the 45 years assumed in the main analysis. While all workers are assumed to have less cumulative exposure under the 25-years-of-exposure assumption, the effective exposed population over time is proportionately increased.

A comparison of exposures over a maximum of 25 working years versus over a potentially 45-year working life shows variations in the number of estimated prevented cases by health outcome. For chronic beryllium disease, there is a substantial increase in the number of estimated baseline and prevented cases if one assumes that the typical maximum exposure period is 25 years, as opposed to 45. This reflects the

[26] Section (6)(b)(5) of the OSH Act states: ''The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' Given that it is necessary for OSHA to reach a determination of significant risk over a working life, it is a logical extension to estimate what this translates into in terms of estimated benefits for the affected population over the same period.

relatively flat CBD risk function within the relevant exposure range, given varying levels of airborne beryllium exposure—shortening the average tenure and increasing the exposed population over time translates into larger total numbers of people sensitized to beryllium. This, in turn, results in larger populations of individuals contracting CBD. Since the lung cancer model itself is based on average, as opposed to cumulative, exposure, it is not adaptable to estimate exposures over a shorter period of time. As a practical matter, however, over 90 percent of illness and mortality attributable to beryllium exposure in this analysis comes from CBD.

Overall, the 45-year-maximum-working-life assumption yields smaller estimates of the number of cases of avoided fatalities and illnesses than does the maximum-25-years-of-exposure assumption. For example, the midpoint estimates of the number of avoided fatalities and illnesses related to CBD under the proposed PEL of 0.2 μg/m³ increases from 92 and 50, respectively, under the maximum-45-year-working-life assumption to 145 and 78, respectively, under the maximum-25-year-working-life assumption—or approximately a 57 to 58 percent increase.[27]

[27] Technically, this analysis assumes that workers receive 25 years' worth of beryllium exposure, but that they receive it over 45 working years, as is assumed by the risk models in the risk assessment. It also accounts for the turnover implied by 25, as opposed to 45, years of work. However, it is possible that an alternate analysis, which accounts for the larger number of post-exposure worker-years implied by workers departing their jobs before the end of their working lifetime, might find even larger health effects for workers receiving 25 years' worth of beryllium exposure.

Table IX-11

Prevented Mortality and Morbidity by PEL Option (45-Year Working Life Case)

(Quartile Model)

Airborne Factor Only

	Baseline Total Cases	PEL Option (μg/m³) Total Number of Avoided Cases			Baseline Annual Cases	PEL Option (μg/m³) Annual Number of Avoided Cases		
		0.1	0.2	0.5		0.1	0.2	0.5
Total Cases								
Be S	16,240	3,826	3,594	3,503	361	85.0	79.9	77.9
CBD	11,017	2,763	2,563	2,463	245	61.4	56.9	54.7
Mortality								
Lung Cancer	279	192	180	163	6.2	4.3	4.0	3.6
CBD-Related	7,161	1,796	1,666	1,601	159	39.9	37.0	35.6
Total Mortality	7,440	1,988	1,846	1,764	165	44.2	41.0	39.2
Morbidity	3,856	967	897	862	86	21.5	19.9	19.2

Non-Airborne Factor Included

	Baseline Total Cases	PEL Option (μg/m³) Total Number of Avoided Cases			Baseline Annual Cases	PEL Option (μg/m³) Annual Number of Avoided Cases		
		0.1	0.2	0.5		0.1	0.2	0.5
Total Cases								
Be S	16,240	14,998	14,975	9,235	361	333.3	332.8	205.2
CBD	11,017	10,191	10,171	6,312	245	226.5	226.0	140.3
Mortality								
Lung Cancer	279	192	180	163	6	4.3	4.0	3.6
CBD-Related	7,161	6,624	6,611	4,103	159	147.2	146.9	91.2
Total Mortality	7,440	6,816	6,791	4,266	165	151.5	150.9	94.8
Morbidity	3,856	3,567	3,560	2,209	86	79.3	79.1	49.1

Midpoint Estimates

	Baseline Total Cases	PEL Option (μg/m³) Total Number of Avoided Cases			Baseline Annual Cases	PEL Option (μg/m³) Annual Number of Avoided Cases		
		0.1	0.2	0.5		0.1	0.2	0.5
Total Cases								
Be S - Total	16,240	9,412	9,284	6,369	361	209.2	206.3	141.5
CBD	11,017	6,477	6,367	4,387	245	143.9	141.5	97.5
Mortality								
Lung Cancer	279	192	180	163	6	4.3	4.0	3.6
CBD-Related	7,161	4,210	4,139	2,852	159	93.6	92.0	63.4
Total Mortality	7,440	4,402	4,318	3,015	165	97.8	96.0	67.0
Morbidity	3,856	2,267	2,228	1,536	86	50.4	49.5	34.1

Source: Office of Regulatory Analysis, Directorate of Standards and Guidance

Step 2—Estimating the Stream of Benefits Over Time

Risk assessments in the occupational environment are generally designed to estimate the risk of an occupationally related illness over the course of an individual worker's lifetime. As demonstrated previously in this section, the current occupational exposure profile for a particular substance for the current cohort of workers can be matched up against the expected profile after the proposed standard takes effect, creating a "steady state" estimate of benefits. However, in order to annualize the benefits for the period of time after the beryllium rule takes effect, it is necessary to create a timeline of benefits for an entire active workforce over that period.

While there are various approaches that could be taken for modeling the workforce, there seem to be two polar extremes. At one extreme, one could assume that none of the benefits occur until after the worker retires, or at least 45 years in the future. In the case of lung cancer, that period would effectively be at least 55 years, since the 45 years of exposure must be added to a 10-year latency period during which it is assumed that lung cancer does not develop.[28] At the other extreme, one could assume that the benefits occur immediately, or at least immediately after a designated lag. However, based on the various risk models discussed in this preamble at Section VI, Risk Assessment, which reflect real-world experience with development of disease over an extended period of time, it appears that the actual pattern occurs at some point between these two extremes.

At first glance, the simplest intermediate approach would be to follow the pattern of the risk assessments, which are based in part on life tables, and observe that typically the risk of the illness grows gradually over the course of a working life and into retirement. Thus, the older the person exposed to beryllium, the higher the odds that that person will have developed the disease.

However, while this is a good working model for an individual exposed over a working life, it is not very descriptive of the effect of lowering exposures for an entire working population. In the latter case, in order to estimate the benefits of the standard over time, one has to consider that workers currently being exposed to beryllium are going to vary considerably in age. Since the calculated health risks from beryllium exposure depend on a worker's cumulative exposure over a working lifetime, the overall benefits of the proposed standard will phase in over several decades, as the cumulative exposure gradually falls for all age groups, until those now entering the workforce reach retirement and the annual stream of beryllium-related illnesses reaches a new, significantly lowered "steady state." [29] That said, the near-term impact of the proposed rule estimated for those workers with similar current levels of cumulative exposure will be greater for workers who are now middle-aged or older. This conclusion follows in part from the structure of the relative risk model used for lung cancer in this analysis and the fact that the background mortality rates for lung cancer increase with age.

In order to characterize the magnitude of benefits before the steady state is reached, OSHA created a linear phase-in model to reflect the potential timing of benefits. Specifically, OSHA estimated that, for all non-cancer cases, while the number of cases of beryllium-related disease would gradually decline as a result of the proposed rule, they would not reach the steady-state level until 45 years had passed. The reduction in cases estimated to occur in any given year in the future was estimated to be equal to the steady-state reduction (the number of cases in the baseline minus the number of cases in the new steady state) times the ratio of the number of years since the standard was implemented and a working life of 45 years. Expressed mathematically:

$$N_t = (C - S) \times (t/45),$$

Where N_t is the number of non-malignant beryllium-related diseases avoided in year t; C is the current annual number of non-malignant beryllium-related diseases; S is the steady-state annual number of non-malignant beryllium-related diseases; and t represents the number of years after the proposed standard takes effect, with $t \leq 45$.

In the case of lung cancer, the function representing the decline in the number of beryllium-related cases as a result of the proposed rule is similar, but there would be a 10-year lag before any reduction in cancer cases would be achieved. Expressed mathematically, for lung cancer:

$$L_t = (C_m - S_m) \times ((t - 10)/45)),$$

Where $10 \leq t \leq 55$ and L_t is the number of lung cancer cases avoided in year t as a result of the proposed rule; C_m is the current annual number of beryllium-related lung cancers; and S_m is the steady-state annual number of beryllium-related lung cancers.

This model was extended to 60 years for all the health effects previously discussed in order to incorporate the 10-year lag, in the case of lung cancer, and a maximum-45-year working life, as well as to capture some occupationally-related disease that manifests itself after retirement.[30] As a practical matter, however, there is no overriding reason for stopping the benefits analysis at 60 years. An internal analysis by OSHA indicated that, both in terms of cases prevented, and even with regard to monetized benefits, particularly when lower discount rates are used, the estimated benefits of the standard are larger on an annualized basis if the analysis extends further into the future. The Agency welcomes comment on the merit of extending the benefits analysis beyond the 60-years analyzed in the PEA.

In order to compare costs to benefits, OSHA assumes that economic conditions remain constant and that annualized costs—and the underlying costs—will repeat for the entire 60-year time horizon used for the benefits analysis (as discussed in Chapter V of the PEA). OSHA welcomes comments on the assumption for both the benefit and cost analysis that economic conditions remain constant for sixty years. OSHA is particularly interested in what assumptions and time horizon should be used instead and why.

Separating the Timing of Mortality

In previous sections, OSHA modeled the timing and incidence of morbidity. OSHA's benefit estimates are based on an underlying CBD-related mortality rate of 65 percent. However, this mortality is not simultaneous with the onset of morbidity. Although mortality from CBD has not been well studied, OSHA believes, based on discussions with experienced clinicians, that the average lag for a larger population has a range of 10 to 30 years between morbidity and mortality. The Agency's review of Workers Compensation data related to beryllium exposure from the Office of Worker Compensation Programs (OWCP) Division of Energy Employees Occupational Illness Compensation is consistent with this range. Hence, for the purposes of this

[28] This assumption is consistent with the 10-year lag incorporated in the lung cancer risk models used in OSHA's preliminary risk assessment.

[29] Technically, the RA lung cancer model is based on average exposure, Nonetheless, as noted in the RA, the underlying studies found lung cancer to be significantly related to cumulative exposure. Particularly since the large majority of the benefits are related to CBD, the Agency considers this fairly descriptive of the overall phase-in of benefits from the standard.

[30] The left-hand columns in the tables in Appendix VII–A of the PEA provide estimates using this model of the stream of prevented fatalities and illnesses due to the proposed beryllium rule.

proposal, OSHA estimates that mortality occurs on average 20 years after the onset of CBD morbidity. Thus, for example, the prevented deaths that would have occurred in year 21 after the promulgation of the rule are associated with the CBD morbidity cases prevented in year one. OSHA requests comment on this estimate and range.

The Agency invites comment on each of these elements of the analysis, particularly on the estimates of the expected life expectancy of a patient with CBD.

Step 3—Monetizing the Benefits of the Proposed Rule

To estimate the monetary value of the reductions in the number of beryllium-related fatalities, OSHA relied, as OMB recommends, on estimates developed from the willingness of affected individuals to pay to avoid a marginal increase in the risk of fatality. While a willingness-to-pay (WTP) approach clearly has theoretical merit, it should be noted that an *individual's* willingness to pay to reduce the risk of fatality would tend to underestimate the total willingness to pay, which would include the willingness of others—particularly the immediate family—to pay to reduce that individual's risk of fatality.

For estimates using the willingness-to-pay concept, OSHA relied on existing studies of the imputed value of fatalities avoided based on the theory of compensating wage differentials in the labor market. These studies rely on certain critical assumptions for their accuracy, particularly that workers understand the risks to which they are exposed and that workers have legitimate choices between high- and low-risk jobs. These assumptions are far from obviously met in actual labor markets.[31] A number of academic studies, as summarized in Viscusi & Aldy (2003), have shown a correlation between higher job risk and higher wages, suggesting that employees demand monetary compensation in return for a greater risk of injury or fatality. The estimated trade-off between lower wages and marginal reductions in fatal occupational risk—that is, workers' willingness to pay for marginal reductions in such risk—yields an imputed value of an avoided fatality: The willingness-to-pay amount for a reduction in risk divided by the reduction in risk.[32]

OSHA has used this approach in many recent proposed and final rules. Although this approach has been criticized for yielding results that are less than statistically robust (see, for example, Hintermann, Alberini and Markandya, 2010), a more recent WTP analysis, by Kniesner *et al.* (2012), of the trade-off between fatal job risks and wages, using panel data, seems to address many of the earlier econometric criticisms by controlling for measurement error, endogeneity, and heterogeneity. In conclusion, the Agency views the WTP approach as the best available and will rely on it to monetize benefits.[33] OSHA welcomes comments on the use of willingness-to-pay measures and estimates based on compensating wage differentials.

Viscusi & Aldy (2003) conducted a meta-analysis of studies in the economics literature that use a willingness-to-pay methodology to estimate the imputed value of life-saving programs and found that each fatality avoided was valued at approximately $7 million in 2000 dollars. Using the GDP Deflator (U.S. BEA, 2010), this $7 million base number in 2000 dollars yields an estimate of $8.7 million in 2010 dollars for each fatality avoided.[34]

In addition to the benefits that are based on the implicit value of fatalities avoided, workers also place an implicit value on occupational injuries or illnesses avoided, which reflect their willingness to pay to avoid monetary costs (for medical expenses and lost wages) and quality-of-life losses as a result of occupational illness. Chronic beryllium disease and lung cancer can adversely affect individuals for years, or even decades, in non-fatal cases, or before ultimately proving fatal. Because measures of the benefits of avoiding these illnesses are rare and difficult to find, OSHA has included a range based on a variety of estimation methods.

For both CBD and lung cancer, there is typically some permanent loss of lung function and disability, on-going medical treatments, side effects of medicines, and major impacts on one's ability to work, marry, enjoy family life, and quality of life.

While diagnosis with CBD is evidence of material impairment of health, placing a precise monetary value on this condition is difficult, in part because the severity of symptoms may vary significantly among individuals. For that reason, for this preliminary analysis, the Agency employed a broad range of valuation, which should encompass the range of severity these individuals may encounter.

Using the willingness-to-pay approach, discussed in the context of the imputed value of fatalities avoided, OSHA has estimated a range in valuations (updated and reported in 2010 dollars) that runs from approximately $62,000 per case—which reflects estimates developed by Viscusi and Aldy (2003), based on a series of studies primarily describing simple accidents—to upwards of $5 million per case—which reflects work developed by Magat, Viscusi, and Huber (1996) for non-fatal cancer. The latter number is based on an approach that places a willingness-to-pay value to avoid serious illness that is calibrated relative to the value of an avoided fatality. OSHA previously used this approach in the Preliminary Economic Analysis (PEA) supporting its respirable crystalline silica proposal (2013) and in the Final Economic Analysis (FEA) supporting its hexavalent chromium final rule (2006), and EPA (2003) used this approach in its Stage 2 Disinfection and Disinfection Byproducts Rule concerning regulation of primary drinking water. Based on Magat, Viscusi, and Huber (1996), EPA used studies on the willingness to pay to avoid nonfatal lymphoma and chronic bronchitis as a basis for valuing a case of nonfatal cancer at 58.3 percent of the value of a fatal cancer. OSHA's estimate of $5 million for an avoided case of non-fatal cancer is based on this 58.3 percent figure.

The Agency believes this range of estimates, between $62,000 and $5 million, is descriptive of the value of preventing morbidity associated with moderate to severe CBD that ultimately results in premature death.[35]

[31] On the former assumption, see the discussion in Chapter II of the PEA on imperfect information. On the latter, see, for example, the discussion of wage compensation for risk for union versus nonunion workers in Dorman and Hagstrom (1998).

[32] For example, if workers are willing to pay $90 each for a 1/100,000 reduction in the probability of dying on the job, then the imputed value of an avoided fatality would be $90 divided by 1/100,000, or $9,000,000. Another way to consider this result would be to assume that 100,000 workers made this trade-off. On average, one life would be saved at a cost of $9,000,000.

[33] Note that, consistent with the economics literature, these estimates would be for reducing the risk of an acute (immediate) fatality. They do not include an individual's willingness to pay to avoid a higher risk of illness prior to fatality, which is separately estimated in the following section.

[34] An alternative approach to valuing an avoided fatality is to monetize, for each year that a life is extended, an estimate from the economics literature of the value of that statistical life-year (VSLY). See, for instance, Aldy and Viscusi (2007) for discussion of VSLY theory and FDA (2003), pp. 41488–9, for an application of VSLY in rulemaking. OSHA has not investigated this approach, but welcomes comment on the issue.

[35] There are several benchmarks for valuation of health impairment due to beryllium exposure, using

Continued

While the Agency has estimated that 65 percent of CBD cases will result in premature mortality, the Agency has also estimated that approximately 35 percent of CBD cases will not result in premature mortality. However, the Agency acknowledges that it is possible there have been new developments in medicine and industrial hygiene related to the benefits of early detection, medical intervention, and greater control of exposure achieved within the past decade. For that reason, as elsewhere, the Agency requests comment on these issues.

Also not clear are the negative effects of the illness in terms of lost productivity, medical costs, and potential side-effects of a lifetime of immunosuppressive medication. Nonetheless, the Agency is assigning a valuation of $62,000 per case, to reflect the WTP value of a prevented injury not estimated to precede premature mortality. The Agency believes this is conservative, in part because, with any given case of CBD, the outcome is not known in advance, certainly not at the point of discovery; indeed much of the psychic value of preventing the cases may come from removing the threat of premature mortality. In addition, as previously noted, some of these cases could involve relatively severe forms of CBD where the worker died of other causes; however, in those cases, the duration of the disease would be shortened. While beryllium sensitization is a critical precursor of CBD, this preliminary analysis does not attempt to assign a separate value to sensitization itself.

Particularly given the uncertainties in valuation on these questions, the Agency is interested in public input on the issue of valuing the cost to society of morbidity associated with CBD, both in cases preceding mortality, and those that may not result in premature mortality. The Agency is also interested in comments on whether it is appropriate to assign a separate valuation to prevented sensitization cases in their own right, and if so, how such cases should be valued.

a. Summary of Monetized Benefits

Table IX–12 presents the estimated annualized (over 60 years, using a 0 percent discount rate) benefits from each of these components of the valuation, and the range of estimates, based on uncertainty of the prevention factor (*i.e.,* the estimated range of prevented cases, depending on how large an impact the rule has on cases beyond an airborne-only effect), and the range of uncertainty regarding valuation of morbidity. (Mid-point estimates of the undiscounted benefits for each of the first 60 years are provided in the middle columns of Table VII–A–1 in Appendix VII–A at the end of Chapter VII in the PEA. The estimates by year reach a peak of $3.5 billion in the 60th year. Note that, by using a 60-year time-period, OSHA is not including any monetized fatality benefits associated with reduced worker CBD cases originating after year 40 because the 20-year lag takes these CBD fatalities beyond the 60-year time horizon. To this extent, OSHA will have underestimated benefits.)

As shown in Table IX–12, the full range of monetized benefits, undiscounted, for the proposed PEL of 0.2 μg/m^3 runs from $291 million annually, in the case of the lowest estimate of prevented cases of CBD, and the lowest valuation for morbidity, up to $2.1 billion annually, for the highest of both. Note that the value of total benefits is more sensitive to the prevention factor used (ranging from $430 million to $1.6 billion, given estimates at the midpoint of the morbidity valuation) than to the valuation of morbidity (ranging from $666 million to $1.3 billion, given estimates at the midpoint of prevention factor).

Also, the analysis illustrates that most of the morbidity benefits are related to CBD and lung cancer cases that are ultimately fatal. At the valuation and case frequency midpoint, $663 million in benefits are related to mortality, $226 million are related to morbidity preceding mortality, and $4.3 million are related to morbidity not preceding mortality.

a variety of techniques, which provide a number of mid-range estimates between OSHA's high and low estimates. For a fuller discussion of these benchmarks, see Chapter VII of the PEA.

TABLE IX-12

Estimated Annualized Undiscounted Monetized Benefits of the Beryllium Proposal for Morbidity and Mortality

PEL	0.1 μg/m³			0.2 μg/m³			0.5 μg/m³		
	Valuation			Valuation			Valuation		
	Low	Midpoint	High	Low	Midpoint	High	Low	Midpoint	High
Cases									
Fatalities - Total									
Low	$308,027,593	$308,027,593	$308,027,593	$285,909,109	$285,909,109	$285,909,109	$272,760,749	$272,760,749	$272,760,749
Midpoint	$666,610,424	$666,610,424	$666,610,424	$653,373,439	$653,373,439	$653,373,439	$458,581,095	$458,581,095	$458,581,095
High	$1,025,193,255	$1,025,193,255	$1,025,193,255	$1,020,660,530	$1,020,660,530	$1,020,660,530	$644,401,440	$644,401,440	$644,401,440
Morbidity Preceding Mortality - CBD and lung cancer deaths									
Low	$3,765,360	$153,711,707	$303,658,053	$3,495,142	$142,680,735	$281,866,327	$3,343,232	$136,479,355	$269,615,478
Midpoint	$8,431,448	$344,193,474	$679,955,500	$8,274,496	$337,786,267	$667,298,039	$5,761,234	$235,188,453	$464,615,672
High	$13,097,537	$534,675,242	$1,056,252,947	$13,053,849	$532,891,800	$1,052,729,751	$8,179,237	$333,897,551	$659,615,865
Morbidity Not Preceding Mortality									
Low	$1,869,166	$1,869,166	$1,869,166	$1,733,636	$1,733,636	$1,733,636	$1,665,847	$1,665,847	$1,665,847
Midpoint	$4,381,675	$4,381,675	$4,381,675	$4,307,133	$4,307,133	$4,307,133	$2,967,849	$2,967,849	$2,967,849
High	$7,320,735	$7,320,735	$7,320,735	$7,306,343	$7,306,343	$7,306,343	$4,321,800	$4,321,800	$4,321,800
TOTAL									
Low	$313,662,119	$463,608,465	$613,554,812	$291,137,887	$430,323,479	$569,509,072	$277,769,829	$410,905,952	$544,042,075
Midpoint	$679,423,547	$1,015,185,573	$1,350,947,599	$665,955,068	$995,466,840	$1,324,978,612	$467,310,178	$696,737,396	$926,164,615
High	$1,045,611,526	$1,567,189,232	$2,088,766,937	$1,041,020,722	$1,560,858,673	$2,080,696,625	$656,902,477	$982,620,791	$1,308,339,106

Source: Office of Regulatory Analysis, Directorate of Standards & Guidance

b. Adjustment of WTP Estimates to Reflect Rising Real Income Over Time

OSHA's estimates of the monetized benefits of the proposed rule are based on the imputed value of each avoided fatality and each avoided beryllium-related disease. As previously discussed, these, in turn, are derived from a worker's willingness to pay to avoid a fatality (with an imputed value per fatality avoided of $8.7 million in 2010 dollars) and to avoid a beryllium-related disease (with an imputed value per disease avoided of between $62,000 and $5 million in 2010 dollars). To this point, these imputed values have been assumed to remain constant over time. However, two related factors suggest that these values will tend to increase over time.

First, economic theory indicates that the value of reducing life-threatening and health-threatening risks—and correspondingly the willingness of individuals to pay to reduce these risks—will increase as real per capita income increases. With increased income, an individual's health and life becomes more valuable relative to other goods because, unlike other goods, they are without close substitutes and in relatively fixed or limited supply. Expressed differently, as income increases, consumption will increase but the marginal utility of consumption will decrease. In contrast, added years of life (in good health) is not subject to the same type of diminishing returns—implying that an effective way to increase lifetime utility is by extending one's life and maintaining one's good health (Hall and Jones, 2007).

Second, real per capita income has broadly been increasing throughout U.S. history, including recent periods. For example, for the period 1950 through 2000, real per capita income grew at an average rate of 2.31 percent a year (Hall and Jones, 2007),[36] although real per capita income for the recent 25-year period 1983 through 2008 grew at an average rate of only 1.3 percent a year (U.S. Census Bureau, 2010). More important is the fact that real U.S. per capita income is projected to grow significantly in future years. For example, the Annual Energy Outlook (AEO) projections, prepared by the Energy Information Administration (EIA) in the Department of Energy (DOE), show an average annual growth rate of per capita income in the United States of 2.7 percent for the period 2011–2035.[37] The U.S. Environmental Protection Agency prepared its economic analysis of the Clean Air Act using the AEO projections. OSHA believes that it is reasonable to use the same AEO projections employed by DOE and EPA, and correspondingly projects that per capita income in the United States will increase by 2.7 percent a year.

On the basis of the predicted increase in real per capita income in the United States over time and the expected resulting increase in the value of avoided fatalities and diseases, OSHA has adjusted its estimates of the benefits of the proposed rule to reflect the anticipated increase in their value over time. This type of adjustment has been recognized by OMB (2003), supported by EPA's Science Advisory Board (EPA, 2000), and applied by EPA [38]. OSHA proposes to accomplish this adjustment by modifying benefits in year i from $[B_i]$ to $[B_i * (1 + k)^i]$, where ''k'' is the estimated annual increase in the magnitude of the benefits of the proposed rule.

What remains is to estimate a value for ''k'' with which to increase benefits annually in response to annual increases in real per capita income, where ''k'' is equal to ''(1+g) * (η)'', ''g'' is the expected annual percentage increase in real per capita income, and ''η'' is the income elasticity of the value of a statistical life. Probably the most direct evidence of the value of ''k'' comes from the work of Costa and Kahn (2003, 2004). They estimate repeated labor market compensating wage differentials from cross-sectional hedonic regressions using census and fatality data from the Bureau of Labor Statistics for 1940, 1950, 1960, 1970, and 1980. In addition, with the imputed income elasticity of the value of life on per capita GNP of 1.7 derived from the 1940–1980 data, they then predict the value of an avoided fatality in 1900, 1920, and 2000. Given the change in the value of an avoided fatality over time, it is possible to estimate a value of ''k'' of 3.4 percent a year from 1900–2000; of 4.3 percent a year from 1940–1980; and of 2.5 percent a year from 1980–2000.

Other, more indirect evidence comes from estimates in the economics literature of ''η'', the income elasticity of the value of a statistical life. Viscusi and Aldy (2003) performed a meta-analysis on 0.2 wage-risk studies and concluded that the confidence interval upper bound on the income elasticity did not exceed 1.0 and that the point estimates across a variety of model specifications ranged between 0.5 and 0.6. Applied to a long-term increase in per capita income of about 2.7 percent a year, this would suggest a value of ''k'' of about 1.5 percent a year.

More recently, Kniesner, Viscusi, and Ziliak (2010), using panel data quintile regressions, developed an estimate of the overall income elasticity of the value of a statistical life of 1.44. Applied to a long-term increase in per capita income of about 2.7 percent a year, this would suggest a value of ''k'' of about 3.9 percent a year.

Based on the preceding discussion of these three approaches for estimating the annual increase in the value of the benefits of the proposed rule and the fact that the projected increase in real per capita income in the United States has flattened in recent years and could flatten in the long run, OSHA suggests a conservative value for ''k'' of approximately two percent a year. The Agency invites comment on this estimate and on estimates of the income elasticity of the value of a statistical life.

The Agency believes that the rising value, over time, of health benefits is a real phenomenon that should be taken into account in estimating the annualized benefits of the proposed rule. Table IX–13, in the following section on discounting benefits, shows estimates of the monetized benefits of the proposed rule (under alternative discount rates) with this estimated increase in monetized benefits over time. The Agency invites comment on this adjustment to monetized benefits.

c. The Discounting of Monetized Benefits

As previously noted, the estimated stream of benefits arising from the proposed beryllium rule is not constant from year to year, both because of the 45-year delay after the rule takes effect until all active workers obtain reduced beryllium exposure over their entire working lives and because of, in the case of lung cancer, a 10-year latency period between reduced exposure and a reduction in the probability of disease. An appropriate discount rate [39] is needed to reflect the timing of benefits over the 60-year period after the rule takes effect and to allow conversion to an equivalent steady stream of annualized benefits.

1. Alternative Discount Rates for Annualizing Benefits

Following OMB (2003) guidelines, OSHA has estimated the annualized benefits of the proposed rule using separate discount rates of 3 percent and 7 percent. Consistent with the Agency's own practices in recent rulemakings, OSHA has also estimated, for benchmarking purposes, undiscounted benefits—that is, benefits using a zero percent discount rate.

[36] The results are similar if the historical period includes a major economic downturn (such as the United States has recently experienced). From 1929 through 2003, a period in U.S. history that includes the Great Depression, real per capita income still grew at an average rate of 2.22 percent a year (Gomme and Rupert, 2004).

[37] The EIA used DOE's National Energy Modeling System (NEMS) to produce the Annual Energy Outlook (AEO) projections (EIA, 2011). Future per capita GDP was calculated by dividing the projected real gross domestic product each year by the projected U.S. population for that year.

[38] See, for example, EPA (2003, 2008).

[39] Here and elsewhere throughout this section, unless otherwise noted, the term ''discount rate'' always refers to the real discount rate—that is, the discount rate net of any inflationary effects.

The question remains, what is the ''appropriate'' or ''preferred'' discount rate to use to monetize health benefits? The choice of discount rate is a controversial topic, one that has been the source of scholarly economic debate for several decades. However, in simplest terms, the basic choices involve a social opportunity cost of capital approach or social rate of time preference approach.

The social opportunity cost of capital approach reflects the fact that private funds spent to comply with government regulations have an opportunity cost in terms of foregone private investments that could otherwise have been made. The relevant discount rate in this case is the pre-tax rate of return on the foregone investments (Lind, 1982, pp. 24–32).

The rate of time preference approach is intended to measure the tradeoff between current consumption and future consumption, or in the context of the proposed rule, between current benefits and future benefits. The *individual* rate of time preference is influenced by uncertainty about the availability of the benefits at a future date and whether the individual will be alive to enjoy the delayed benefits. By comparison, the *social* rate of time preference takes a broader view over a longer time horizon—ignoring individual mortality and the riskiness of individual investments (which can be accounted for separately).

The usual method for estimating the social rate of time preference is to calculate the post-tax real rate of return on long-term, risk-free assets, such as U.S. Treasury securities (OMB, 2003, p. 33). A variety of studies have estimated these rates of return over time and reported them to be in the range of approximately 1–4 percent.

In accordance with OMB Circular A–4 (2003), OSHA presents benefits and net benefits estimates using discount rates of 3 percent (representing the social rate of time preference) and 7 percent (a rate estimated using the social cost of capital approach). The Agency is interested in any evidence, theoretical or applied, that would inform the application of discount rates to the costs and benefits of a regulation.

2. Summary of Annualized Benefits under Alternative Discount Rates

Table IX–13 presents OSHA's estimates of the sum of the annualized benefits of the proposed rule, using alternative discount rates of 0, 3, and 7 percent, with the suggested adjustment for increasing monetized benefits in response to annual increases in per capita income over time.

Given that the stream of benefits extends out 60 years, the value of future benefits is sensitive to the choice of discount rate. The undiscounted benefits in Table IX–13 range from $291 million to $2.1 billion annually. Using a 7 percent discount rate, the annualized benefits range from $60 million to $591 million. As can be seen, going from undiscounted benefits to a 7 percent discount rate has the effect of cutting the annualized benefits of the proposed rule by about 74 percent.

Taken as a whole, the Agency's best preliminary estimate of the total annualized benefits of the proposed rule—using a 3 percent discount rate with an adjustment for the increasing value of health benefits over time—is between $158 million and $1.2 billion, with a mid-point value of $576 million.

Table IX-13			
Total Annualized Monitized Benefits - Midpoint Estimates ($Millions)			
	(Quartile Model)		
	PEL Option (µg/m³)		
	0.1	0.2	0.5
Discount Rate			
Low Estimates			
Undiscounted (0%)	$313.7	$291.1	$277.8
Discounted at 3%	$170.3	$158.0	$150.7
Discounted at 7%	$64.9	$60.2	$57.4
High Estimates			
Undiscounted (0%)	$2,088.8	$2,080.7	$1,308.3
Discounted at 3%	$1,250.0	$1,245.2	$782.8
Discounted at 7%	$593.3	$591.1	$371.3
Midpoint Estimates			
Undiscounted (0%)	$1,015.2	$995.5	$696.7
Discounted at 3%	$587.3	$575.8	$403.1
Discounted at 7%	$260.4	$255.3	$178.8

Source: Office of Regulatory Analysis, Directorate of Standards and Guidance

Step 4: Net Benefits of the Proposed Rule

OSHA has estimated, in Table IX–14, the monetized and annualized net benefits of the proposed rule (with a PEL of 0.2 µg/m³), based on the benefits and costs previously presented. Table IX–14 also provides estimates of annualized net benefits for alternative PELs of 0.1 and 0.5 µg/m³. Both the proposed rule and the alternatives PEL options have the same ancillary provisions and an action level equal to half of the PEL in both cases.

Table IX–14 is being provided for informational purposes only. As previously noted, the OSH Act requires the Agency to set standards based on eliminating significant risk to the extent feasible. An alternative criterion of maximizing net (monetized) benefits may result in very different regulatory outcomes. Thus, this analysis of net benefits has not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for the proposed beryllium rule.

Table IX–14 shows net benefits using alternative discount rates of 0, 3, and 7 percent for benefits and costs, having previously included an adjustment to monetized benefits to reflect increases in real per capita income over time. OSHA has relied on a uniform discount rate applied to both costs and benefits. The Agency is interested in any evidence, theoretical or applied, that would support or refute the application of differential discount rates to the costs and benefits of a regulation.

As previously noted in this section, the choice of discount rate for annualizing benefits has a significant effect on annualized benefits. The same is true for net benefits. For example, the net benefits using a 7 percent discount rate for benefits are considerably smaller than the net benefits using a 3 percent discount rate, declining by over half under all scenarios. (Conversely, as noted in Chapter V of the PEA, the choice of discount rate for annualizing costs has a relatively minor effect on annualized costs.)

Based on the results presented in Table IX–14, OSHA finds:

- While the net benefits of the proposed rule vary considerably—depending on the choice of discount rate used to annualize benefits and on whether the benefits being used are in the high, midpoint, or low range—benefits exceed costs for the proposed 0.2 µg/m³ PEL in all cases that OSHA considered.

• The Agency's best estimate of the net annualized benefits of the proposed rule—using a uniform discount rate for both benefits and costs of 3 percent—is between $120 million and $1.2 billion, with a midpoint value of $538 million.

• The alternative of a 0.5 μg/m³ PEL has lower net benefits under all assumptions, whereas the effect on net benefits of the 0.1 μg/m³ PEL is mixed, relative to the proposed 0.2 μg/m³ PEL. However, for these alternative PELs, benefits were also found to exceed costs in all cases that OSHA considered.

Table IX-14

Annual Monetized Net Benefits Resulting from a Reduction in Exposure to Beryllium to Proposed PEL of 0.2 μg/m³ and Alternative PELS of 0.1 μg/m³ and 0.5 μg/m3

($Millions)

PEL		0.1	0.2	0.5
Discount Rate	Range			
Undiscounted (0%)	Low	$271.1	$254.6	$245.5
	Midpoint	$972.6	$958.9	$664.4
	High	$2,046.2	$2,044.2	$1,276.0
Discounted at 3%	Low	$126.5	$120.4	$117.6
	Midpoint	$543.5	$538.2	$370.0
	High	$1,206.3	$1,207.6	$749.6
Discounted at 7%	Low	$19.5	$21.0	$23.0
	Midpoint	$214.9	$216.2	$144.4
	High	$547.8	$552.0	$336.9

Source: Office of Regulatory Analysis, Directorate of Standards & Guidance

Incremental Benefits of the Proposed Rule

Incremental costs and benefits are those that are associated with increasing the stringency of the standard. A comparison of incremental benefits and costs provides an indication of the relative efficiency of the proposed PEL and the alternative PELs. Again, OSHA has conducted these calculations for informational purposes only and has not used these results as the basis for selecting the PEL for the proposed rule.

OSHA provides, in Table IX–15, estimates of the net benefits of the alternative 0.1 and 0.5 μg/m³ PELs. The incremental costs, benefits, and net benefits of meeting a 0.5μg/m³ PEL and then going to a 0.2 μg/m³ PEL (as well as meeting a 0.2 μg/m³ PEL and then going to a 0.1 μg/m³ PEL—which the Agency has not yet determined is feasible), for alternative discount rates of 3 and 7 percent, are presented in Table IX–15. Table IX–15 breaks out costs by provision and benefits by type of disease and by morbidity/mortality. As Table IX–15 shows, at a discount rate of 3 percent, a PEL of 0.2 μg/m³, relative to a PEL of 0.5 μg/m³, imposes additional costs of $4.4 million per year; additional benefits of $172.7 million per year; and additional net benefits of $168.2 million per year. The proposed PEL of 0.2 μg/m³ also has higher net benefits, relative to a PEL of 0.5 μg/m³, using a 7 percent discount rate.

Table IX–15 demonstrates that, regardless of discount rate, there are net benefits to be achieved by lowering exposures from the current PEL of 2.0 μg/m³ to 0.5 μg/m³ and then, in turn, lowering them further to 0.2 μg/m³. However, the majority of the benefits and costs attributable to the proposed rule are from the initial effort to lower exposures to 0.5 μg/m³. Consistent with the previous analysis, net benefits decline across all increments as the discount rate for annualizing benefits increases. As also shown in Table IX–15, there is a slight positive net incremental benefit from going from a PEL of 0.2 μg/m³ to 0.1 μg/m³ for a discount rate of 3 percent, and a slight negative net increment for a discount rate of 7 percent. (Note that these results are for OSHA's midpoint estimate of benefits, although as indicated in Table IX–14, this is not universal across all estimation parameters.)

In addition to examining alternative PELs, OSHA also examined alternatives to other provisions of the standard. These regulatory alternatives are discussed Section IX.H of this preamble.

Table IX-15: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of of 0.1 μg/m3 and 0.5 μg/m3 PEL Alternative
Millions ($2010)

	Alternative 4 (PEL = 0.1 μg/m³, AL = 0.05 μg/m³)			Alternative 4 Incremental Costs/Benefits			Proposed PEL			Alternative 5 Incremental Costs/Benefits			Alternative 5 (PEL = 0.5 μg/m³, AL = 0.25 μg/m³)		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Control Costs		$12.9	$13.9		$3.3	$3.5		$9.5	$10.3		$3.6	$3.9		$6.0	$6.5
Respirators		$0.7	$0.7		$0.4	$0.5		$0.2	$0.3		$0.1	$0.1		$0.1	$0.1
Exposure Assessment		$3.8	$3.9		$1.6	$1.5		$2.2	$2.4		$0.3	$0.3		$1.9	$2.1
Regulated Areas		$0.9	$0.9		$0.3	$0.3		$0.6	$0.7		$0.3	$0.3		$0.3	$0.4
Medical Surveillance		$3.0	$3.1		$0.1	$0.1		$2.9	$3.0		$0.1	$0.1		$2.8	$2.9
Medical Removal		$0.4	$0.5		$0.3	$0.3		$0.1	$0.2		$0.1	$0.1		$0.1	$0.1
Exposure Control Plan		$1.8	$1.8		$0.0	$0.0		$1.8	$1.8		$0.0	$0.0		$1.8	$1.8
Protective Clothing and Equipment		$1.4	$1.4		$0.0	$0.0		$1.4	$1.4		$0.0	$0.0		$1.4	$1.4
Hygiene Areas and Practices		$0.6	$0.6		$0.2	$0.2		$0.4	$0.4		$0.0	$0.0		$0.4	$0.4
Housekeeping		$12.6	$12.9		$0.0	$0.0		$12.6	$12.9		$0.0	$0.0		$12.6	$12.9
Training		$5.8	$5.8		$0.0	$0.0		$5.8	$5.8		$0.0	$0.0		$5.8	$5.8
Total Annualized Costs (point estimate)		**$43.7**	**$45.5**		**$6.1**	**$6.3**		**$37.6**	**$39.1**		**$4.4**	**$4.8**		**$33.2**	**$34.4**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	4			0			4			0			4		
Fatal Chronic Beryllium Disease	94			2			92			29			63		
Beryllium-Related Mortality	98	$584.4	$258.8	2	$11.1	$4.9	96	$573.0	$253.7	29	$171.8	$76.1	67	$401.2	$177.7
Beryllium Morbidity	50	$2.9	$1.6	1	$0.0	$0.0	50	$2.8	$1.6	15	$0.9	$0.5	34	$2.0	$1.1
Monetized Annual Benefits (midpoint estimate)		**$587.3**	**$260.4**		**$11.2**	**$5.1**		**$575.8**	**$255.3**		**$172.7**	**$76.6**		**$403.1**	**$178.8**
Net Benefits		**$543.5**	**$214.9**		**$5.3**	**-$1.3**		**$538.2**	**$216.2**		**$168.2**	**$71.8**		**$370.0**	**$144.4**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Step 5: Sensitivity Analysis

In this section, OSHA presents the results of two different types of sensitivity analysis to demonstrate how robust the estimates of net benefits are to changes in various cost and benefit parameters. In the first type of sensitivity analysis, OSHA made a series of isolated changes to individual cost and benefit input parameters in order to determine their effects on the Agency's estimates of annualized costs, annualized benefits, and annualized net benefits. In the second type of sensitivity analysis—a so-called ''break-even'' analysis—OSHA also investigated isolated changes to individual cost and benefit input parameters, but with the objective of determining how much they would have to change for annualized costs to equal annualized benefits. For both types of sensitivity analyses, OSHA used the annualized costs and benefits obtained from a three-percent discount rate as the reference point.

Again, the Agency has conducted these calculations for informational purposes only and has not used these results as the basis for selecting the PEL for the proposed rule.

a. Analysis of Isolated Changes to Inputs

The methodology and calculations underlying the estimation of the costs and benefits associated with this rulemaking are generally linear and additive in nature. Thus, the sensitivity of the results and conclusions of the analysis will generally be proportional to isolated variations in a particular input parameter. For example, if the estimated time that employees need to travel to (and from) medical screenings were doubled, the corresponding labor costs would double as well.

OSHA evaluated a series of such changes in input parameters to test whether and to what extent the general conclusions of the economic analysis held up. OSHA first considered changes to input parameters that affected only costs and then changes to input parameters that affected only benefits. Each of the sensitivity tests on cost parameters had only a very minor effect on total costs or net costs. Much larger effects were observed when the benefits parameters were modified; however, in all cases, net benefits remained significantly positive. On the whole, OSHA found that the conclusions of the analysis are reasonably robust, as changes in any of the cost or benefit input parameters still show significant net benefits for the proposed rule. The results of the individual sensitivity tests are summarized in Table IX–16 and are described in more detail below.

In the first of these sensitivity tests, where OSHA doubled the estimated portion of employees in need of protective clothing and equipment (PPE), essentially doubling the estimated baseline non-compliance rate (*e.g.,* from 10 to 20 percent), and estimates of other input parameters remained unchanged, Table IX–16 shows that the estimated total costs of compliance would increase by $1.4 million annually, or by about 3.7 percent, while net benefits would also decline by $1.4 million annually, from $538.2 million to $536.8 million annually.

In a second sensitivity test, OSHA increased the estimated unit cost of ventilation from $13.18 per cfm for most sectors to $25 per cfm for most sectors. As shown in Table IX–16, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $2.0 million annually, or by about 5.3 percent, while net benefits would also decline by $2.0 million annually, from $538.2 million to $536.2 million annually.

Table IX-16 Sensitivity Tests

Uncertainty Scenarios	Change from OSHA's Primary Estimate	Difference From Primary Estimate	Percentage Impact on Costs or Benefits	Total Annualized Cost or Benefit	Net Benefit
Cost Scenarios					
Proposed Rule - OSHA's best estimate	NA	$0	0.0%	$37,597,325	$538,229,309
Reduced PPE Compliance Rates	Double PPE non-compliance rates	$1,385,575	3.7%	$38,982,900	$536,843,733
Increased CFM Unit Cost	Increase CFM Unit Cost to $25 for most sectors	$1,993,863	5.3%	$39,591,188	$536,235,445
Increased share of workers showing signs and symptoms	Increase share of workers showing signs and symtoms to 25%	$1,545,310	4.1%	$39,142,635	$536,683,999
Increased housekeeping	Increase the estimated incremental time per worker for housekeeping by 50%	$5,429,113	14.4%	$43,026,437	$532,800,196
Increased establishment-based costs	For establishment-based costs, increased the number of affected establishments by up to 100%	$4,483,148	11.9%	$42,080,472	$533,746,161
Benefit Secnarios					
Proposed Rule - OSHA's best estimate	NA	$0	0.0%	$575,826,633	$538,229,309
Low morbidity valuation	Benefits estimated using low morbidity value	-$216,839,627	-37.7%	$358,987,006	$321,389,682
High morbidity valuation	Benefits estimated using high morbidity value	$443,411,757	77.0%	$1,019,238,390	$981,641,066
Remove adjustment for future valuation of benefits (due to positive income elasticity of health benefits	Set the growth in future benefits to 0.0%	-$314,319,477	-54.6%	$261,507,156	$223,909,831

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

In a third sensitivity test, OSHA increased the estimated share of workers showing signs and symptoms of CBD from 15 to 25 percent, thereby adding these workers to the group eligible for medical surveillance and assuming that they would not be otherwise eligible for another reason (working in a regulated area, exposed during an emergency, etc.). As shown in Table IX–16, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $1.5 million annually, or by about 4.1 percent, while net benefits would also decline by $1.5 million annually, from $538.2 million to $536.7 million annually.

In a fourth sensitivity test, OSHA increased its estimated incremental time per workers for housekeeping by 50 percent. As shown in Table IX–16, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $5.4 million annually, or by about 14.4 percent, while net benefits would also decline by $5.4 million annually, from $538.2 million to $532.8 million annually.

In a fifth sensitivity test, OSHA increased the estimated number of establishments needing engineering controls. For this sensitivity test, if less than 50 percent of the establishments in an industry needed engineering controls, OSHA doubled the percentage of establishments needing engineering controls. If more than 50 percent of establishments in an industry needed engineering controls, then OSHA increased the percentage of establishment needing engineering control to 100 percent. The purpose of this sensitivity analysis was to check the importance of using a methodology that treated 50 percent of workers in a given occupation exposed above the PEL as equivalent to 50 percent of facilities lacking adequate exposure controls. As shown in Table IX–16, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $4.5 million, or by about 11.9 percent, while net benefits would also decline by $4.5 million, from $538.2 million to $533.7 million annually.

The Agency also performed sensitivity tests on several input parameters used to estimate the benefits of the proposed rule. In the first two tests, in an extension of results previously presented in Table IX–12, the Agency examined the effect on annualized net benefits of employing the high-end estimate of the benefits, as well as the low-end estimate, specifically examining the effect on undiscounted benefits of varying the valuation of individual morbidity cases. Table IX–16 presents the effect on annualized net benefits of using the extreme values of these ranges: the high morbidity valuation case and the low morbidity valuation case. For the low estimate of valuation, the benefits decline by 37.7 percent, to $359 million annually, yielding net benefits of $321 million annually. As shown, using the high estimate of morbidity valuation, the benefits rise by 77.0 percent to $1.0 billion annually, yielding net benefits of $982 million annually.

In a third sensitivity test of benefits, the Agency examined the effect of removing the component for the estimated rising value of health and safety over time. This would reduce the benefits by 54.6 percent, or $314 million annually, lowering the net benefits to $224 million annually.

In Chapter VII of the PEA the Agency examined the effect of raising the discount rate for costs and benefits to 7 percent. Raising the discount rate to 7 percent would increase costs by $1.5 million annually and lower benefits by $320.5 million annually, yielding annualized net benefits of $216.2 million.

Also in Chapter VII of the PEA the Agency performed a sensitivity analysis of dental lab substitution. In the PEA, OSHA estimates that 75 percent of the dental laboratory industry will react to a new standard on beryllium by substituting away from using beryllium to the use of other materials. Substitution is not costless, and Chapter V of the PEA estimates the increased cost due to the higher costs of using non-beryllium alloys. These costs are smaller than the avoided costs of the ancillary provisions and engineering controls. Thus, as indicated in Table VII–8 of the PEA, the benefits of the proposal would be lower and the costs higher if there were less substitution out of beryllium in dental labs. The lowest net benefits would occur if labs were unable to substitute out beryllium-containing materials at all, and had to use ventilation to control exposures. In this case, the proposal would yield only $420 million in net benefits. The highest net benefits, larger than assumed for OSHA's primary estimate, would be if all dental labs substituted out of beryllium-containing materials as a result of the proposal; as a result, the proposal would yield $573 million in net benefits. Another possibility is a scenario is which technology and the market move along rapidly away from using beryllium-containing materials, independently of an OSHA rule, and the proposal itself would therefore produce neither costs nor benefits in this sector. If dental labs are removed from the PEA, the net benefits for the proposal—for the remaining industry sectors—decline to $284 million. This analysis demonstrates, however, that regardless of any assumption regarding substitution in dental labs, the proposal would generate substantially more monetized benefits than costs.

Finally, the Agency examined in Chapter VII of the PEA the effects of changes in two important inputs to the benefits analysis: the factor that transforms CBD prevalence rates into incidence rates, needed for the equilibrium lifetime risk model, and the percentage of CBD cases that eventually lead to a fatality.

From the Cullman dataset, the Agency has estimated the prevalence of CBD cases at any point in time as a function of cumulative beryllium exposure. In order to utilize the lifetime risk model, which tracks workers over their working life in a job, OSHA has turned these prevalence rates into an incidence rate, which is the rate of contracting CBD at a point in time. OSHA's baseline estimate of the turnover rate in the model is 10 percent. In Table VII–10 in the PEA, OSHA also presented alternative turnover rates of 5 percent and 20 percent. A higher turnover rate translates into a higher incidence rate, and the table shows that, from a baseline midpoint estimate with 10 percent turnover the number of CBD cases prevented is 6,367, while raising the turnover rate to 20 percent causes this midpoint estimate to rise to 11,751. Conversely, a rate of 5 percent lowers the number of CBD cases prevented to 3,321. Translated into monetary benefits, the table shows that the baseline midpoint estimate of $575.8 million now ranges from $314.4 million to $1,038 million.

Also in TableVII–10 of the PEA, the Agency looked at the effects of varying the percentage of CBD cases that eventuate in fatality. The Agency's baseline estimate of this outcome is 65 percent, with half of this occurring relatively soon, and the other half after an extended debilitating condition. The Agency judged that a reasonable range to investigate was a low of 50 percent and a high of 80 percent, while maintaining the shares of short-term and long-term endpoint fatality. At a baseline of 65 percent, the midpoint estimate of total CBD cases prevented is 4,139. At the low end of 50 percent mortality this estimate lowers to 3,183 while at the high end of 80 percent mortality this estimate rises to 5,094. Translated into monetary benefits, the table shows that the baseline midpoint estimate of $575.8 million now ranges from $500.1 million to $651.5 million.

b. ''Break-Even'' Analysis

OSHA also performed sensitivity tests on several other parameters used to estimate the net costs and benefits of the proposed rule. However, for these, the Agency performed a ''break-even'' analysis, asking how much the various cost and benefits inputs would have to vary in order for the costs to equal, or break even with, the benefits. The results are shown in Table IX–17.

In one break-even test on cost estimates, OSHA examined how much total costs would have to increase in order for costs to equal benefits. As shown in Table IX–17, this point would be reached if costs increased by $538.2 million, or by 1,431 percent.

In a second test, looking specifically at the estimated engineering control costs, the Agency found that these costs would need to increase by $566.7 million, or 6,240 percent, for costs to equal benefits.

In a third sensitivity test, on benefits, OSHA examined how much its estimated monetary valuation of an avoided illness or an avoided fatality would need to be reduced in order for the costs to equal the benefits. Since the total valuation of prevented mortality and morbidity are each estimated to exceed the estimated costs of $38 million, an independent break-even point for each is impossible. In other words, for example, if no value is attached to an avoided illness associated with the rule, but the estimated value of an avoided fatality is held constant, the rule still has substantial net benefits. Only through a reduction in the estimated net value of both components is a break-even point possible.

The Agency, therefore, examined how large an across-the-board reduction in the monetized value of all avoided illnesses and fatalities would be necessary for the benefits to equal the costs. As shown in Table IX–17, a 94 percent reduction in the monetized value of all avoided illnesses and fatalities would be necessary for costs to equal benefits, reducing the estimated value to $733,303 per fatality prevented, and an equivalent percentage reduction to about $4,048 per illness prevented.

In a fourth break-even sensitivity test, OSHA estimated how many fewer beryllium-related fatalities and illnesses would be required for benefits to equal costs. Paralleling the previous discussion, eliminating either the prevented mortality or morbidity cases alone would be insufficient to lower benefits to the break-even point. The Agency therefore examined them as a group. As shown in Table IX–17, a reduction of 96 percent, for both simultaneously, is required to reach the break-even point—90 fewer fatalities prevented annually, and 46 fewer beryllium-related illnesses-only cases prevented annually.

Taking into account both types of sensitivity analysis the Agency performed on its point estimates of the annualized costs and annualized benefits of the proposed rule, the results demonstrate that net benefits would be positive in all plausible cases tested. In particular, this finding would hold even with relatively large variations in individual input parameters. Alternately, one would have to imagine extremely large changes in costs or benefits for the rule to fail to produce net benefits. OSHA concludes that its finding of significant net benefits resulting from the proposed rule is a robust one.

OSHA welcomes input from the public regarding all aspects of this sensitivity analysis, including any data or information regarding the accuracy of the preliminary estimates of compliance costs and benefits and how the estimates of costs and benefits may be affected by varying assumptions and methodological approaches. OSHA also invites comment on the risk analysis and risk estimates from which the benefits estimates were derived.

Table IX-17

Break-Even Sensitivity Analysis

	OSHA's Best Estimate of Annualized Cost or Benefit Factor	Factor Value at Which Benefits Equal Costs	Required Factor Dollar/Number Change	Percentage Factor Change
Total Costs	$37,597,325	$575,826,633	$538,229,309	1431.6%
Engineering Control Costs	$9,082,884	$575,826,633	$566,743,749	6239.7%
Benefits Valuation per Case Avoided				
Monetized Benefit per Fatality Avoided	$11,231,000	$733,303	-$10,497,697	-93.5%
Monetized Benefit per Illness Avoided	$62,000	$4,048	-$57,952	-93.5%
Cases Avoided				
Deaths Avoided	96	6	-90	-93.5%
Illnesses Avoided	50	3	-46	-93.5%

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

H. Regulatory Alternatives

This section discusses various regulatory alternatives to the proposed OSHA beryllium standard. Executive Order 12866 instructs agencies to "select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach." The OSH Act, as interpreted by the courts, requires health regulations to reduce significant risk to the extent feasible. Nevertheless OSHA has examined possible regulatory alternatives that may not meet its statutory requirements.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's preliminary findings of significant risk and feasibility. To facilitate comment, OSHA has organized some two dozen specific regulatory alternatives into five categories: (1) Scope; (2) exposure limits; (3) methods of compliance; (4) ancillary provisions; and (5) timing.

1. Scope Alternatives

The first set of regulatory alternatives would alter scope of the proposed standard—that is, the groups of employees and employers covered by the proposed standard. The scope of the current beryllium proposal applies only to general industry work, and does not apply to employers when engaged in construction or maritime activities. In addition, the proposed rule provides an exemption for those working with materials that contain beryllium only as a trace contaminant (less than 0.1percent composition by weight).[40]

As discussed in the explanation of paragraph (a) in Section XVIII of this preamble, Summary and Explanation of the Proposed Standard, OSHA is considering alternatives to the proposed scope that would increase the range of employers and employees covered by the standard. OSHA's review of several industries indicates that employees in some construction and maritime industries, as well as some employees who deal with materials containing less than 0.1 percent beryllium, may be at significant risk of CBD and lung cancer as a result of their occupational exposures. Regulatory Alternatives #1a, #1b, #2a, and #2b would increase the scope of the proposed standard to provide additional protection to these workers.

Regulatory Alternative #1a would expand the scope of the proposed standard to also include all operations in general industry where beryllium exists only as a trace contaminant; that is, where the materials used contain less than 0.1 percent beryllium by weight. Regulatory Alternative #1b is similar to Regulatory Alternative #1a, but exempts operations where beryllium exists only as a trace contaminant and the employer can show that employees' exposures will not meet or exceed the action level or exceed the STEL. Where the employer has objective data demonstrating that a material containing beryllium or a specific process, operation, or activity involving beryllium cannot release beryllium in concentrations at or above the proposed action level or above the proposed STEL under any expected conditions of use, that employer would be exempt from the proposed standard except for recordkeeping requirements pertaining to the objective data. Alternative #1a and Alternative #1b, like the proposed rule, would not cover employers or employees in construction or shipyards.

OSHA has identified two industries with workers engaged in general industry work that would be excluded under the proposed rule but would fall within the scope of the standard under Regulatory Alternatives #1a and #1b: Primary aluminum production and coal-fired power generation. Beryllium exists as a trace contaminant in aluminum ore and may result in exposures above the proposed permissible exposure limits (PELs) during aluminum refining and production. Coal fly ash in coal-powered power plants is also known to contain trace amounts of beryllium, which may become airborne during furnace and baghouse operations and might also result in worker exposures. See Appendices VIII–A and VIII–B at the end of Chapter VIII in the PEA for a discussion of beryllium exposures and available controls in these two industries.

As discussed in Appendix IV–B of the PEA, beryllium exposures from fly ash high enough to exceed the proposed PEL would usually be coupled with arsenic exposures exceeding the arsenic PEL. Employers would in that case be required to implement all feasible engineering controls, work practices, and necessary PPE (including respirators) to comply with the OSHA Inorganic Arsenic standard (29 CFR 1910.1018)—which would be sufficient to comply with those aspects of the proposed beryllium standard as well. The degree of overlap between the applicability of the two standards and, hence, the increment of costs attributable to this alternative are difficult to gauge. To account for this uncertainty, the Agency at this time is presenting a range of costs for Regulatory Alternative #1a: From no costs being taken for ancillary provisions under Regulatory Alternative #1a to all such costs being included. At the low end, the only additional costs under Regulatory Alternative #1a are due to the engineering control costs incurred by the aluminum smelters (see Appendix VIII–A).

Similarly, the proposed beryllium standard would not result in additional benefits from a reduction in the beryllium PEL or from ancillary provisions similar to those already in place for the arsenic standard, but OSHA does anticipate some benefits will flow from ancillary provisions unique to the proposed beryllium standard. To account for significant uncertainty in the benefits that would result from the proposed beryllium standard for workers in primary aluminum production and coal-fired power generation, OSHA estimated a range of benefits for Regulatory Alternative #1a. The Agency estimated that the proposed ancillary provisions would avert between 0 and 45 percent[41] of those baseline CBD cases not averted by the proposed PEL. Though the Agency is presenting a range for both costs and benefits for this alternative, the Agency judges the degree of overlap with the arsenic standard is likely to be substantial, so that the actual costs and benefits are more likely to be found at the low end of this range. The Agency invites comment on all these issues.

Table IX–18 presents, for informational purposes, the estimated costs, benefits, and net benefits of Regulatory Alternative #1a using alternative discount rates of 3 percent and 7 percent. In addition, this table presents the incremental costs, incremental benefits, and incremental net benefits of this alternative relative to the proposed rule. Table IX–18 also breaks out costs by provision, and benefits by type of disease and by morbidity/mortality.

As shown in Table IX–18, Regulatory Alternative #1a would increase the annualized cost of the rule from \$37.6 million to between \$39.6 and \$56.0 million using a 3 percent discount rate and from \$39.1 million to between \$41.3 and \$58.1 million using a 7 percent discount rate. OSHA estimates that regulatory Alternative #1a would prevent as few as an additional 0.3 (*i.e.,* almost one fatality every 3 years) or as many as an additional 31.8 beryllium-related fatalities annually, relative to the proposed rule. OSHA also estimates that Regulatory Alternative #1a would prevent as few as an additional 0.002 or as many as an additional 9 beryllium-related non-fatal illnesses annually, relative to the proposed rule. As a result, annualized benefits in monetized

[40] Employers engaged in general industry activities exempted from the proposed rule must still ensure that their employees are protected from beryllium exposure above the current PEL, as listed in 29 CFR 1910.1000 Table Z–2.

[41] As discussed in Chapter VII of the PEA, OSHA used 45 percent to develop its best estimate.

terms would increase from $575.8 million to between $578.0 and $765.2 million, using a 3 percent discount rate, and from $255.3 million to between $256.3 and $339.3 million using a 7 percent discount rate. Net benefits would increase from $538.2 million to between $538.4 and $709.2 million using a 3 percent discount rate and from $216.2 million to somewhere between $215.1 to $281.2 million using a 7 percent discount rate. As noted in Appendix VIII–B of Chapter VIII in the PEA, the Agency emphasizes that these estimates of benefits are subject to a significant degree of uncertainty, and the benefits associated with Regulatory Alternative #1a arguably could be a small fraction of OSHA's best estimate presented here.

OSHA estimates that the costs and the benefits of Regulatory Alternative #1b will be somewhat lower than the costs of Regulatory Alternative #1a, because most—but not all—of the provisions of the proposed standard are triggered by exposures at the action level, 8-hour time-weighted average (TWA) PEL, or STEL. For example, where exposures exist but are below the action level and at or below the STEL, Alternative #1a would require employers to establish work areas; develop, maintain, and implement a written exposure control plan; provide medical surveillance to employees who show signs or symptoms of CBD; and provide PPE in some instances. Regulatory Alternative #1b would not require employers to take these measures in operations where they can produce objective data demonstrating that exposures are below the action level and at or below the STEL. OSHA only analyzed costs, not benefits, for this alternative, consistent with the Agency's treatment of Regulatory Alternatives in the past. Total costs for Regulatory Alternative #1b versus #1a, assuming full ancillary costs, drop from to $56.0 million to $49.9 million using a 3 percent discount rate, and from $58.1 million to $51.8 million using a 7 percent discount rate.

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Table IX-8: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of Alternative Scope
Millions ($2010)

	Alternative 1a (Include trace contaminants)			Alternative 1a Incremental Costs/Benefits			Proposed PEL (PEL = 0.2 μg/m^3, AL = 0.10 μg/m^3)		
Discount Rate		3%	7%		3%	7%		3%	7%
Annualized Costs									
Control Costs		$10.8 - $10.8	$11.7 - $11.7		$1.3 - $1.3	$1.3 - $1.3		$9.5	$10.3
Respirators		$0.3 - $0.3	$0.3 - $0.3		$0.0 - $0.0	$0.0 - $0.0		$0.2	$0.3
Exposure Assessment		$2.3 - $3.8	$2.5 - $4.1		$0.1 - $1.5	$0.1 - $2.1		$2.2	$2.4
Regulated Areas and Beryllium Work Areas		$0.7 - $0.7	$0.7 - $0.7		$0.0 - $0.1	$0.0 - $0.1		$0.6	$0.7
Medical Surveillance		$3.0 - $4.3	$3.1 - $4.5		$0.1 - $1.5	$0.7 - $2.7		$2.9	$3.0
Medical Removal		$0.2 - $0.3	$0.2 - $0.3		$0.0 - $0.1	$0.0 - $0.1		$0.1	$0.2
Exposure Control Plan		$1.8 - $2.8	$1.8 - $2.8		$0.0 - $1.0	$0.0 - $1.3		$1.8	$1.8
Protective Clothing and Equipment		$1.4 - $1.4	$0.0 - $0.0		$0.0 - $0.0	$0.2 - $0.2		$1.4	$1.4
Hygiene Areas and Practices		$0.4 - $0.4	$0.4 - $0.4		$0.0 - $0.0	$0.0 - $0.0		$0.4	$0.4
Housekeeping		$12.9 - $21.4	$13.3 - $22.0		$0.4 - $8.8	$0.4 - $10.9		$12.6	$12.9
Training		$6.0 - $9.9	$6.0 - $9.9		$0.2 - $4.1	$0.2 - $4.9		$5.8	$5.8
Total Annualized Costs (point estimate)		$39.6 - $56.0	$41.3 - $58.1		$2.0 - $18.4	$0.1 - $17.9		**$37.6**	**$39.1**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	4.1 - 4.1			0.1 - 0.1			4		
Fatal Chronic Beryllium Disease	92.1 - 123.7			0.2 - 31.7			92		
Beryllium-Related Mortality	96.3 - 127.8	$575.0 - $761.4	$254.6 - $337.2	0.3 - 31.8	$2.0 - $188.4	$0.9 - $83.4	96	$573.0	$253.7
Beryllium Morbidity	49.5 - 58.5	$3.0 - $3.8	$1.7 - $2.1	0.0 - 9.0	$0.2 - $1.0	$0.1 - $0.5	50	$2.8	$1.6
Monetized Annual Benefits (midpoint estimate)		**$578.0 - $765.2**	**$256.3 - $339.3**		**$2.2 - $189.4**	**$1.0 - $84.0**		**$575.8**	**$255.3**
Net Benefits		**$538.4 - $709.2**	**$215.1 - $281.2**		**$0.2 - $171.0**	**$-1.1 - $65.0**		**$538.2**	**$216.2**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

Regulatory Alternative #2a would expand the scope of the proposed standard to include employers in construction and maritime. For example, this alternative would cover abrasive blasters, pot tenders, and cleanup staff working in construction and shipyards who have the potential for airborne beryllium exposure during blasting operations and during cleanup of spent media. Regulatory Alternative #2b would update 29 CFR 1910.1000 Tables Z–1 and Z–2, 1915.1000 Table Z, and 1926.55 Appendix A so that the proposed TWA PEL and STEL would apply to all employers and employees in general industry, shipyards, and construction, including occupations where beryllium exists only as a trace contaminant. For example, this alternative would cover abrasive blasters, pot tenders, and cleanup staff working in construction and shipyards who have the potential for significant airborne exposure during blasting operations and during cleanup of spent media. The changes to the Z tables would also apply to workers exposed to beryllium during aluminum refining and production, and workers engaged in maintenance operations at coal-powered utility facilities. All provisions of the standard other than the PELs, such as exposure monitoring, medical removal, and PPE, would be in effect only for employers and employees that fall within the scope of the proposed rule.[42] Alternative #2b would not be as protective as Alternative #1a or Alternative #1b for employees in aluminum refining and production or coal-powered utility facilities because the other provisions of the proposed standard would not apply.

As discussed in the explanation of proposed paragraph (a) in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, abrasive blasting is the primary application group in construction and maritime industries where workers may be exposed to beryllium. OSHA has judged that abrasive blasters and their helpers in construction and maritime industries have the potential for significant airborne exposure during blasting operations and during cleanup of spent media. Airborne concentrations of beryllium have been measured above the current TWA PEL of 2 μg/m³ when blast media containing beryllium are used as intended (see Appendix IV–C in the PEA for details).

To address high concentrations of various hazardous chemicals in abrasive blasting material, employers must already be using engineering and work practice controls to limit workers' exposures and must be supplementing these controls with respiratory protection when necessary. For example, abrasive blasters in the construction industry fall under the protection of the Ventilation standard (29 CFR 1926.57). The Ventilation standard includes an abrasive blasting subsection (29 CFR 1926.57(f)), which requires that abrasive blasting respirators be worn by all abrasive blasting operators when working inside blast-cleaning rooms (29 CFR 1926.57(f)(5)(ii)(A)), or when using silica sand in manual blasting operations where the nozzle and blast are not physically separated from the operator in an exhaust-ventilated enclosure (29 CFR 1926.57(f)(5)(ii)(B)), or when needed to protect workers from exposures to hazardous substances in excess of the limits set in § 1926.55 (29 CFR 1926.57(f)(5)(ii)(C); ACGIH, 1971). For maritime, standard 29 CFR 1915.34(c) covers similar requirements for respiratory protection needed in blasting operations. Due to these requirements, OSHA believes that abrasive blasters already have controls in place and wear respiratory protection during blasting operations. Thus, in estimating costs for Regulatory Alternatives #2a and #2b, OSHA judged that the reduction of the TWA PEL would not impose costs for additional engineering controls or respiratory protection in abrasive blasting (see Appendix VIII–C of Chapter VIII in the PEA for details). OSHA requests comment on this issue—in particular, whether abrasive blasters using blast material that may contain beryllium as a trace contaminant are already using all feasible engineering and work practice controls, respiratory protection, and PPE that would be required by Regulatory Alternatives #2a and #2b.

In the estimation of benefits for Regulatory Alternative #2a, OSHA has estimated a range to account for significant uncertainty in the benefits to this population from some of the ancillary provisions of the proposed beryllium standard. It is unclear how many of the workers associated with abrasive blasting work would benefit from dermal protection, as comprehensive dermal protection may already be used by most blasting operators. It is also unclear whether the housekeeping requirements of the proposed standard would be feasible to implement in the context of abrasive blasting work, and to what extent they would benefit blasting helpers, who are themselves exposed while performing cleanup activities. OSHA estimated that the proposed ancillary provisions would avert between 0 and 45 percent of those baseline CBD cases not averted by the proposed PEL.

These considerations also lead the Agency to present a range for the costs of this alternative: From no costs being estimated for ancillary provisions under Regulatory Alternative #2a to including all such costs. Based on the considerations discussed above, the Agency judges that costs and benefits at the low end of this range are more likely to be correct. The Agency invites comment on these issues.

In addition, OSHA believes that a small number of welders in the maritime industry may be exposed to beryllium via arc and gas welding (and none through resistance welding). The number of maritime welders was estimated using the same methodology as was used to estimate the number of general industry welders. Brush Wellman's customer survey estimated 2,000 total welders on beryllium-containing products (Kolanz, 2001). Based on ERG's assumption of 4 welders per establishment, ERG estimated that a total of 500 establishments would be affected. These affected establishments were then distributed among the 26 NAICS industries with the highest number of IMIS samples for welders that were positive for beryllium. To do this, ERG first consulted the BLS OES survey to determine what share of establishments in each of the 26 NAICS employed welders and estimated the total number of establishments that perform welding regardless of beryllium exposure (BLS, 2010a). Then ERG distributed the 500 affected beryllium welding facilities among the 26 NAICS based on the relative share of the total number of establishments performing welding. Finally, to estimate the number of welders, ERG used the assumption of four welders per establishment. Based on the information from ERG, OSHA estimated that 30 welders would be covered in the maritime industry under this regulatory alternative. For these welders, OSHA used the same controls and exposure profile that were used to estimate costs for arc and gas welders in Chapter V of the PEA. ERG judged there to be no construction welders exposed to beryllium due to a lack of any evidence that the construction sector uses beryllium-containing products or electrodes in resistance welding. OSHA solicits comment and any relevant data on beryllium exposures for welders in construction and maritime employment.

Estimated costs and benefits for Regulatory Alternative #2a are shown in Table IX–18a. Regulatory Alternative

[42] However, many of the occupations excluded from the scope of the proposed beryllium standard receive some ancillary provision protections from other rules, such as Personal Protective Equipment (29 CFR 1910 subpart I, 1915 subpart I, 1926.28, also 1926 subpart E), Ventilation (including abrasive blasting) (§§ 1926.57 and 1915.34), Hazard Communication (§ 1910.1200), and specific provisions for welding (parts 1910 subpart Q, 1915 subpart D, and 1926 subpart J).

#2a would increase costs from $37.6 million to between $37.7 and $55.3 million, using a 3 percent discount rate, and from $39.1 million to between $39.2 and $57.3 million using a 7 percent discount rate. Annualized benefits would increase from $575.8 million to between $575.9 and $675.3 million using a 3 percent discount rate, and from $255.3 million to between $255.4 and $299.4 million using a 7 percent discount rate. Net benefits would change from $538.2 million to between $538.2 and $620.0 million using a 3 percent discount rate, and from $216.2 million to between $216.1 and $242.1 million using a 7 percent discount rate.

Table IX–18b presents, for informational purposes, the estimated costs, benefits, and net benefits, of Regulatory Alternative #2b using alternative discount rates of 3 percent and 7 percent. In addition, this table presents the incremental costs, incremental benefits, and incremental net benefits of this alternative relative to the proposed rule. Table IX–18b also breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

As shown in Table IX–18b, this regulatory alternative would increase the annualized cost of the rule from $37.6 million to $39.6 million, using a 3 percent discount rate, and from $39.1 million to $41.1 million using a 7 percent discount rate. Regulatory Alternative #2b would prevent less than one additional beryllium-related fatalities and less than one beryllium-related illness annually relative to the proposed rule. As a result, annualized benefits would increase from $575.8 million to $578.1 million, using a 3 percent discount rate, and from $255.3 million to $256.3 million using a 7 percent discount rate. Net benefits would increase from $538.2 million to $538.5 million using a 3 percent discount rate and slightly decrease from $216.2 million to $215.2 million using a 7 percent discount rate.

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Table IX-18a: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of Alternative Scope Including Maritime and Construction
Millions ($2010)

	Alternative 2a Include Maritime and Construction Sectors			Alternative 2a Include Maritime and Construction Sectors (incremental costs and benefits)			Proposed PEL (PEL = 0.2 μg/m³, AL = 0.10 μg/m³)		
Discount Rate		3%	7%		3%	7%		3%	7%
Annualized Costs									
Control Costs		$9.6 - $9.6	$10.4 - $10.4		$0.0 - $0.0	$0.0 - $0.0		$9.5	$10.3
Respirators		$0.3 - $0.3	$0.3 - $0.3		$0.0 - $0.0	$0.0 - $0.0		$0.2	$0.3
Exposure Assessment		$2.2 - $3.8	$2.4 - $4.0		$0.0 - $1.5	$0.0 - $1.6		$2.2	$2.4
Regulated areas and Beryllium Work Areas		$0.6 - $1.4	$0.7 - $1.4		$0.0 - $0.7	$0.0 - $0.7		$0.6	$0.7
Medical Surveillance		$2.9 - $6.2	$3.0 - $6.4		$0.0 - $3.3	$0.0 - $3.3		$2.9	$3.0
Medical Removal		$0.1 - $0.5	$0.2 - $0.6		$0.0 - $0.4	$0.0 - $0.4		$0.1	$0.2
Exposure Control Plan		$1.8 - $2.7	$1.8 - $2.8		$0.0 - $1.0	$0.0 - $1.0		$1.8	$1.8
Protective Clothing and Equipment		$1.4 - $1.4	$1.4 - $1.4		$0.0 - $0.0	$0.0 - $0.0		$1.4	$1.4
Hygiene Areas and Practices		$0.4 - $1.6	$0.4 - $1.6		$0.0 - $1.2	$0.0 - $1.1		$0.4	$0.4
Housekeeping		$12.6 - $19.1	$12.9 - $19.6		$0.0 - $6.6	$0.0 - $6.7		$12.6	$12.9
Training		$5.6 - $8.8	$5.8 - $8.9		$0.0 - $3.0	$0.0 - $3.0		$5.6	$5.8
		$37.7 - $55.3	$39.2 - $57.3		$0.1 - $17.7	$0.1 - $17.9			
Total Annualized Costs (point estimate)								**$37.6**	**$39.1**
Annual Benefits: Number of Cases Prevented	**Cases**			**Cases**			**Cases**		
Fatal Lung Cancers (midpoint estimate)	4.0 - 4.0			0.0 - 0.0			4		
Fatal Chronic Beryllium Disease	92.0 - 108.7			0.0 - 16.7			92		
Beryllium-Related Mortality	96.0 - 112.7	$573.0 - $671.9	$253.8 - $297.6	0.0 - 16.7	$0.0 - $99.0	$0.0 - $43.8	96	$573.0	$253.7
Beryllium Morbidity	49.5 - 58.5	$2.8 - $3.4	$1.6 - $1.9	0.0 - 9.0	$0.0 - $0.5	$0.0 - $0.3	50	$2.8	$1.6
Monetized Annual Benefits (midpoint estimate)		**$575.9 - $675.3**	**$255.4 - $299.4**		**$0.0 - $99.0**	**$0.0 - $44.1**		**$575.8**	**$255.3**
Net Benefits		**$538.2 - $620.0**	**$216.1 - $242.1**		**$0.0 - $81.8**	**$0.0 - $25.9**		**$538.2**	**$216.2**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

Table IX-18b: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of Updating Z Tables 1910.1000, 1915.1000, and 1926.55 and Requiring Control Costs for Industries with Trace Contaminants
Millions ($2010)

	Alternative 2b: Update Z Tables 1910.1000, 1915.1000, and 1926.55 and Require Control Costs for Industries with Trace Contaminants			Alternative 2b: Update Z Tables 1910.1000, 1915.1000, and 1926.55 and Require Control Costs for Industries with Trace Contaminants (incremental costs and benefits)			Proposed PEL (PEL = 0.2 μg/m^3, AL = 0.10 μg/m^3)		
Discount Rate		3%	7%		3%	7%		3%	7%
Annualized Costs									
Control Costs		$11.5	$12.3		$2.0	$2.0		$9.5	$10.3
Respirators		$0.2	$0.3		$0.0	$0.0		$0.2	$0.3
Exposure Assessment		$2.2	$2.4		$0.0	$0.0		$2.2	$2.4
Regulated areas and Beryllium Work Areas		$0.6	$0.7		$0.0	$0.0		$0.6	$0.7
Medical Surveillance		$2.9	$3.0		$0.0	$0.0		$2.9	$3.0
Medical Removal		$0.1	$0.2		$0.0	$0.0		$0.1	$0.2
Exposure Control Plan		$1.8	$1.8		$0.0	$0.0		$1.8	$1.8
Protective Clothing and Equipment		$1.4	$1.4		$0.0	$0.0		$1.4	$1.4
Hygiene Areas and Practices		$0.4	$0.4		$0.0	$0.0		$0.4	$0.4
Housekeeping		$12.6	$12.9		$0.0	$0.0		$12.6	$12.9
Training		$5.8	$5.8		$0.0	$0.0		$5.8	$5.8
Total Annualized Costs (point estimate)		**$39.6**	**$41.1**		**$2.0**	**$2.0**		**$37.6**	**$39.1**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	4.1			0.1			4.0		
Fatal Chronic Beryllium Disease	92.1			0.2			92.0		
Beryllium-Related Mortality	96.3	$575.0	$254.6	0.3	$2.02	$0.90	96.0	$573.0	$253.7
Beryllium Morbidity	49.6	$3.0	$1.7	0.1	$0.20	$0.11	49.5	$2.8	$1.6
Monetized Annual Benefits (midpoint estimate)		**$578.1**	**$256.3**		**$2.2**	**$1.0**		**$575.8**	**$255.3**
Net Benefits		**$538.5**	**$215.2**		**$0.3**	**-$1.0**		**$538.2**	**$216.2**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

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2. Exposure Limit (TWA PEL, STEL, and ACTION LEVEL) Alternatives

OSHA is proposing a new TWA PEL for beryllium of 0.2 μg/m^3 and a STEL of 2.0 μg/m^3 for all application groups covered by the rule. OSHA's proposal is based on the requirements of the Occupational Safety and Health Act (OSH Act) and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act, OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so. See Section II of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

Paragraph (c) of the proposed standard establishes two PELs for beryllium in all forms, compounds, and mixtures: An 8-hour TWA PEL of 0.2 μg/m³ (proposed paragraph (c)(1)), and a 15-minute short-term exposure limit (STEL) of 2.0 μg/m³ (proposed paragraph (c)(2)). OSHA has defined the action level for the proposed standard as an airborne concentration of beryllium of 0.1 μg/m³ calculated as an eight-hour TWA (proposed paragraph (b)). In this proposal, as in other standards, the action level has been set at one-half of the TWA PEL.

As discussed in this preamble explanation of paragraph (c) in Section XVIII, Summary and Explanation of the Proposed Standard, OSHA is considering three regulatory alternatives that would modify the PELs for the proposed standard.

Regulatory Alternative #3 would modify the proposed STEL to be five times the TWA PEL, as is typical for OSHA standards that have STELs. A STEL five times the TWA PEL has more practical effect because a STEL ten times the TWA PEL will rarely be exceeded without also driving exposures above the TWA PEL. For example, assuming a background exposure level of 0.1 μg/m³, a STEL ten times the TWA PEL could only be exceeded once in a work shift for 15 minutes without driving exposures above the TWA PEL, whereas a STEL five times the TWA PEL could be exceeded three times before driving exposures above the TWA PEL. OSHA's standards for methylene chloride (29 CFR 1910.1052), acrylonitrile (29 CFR 1910.1045), benzene (29 CFR 1910.1028), ethylene oxide (29 CFR 1910.1047), and 1,3-Butadiene (29 CFR 1910.1051) all set STELs at five times the TWA PEL. Thus, if OSHA promulgates the proposed TWA PEL of 0.2 μg/m³, the accompanying STEL under this regulatory alternative would be set at 1 μg/m³.

As discussed in this preamble at Section V, Health Effects, immunological sensitization can be triggered by short-term exposures. OSHA believes a STEL for beryllium will help reduce the risk of sensitization and CBD in beryllium-exposed employees. For instance, without a STEL, workers' exposures could be as high as 6.4 μg/m³ (32 × 0.2 μg/m³) for 15 minutes under the proposed TWA PEL, if exposures during the remainder of the 8-hour work shift are non-detectable. A STEL serves to minimize high task-based exposures by requiring feasible controls in these situations, and has the added effect of further reducing the TWA exposure.

OSHA requests comment on the range of short-term exposures in covered industries, the types of operations where these are occurring, and on the proposed and alternative STELs, including any data or information that may help OSHA choose between them.

OSHA identified two job categories where workers would be expected to have short-term exposures in the range between the proposed STEL and the STEL under Regulatory Alternative #3 (that is, between 2.0 and 1.0 μg/m³): Furnace operators in nonferrous foundries and material preparation operators in the beryllium oxide ceramics application group. To estimate the costs for this alternative, OSHA judged, conservatively, that all workers in these job categories would need to wear respirators to meet a STEL of 1.0. OSHA also estimated costs for additional regulated areas and medical surveillance for workers in these two job categories. The costs for this alternative are presented in Table IX–19. Total costs rise from $37.6 million to $37.7 million using a 3 percent discount rate and from $39.1 million to $39.3 million using a 7 percent discount rate.

Table IX-19: Cost of Regulatory Alternatives, Alternative 3
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

3% Discount Rate	Total Cost	Incremental Cost Relative to Proposal
Proposed Rule	$37,597,325	——
Alternative 3: STEL=1.0, all else the same	$37,742,714	$145,389
7% Discount Rate	**Total Cost**	**Incremental Cost Relative to Proposal**
Proposed Rule	$39,147,434	——
Alternative 3: STEL=1.0, all else the same	$39,294,987	$147,553

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Under Regulatory Alternative #4, the TWA PEL would be 0.1 μg/m³ with an action level of 0.05 μg/m³. The Agency's preliminary risk assessment indicates that the risks remaining at the proposed TWA PEL of 0.2 μg/m³—while lower than risks at the current TWA PEL—are still significant (see this preamble at Section VIII, Significance of Risk). A

TWA PEL of 0.1 μg/m³ would reduce some of the remaining risks to workers at the proposed PEL. The OSH Act requires the Agency to set its standards to address significant risks of harm to the extent economically and technologically feasible, so OSHA would have very limited flexibility to adopt a higher PEL if a lower PEL is technologically and economically feasible.

While OSHA's preliminary analysis indicates that the proposed TWA PEL of 0.2 μg/m³ is economically and technologically feasible, OSHA has less confidence in the feasibility of a TWA PEL of 0.1 μg/m³. In some industry sectors it is difficult to determine whether a TWA PEL of 0.1 μg/m³ could be achieved in most operations most of the time (see Section IX.D of this preamble, Technological Feasibility). OSHA believes that one way this uncertainty could be resolved would be with additional information on exposure control technologies and the exposure levels that are currently being achieved in these industry sectors. OSHA requests additional data and information to inform its final determinations on feasibility (see Section IX.D of this preamble, Technological Feasibility) and the alternative PELs under consideration.

Regulatory Alternative #5, which would set a TWA PEL at 0.5 μg/m³ and an action level at 0.25 μg/m³, both higher than in the proposal, responds to an issue raised during the Small Business Advocacy Review (SBAR) process conducted in 2007 to consider a draft OSHA beryllium proposed rule that culminated in an SBAR Panel report (SBAR, 2008). That report included a recommendation that OSHA consider both the economic impact of a low TWA PEL and regulatory alternatives that would ease cost burden for small entities. OSHA has provided a full analysis of the economic impact of its proposed PELs (see Chapter VI of the PEA), and Regulatory Alternative #5 addresses the second half of that recommendation. However, the higher 0.5 μg/m³ TWA PEL does not appear to be consistent with the Agency's mandate under the OSH Act to promulgate a lower PEL if it is feasible and could prevent additional fatalities and non-fatal illnesses. The data presented in Table IX–20 below indicate that the lower TWA PEL would prevent additional fatalities and non-fatal illnesses, but nevertheless the Agency solicits comments on this alternative and OSHA's analysis of the costs and benefits associated with it.

Table IX–20 below presents, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed TWA PEL of 0.2 μg/m³ and for the regulatory alternatives of a TWA PEL of 0.1 μg/m³ and a TWA PEL of 0.5 μg/m³ (Regulatory Alternatives #4 and #5, respectively), using alternative discount rates of 3 percent and 7 percent. In addition, the table presents the incremental costs, the incremental benefits, and the incremental net benefits, of going from a TWA PEL of 0.5 μg/m³ to the proposed TWA PEL of 0.2 μg/m³ and then of going from the proposed TWA PEL of 0.2 μg/m³ to a TWA PEL of 0.1 μg/m³. Table IX–20 also breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

OSHA has not made a determination that a TWA PEL of 0.1 μg/m³ would be feasible for all application groups (that is, engineering and work practices would be sufficient to reduce and maintain beryllium exposures to a TWA PEL of 0.1 μg/m³ or below in most operations most of the time in the affected industries). For Regulatory Alternative #4, the Agency attempted to identify engineering controls and their costs for those affected application groups where the technology feasibility analysis in Chapter IV of the PEA indicated that a TWA PEL of 0.1 μg/m³ could be achieved. For those application groups, OSHA costed out the set of feasible controls necessary to meet this alternative PEL. For the rest of the affected application groups, OSHA assumed that all workers exposed between 0.2 μg/m³ and 0.1 μg/m³ would have to wear respirators to achieve compliance with the 0.1 μg/m³ TWA PEL and estimated the associated additional costs for respiratory protection. For all affected industries, OSHA also estimated the costs to satisfy the ancillary requirements specified in the proposed rule for all affected workers under the alternative TWA PEL of 0.1 μg/m³. For both controls and respirators, the unit costs were the same as presented in Chapter V of the PEA.

The estimated benefits for Regulatory Alternative #4 were calculated based on the number of workers identified with exposures between 0.1 and 0.2 μg/m³, using the methods and unit benefit values developed in Chapter VII of the PEA.

As Table IX–20 shows, going from a TWA PEL of 0.5 μg/m³ to a TWA PEL of 0.2 μg/m³ would prevent, annually, an additional 29 beryllium-related fatalities and an additional 15 non-fatal illnesses. This is consistent with OSHA's preliminary risk assessment, which indicates significant risk to workers exposed at a TWA PEL of 0.5 μg/m³; furthermore, OSHA's preliminary feasibility analysis indicates that a lower TWA PEL than 0.5 μg/m³ is feasible. Net benefits of this regulatory alternative versus the proposed TWA PEL of 0.2 μg/m³ would decrease from $538.2 million to $370.0 million using a 3 percent discount rate and from $216.2 million to $144.4 million using 7 percent discount rate.

Table IX–20 also shows the costs and benefits of going from the proposed TWA PEL of 0.2 μg/m³ to a TWA PEL of 0.1 μg/m³. As shown there, going from a TWA PEL of 0.2 μg/m³ to a TWA PEL of 0.1 μg/m³ would prevent an additional 2 beryllium-related fatalities and 1 additional non-fatal illness. Net benefits of this regulatory alternative versus the proposed TWA PEL of 0.2 μg/m³ would increase from $538.2 million to $543.5 million using a 3 percent discount rate and decrease from $216.2 million to $214.9 million using a 7 percent discount rate.

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Table IX-20: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of 0.1 μg/m3 and 0.5 μg/m3 PEL Alternative
Millions ($2010)

	Alternative 4 (PEL = 0.1 μg/m^3, AL = 0.05 μg/m^3)			Alternative 4 Incremental Costs/Benefits			Proposed PEL (PEL = 0.2 μg/m^3, AL = 0.10 μg/m^3)			Alternative 5 Incremental Costs/Benefits			Alternative 5 (PEL = 0.5 μg/m^3, AL = 0.25 μg/m^3)		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Control Costs		$12.9	$13.9		$3.3	$3.5		$9.5	$10.3		$3.6	$3.9		$6.0	$6.5
Respirators		$0.7	$0.7		$0.4	$0.5		$0.2	$0.3		$0.1	$0.1		$0.1	$0.1
Exposure Assessment		$3.8	$3.9		$1.6	$1.5		$2.2	$2.4		$0.3	$0.3		$1.9	$2.1
Regulated areas and Beryllium Work Areas		$0.9	$0.9		$0.3	$0.3		$0.6	$0.7		$0.3	$0.3		$0.3	$0.4
Medical Surveillance		$3.0	$3.1		$0.1	$0.1		$2.9	$3.0		$0.1	$0.1		$2.8	$2.9
Medical Removal		$0.4	$0.5		$0.3	$0.3		$0.1	$0.2		$0.1	$0.1		$0.1	$0.1
Exposure Control Plan		$1.8	$1.8		$0.0	$0.0		$1.8	$1.8		$0.0	$0.0		$1.8	$1.8
Protective Clothing and Equipment		$1.4	$1.4		$0.0	$0.0		$1.4	$1.4		$0.0	$0.0		$1.4	$1.4
Hygiene Areas and Practices		$0.6	$0.6		$0.2	$0.2		$0.4	$0.4		$0.0	$0.0		$0.4	$0.4
Housekeeping		$12.6	$12.9		$0.0	$0.0		$12.6	$12.9		$0.0	$0.0		$12.6	$12.9
Training		$5.8	$5.8		$0.0	$0.0		$5.8	$5.8		$0.0	$0.0		$5.8	$5.8
Total Annualized Costs (point estimate)		**$43.7**	**$45.5**		**$6.1**	**$6.3**		**$37.6**	**$39.1**		**$4.4**	**$4.8**		**$33.2**	**$34.4**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	4			0			4			0			4		
Fatal Chronic Beryllium Disease	94			2			92			29			63		
Beryllium-Related Mortality	98	$584.4	$258.8	2	$11.4	$5.0	96	$573.0	$253.7	29	$171.8	$76.1	67	$401.2	$177.7
Beryllium Morbidity	50	$2.9	$1.6	1	$0.0	$0.0	50	$2.8	$1.6	15	$0.9	$0.5	34	$2.0	$1.1
Monetized Annual Benefits (midpoint estimate)		**$587.3**	**$260.4**		**$11.4**	**$5.1**		**$575.8**	**$255.3**		**$172.7**	**$76.6**		**$403.1**	**$178.8**
Net Benefits		**$543.5**	**$214.9**		**$5.3**	**-$1.3**		**$538.2**	**$216.2**		**$168.2**	**$71.9**		**$370.0**	**$144.4**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years. which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

Informational Alternative Featuring Unchanged PEL but Full Ancillary Provisions

An Informational Analysis: This proposed regulation has the somewhat unusual feature for an OSHA substance-specific health standard that most of the quantified benefits would come from the ancillary provisions rather than from meeting the PEL with engineering controls. OSHA decided to analyze for informational purposes the effect of retaining the existing PEL but applying all of the ancillary provisions, including respiratory protection. Under this approach, the TWA PEL would remain at 2.0 micrograms per cubic meter, but all of the other proposed provisions (including respiratory protection, which OSHA does not consider an ancillary provision) would be required with their triggers remaining the same as in the proposed rule—either the presence of airborne beryllium at any level (*e.g.*, initial monitoring, written exposure control plan), at certain kinds of dermal exposure (PPE), at the action level of 0.1 μg/m³ (*e.g.*, periodic monitoring, medical removal), or at 0.2 μg/m³ (*e.g.*, regulated areas, respiratory protection, medical surveillance).

Given the record regarding beryllium exposures, this approach is not one OSHA could legally adopt because the absence of a more protective requirement for engineering controls would not be consistent with section 6(b)(5) of the OSH Act, which requires OSHA to ''set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' For that reason, this additional analysis is provided strictly for informational purposes. E.O. 12866 and E.O. 13563 direct agencies to identify approaches that maximize net benefits, and this analysis is purely for the purpose of exploring whether this approach would hold any real promise to maximize net benefits if it was permissible under the OSH Act. It does not appear to hold such promise because an ancillary-provisions-only approach would not be as protective and thus offers fewer benefits than one that includes a lower PEL and engineering controls, and OSHA estimates the costs would be about the same (or slightly lower, depending on certain assumptions) under that approach as under the traditional proposed approach.

On an industry by industry basis, OSHA found that some industries would have lower costs if they could adopt the ancillary-provisions-only approach. Some employers would use engineering controls where they are cheaper, even if they are not mandatory. OSHA does not have sufficient information to do an analysis of the employer-by-employer situations in which there exist some employers for whom the ancillary-provisions-only approach might be cheaper. In the majority of affected industries, the Agency estimates there are no costs saving to the ancillary-provisions-only approach. However, OSHA estimates a total of $2,675,828 per year in costs saving for entire industries where the ancillary-provisions-only approach would be less expensive.

The above discussion does not account for the possibility that the lack of engineering controls would result in higher beryllium exposures for workers in adjacent (non-production) work areas due to the increased level of beryllium in the air. Because of a lack of data, and because the issue did not arise in the other regulatory alternatives OSHA considered (all of which have a PEL of less than 2.0 μg/m³), OSHA did not carefully examine exposure levels in non-production areas for either cost or benefit purposes. To the extent such exposure levels would be above the action level, there would be additional costs for respiratory protection.

The ancillary-provisions-only approach adds uncertainty to the benefits analysis such that the benefits of the rule as proposed may exceed, and perhaps greatly exceed, the benefits of this ancillary-provisions-only approach:

(1) Most exposed individuals would be in respirators, which OSHA considers less effective than engineering controls in preventing employee exposure to beryllium. OSHA last did an extensive review of the evidence on effectiveness of respirators for its APFs rulemaking in 2006 (71 FR 50128–45, August 24, 2006). OSHA has not in the past tried to quantify the size of this effect, but it could partially negate the estimated benefits of 92 CBD deaths prevented per year and 4 lung cancer cases prevented per year by the proposed standard.

(2) As noted above, in the proposal OSHA did not consider benefits caused by reductions in exposure in non-production areas. Unless employers act to reduce exposures in the production areas, the absence of a requirement for such controls would largely negate such benefits from reductions in exposure in the non-productions areas.

(3) OSHA believes that there is a strong possibility that the benefits of the ancillary provisions (a midpoint estimate of eliminating 45 percent of all remaining cases of CBD) would be partially or wholly negated in the absence of engineering controls that would reduce both airborne and surface dust levels. The measured reduction in benefits from ancillary provision was in a facility with average exposure levels of less than 0.2 μg/m³.

Based on these considerations, OSHA believes that the ancillary-provisions-only approach is not one that is likely to maximize net benefits. The costs saving, if any, are estimated to be small, and the difficult-to-measure declines in benefits could be substantial.

3. A Method-of-Compliance Alternative

Paragraph (f)(2) of the proposed rule contains requirements for the implementation of engineering and work practice controls to minimize beryllium exposures in beryllium work areas. For each operation in a beryllium work area, employers must ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure: Material and/or process substitution; ventilated enclosures; local exhaust ventilation; or process controls, such as wet methods and automation. Employers are exempt from using engineering and work practice controls only when they can show that such controls are not feasible or where exposures are below the action level based on two exposure samples taken seven days apart.

These requirements, which are based on the stakeholders' recommended beryllium standard that beryllium industry and union stakeholders submitted to OSHA in 2012 (Materion and United Steelworkers, 2012), address a concern associated with the proposed TWA PEL. OSHA expects that day-to-day changes in workplace conditions, such as workers' positioning or patterns of airflow, may cause frequent exposures above the TWA PEL in workplaces where periodic sampling indicates exposures are between the action level and the TWA PEL. As a result, the default under the standard is that the controls are required until the employer can demonstrate that exposures have not exceeded the action level from at least two separate measurements taken seven days apart.

OSHA believes that substitution or engineering controls such as those outlined in paragraph (f)(2)(i) provide the most reliable means to control variability in exposure levels. However, OSHA also recognizes that the requirements of paragraph (f)(2)(i) are not typical of OSHA standards, which usually require engineering controls only where exposures exceed the TWA PEL or STEL. The Agency is therefore considering Regulatory Alternative #6, which would drop the provisions of (f)(2)(i) from the proposed standard and make conforming edits to paragraphs (f)(2)(ii) and (iii). This regulatory alternative does not eliminate the need for engineering controls to comply with the proposed TWA PEL and STEL, but does eliminate the requirement to use one or more of the specified engineering or work practice controls where exposures equal or exceed the action level. As shown in Table IX–21, Regulatory Alternative #6 would decrease the annualized cost of the proposed rule by about $457,000 using a discount rate of 3 percent and by about $480,000 using a discount rate of 7 percent. OSHA has not been able to estimate the change in benefits resulting from Regulatory Alternative #6 at this time and invites public comment on this issue.

Table IX-21: Cost of Regulatory Alternatives, Alternative 6 (Proposed PEL=0.2, STEL=2.0, AL=0.1)

3% Discount Rate	Total Cost	Incremental Cost Relative to Proposal
Proposed Rule	$37,597,325	——
Alternative 6: Eliminate (f)(2) controls	$37,140,020	-$457,304

7% Discount Rate	Total Cost	Incremental Cost Relative to Proposal
Proposed Rule	$39,147,434	——
Alternative 6: Eliminate (f)(2) controls	$38,667,896	-$479,538

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

4. Regulatory Alternatives That Affect Ancillary Provisions

The proposed standard contains several ancillary provisions (provisions other than the exposure limits), including requirements for exposure assessment, medical surveillance, medical removal, training, and regulated areas or access control. As reported in Chapter V of the PEA, these ancillary provisions account for $27.8 million (about 72 percent) of the total annualized costs of the rule ($37.6 million) using a 3 percent discount rate, or $28.6 million (about 73 percent) of the total annualized costs of the rule ($39.1 million) using a 7 percent discount rate. The most expensive of the ancillary provisions are the requirements for housekeeping and training, with annualized costs of $12.6 million and $5.8 million, respectively, at a 3 percent discount rate ($12.9 million and $5.8 million, respectively, at a 7 percent discount rate).

OSHA's reasons for including each of the proposed ancillary provisions are explained in Section XVIII of this preamble, Summary and Explanation of the Standards.

In particular, OSHA is proposing the requirements for exposure assessment to provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is especially important because workers exposed above the proposed TWA PEL, as well as many workers exposed below the proposed TWA PEL, are at significant risk of death and illness. Medical surveillance would allow for identification of beryllium-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA is proposing regulated areas and access control because they serve to limit exposure to beryllium to as few employees as possible. OSHA is proposing worker training to ensure that employers inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize their exposure to beryllium. Worker training on beryllium-related work practices is particularly important in controlling beryllium exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA has examined a variety of regulatory alternatives involving changes to one or more of the proposed ancillary provisions. The incremental cost of each of these regulatory alternatives and its impact on the total costs of the proposed rule is summarized in Table IX–22 at the end of this section. OSHA has preliminarily determined that several of these ancillary provisions will increase the benefits of the proposed rule, for example, by helping to ensure the TWA PEL is not exceeded or by lowering the risks to workers given the significant risk remaining at the proposed TWA PEL. However, except for Regulatory Alternative #7 (involving the elimination of all ancillary provisions), OSHA did not estimate changes in monetized benefits for the regulatory alternatives that affect ancillary provisions. Two regulatory alternatives that involve all ancillary provisions are presented below (#7 and #8), followed by regulatory alternatives for exposure monitoring (#9, #10, and #11), for regulated areas (#12), for personal protective clothing and equipment (#13), for medical surveillance (#14 through #21), and for medical removal (#22).

a. All Ancillary Provisions

The SBAR Panel recommended that OSHA analyze a PEL-only standard as a regulatory alternative. The Panel also recommended that OSHA consider not applying ancillary provisions of the standard where exposure levels are low so as to minimize costs for small businesses (SBAR, 2008). In response to these recommendations, OSHA analyzed Regulatory Alternative #7, a PEL-only standard, and Regulatory Alternative #8, which would apply ancillary provisions of the beryllium standard only where exposures exceed the proposed TWA PEL of 0.2 $\mu g/m^3$ or the proposed STEL of 2 $\mu g/m^3$.

Regulatory Alternative #7 would solely update 1910.1000 Tables Z–1 and Z–2, so that the proposed TWA PEL and STEL would apply to all workers in general industry. This alternative would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, medical removal, PPE, housekeeping, training, and regulated areas or access control. Under this regulatory alternative, OSHA estimates that the costs for the proposed ancillary provisions of the rule (estimated at $27.8 million annually at a 3 percent discount rate) would be eliminated. In order to meet the PELs, employers would still commonly need to do monitoring, train workers on the use of controls, and set up some kind of regulated areas to indicate where respirator use would be required. It is also likely that, under this alternative, many employers would follow the recommendations of Materion and the United Steelworkers to provide medical surveillance, PPE, and other protective measures for their workers (Materion and USW, 2012). OSHA has not attempted to estimate the extent to which these ancillary-provision costs would be incurred if they were not formally required or whether any of these costs under Regulatory Alternative #7 would reasonably be attributable to the proposed rule. OSHA welcomes comment on the issue.

OSHA has also estimated the effect of this regulatory alternative on the benefits of the rule. As a result of eliminating all of the ancillary provisions, annualized benefits are estimated to decrease 57 percent, relative to the proposed rule, from $575.8 million to $249.1 million, using a 3 percent discount rate, and from $255.3 million to $110.4 million using a 7 percent discount rate. This estimate follows from OSHA's analysis of benefits in Chapter VII of the PEA, which found that about 57 percent of the benefits of the proposed rule, evaluated at their mid-point value, were attributable to the combination of the ancillary provisions. As these estimates show, OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to beryllium. The stakeholders' recommended standard that representatives of the primary beryllium manufacturing industry and the United Steelworkers union provided to OSHA confirms the importance of ancillary provisions in protecting workers from the harmful effects of beryllium exposure (Materion and USW, 2012). Ancillary provisions such as personal protective clothing and equipment, regulated areas, medical surveillance, hygiene areas, housekeeping requirements, and hazard communication all serve to reduce the risks to beryllium-exposed workers beyond that which the proposed TWA PEL alone could achieve.

Moreover, where there is continuing significant risk at the TWA PEL, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (D.C. Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. Nevertheless, OSHA requests comment on this alternative.

Under Regulatory Alternative #8, several ancillary provisions that the current proposal would require under a variety of exposure conditions (*e.g.,* dermal contact, any airborne exposure, exposure at or above the action level) would instead only apply where exposure levels exceed the TWA PEL or STEL. Regulatory Alternative #8 affects the following provisions of the proposed standard:

—Exposure monitoring: Whereas the proposed standard requires annual monitoring when exposure levels are at or above the action level and at or below the TWA PEL, Regulatory Alternative #8 would require annual exposure monitoring only where exposure levels exceed the TWA PEL or STEL;
—Written exposure control plan: Whereas the proposed standard requires written exposure control plans to be maintained in any facility covered by the standard, Regulatory Alternative #8 would require only facilities with exposures above the TWA PEL or STEL to maintain a plan;
—Housekeeping: Whereas the proposed standard's housekeeping requirements apply across a wide variety of beryllium exposure conditions, Alternative #8 would limit housekeeping requirements to areas and employees with exposures above the TWA PEL or STEL;
—PPE: Whereas the proposed standard requires PPE for employees under a variety of conditions, such as exposure to soluble beryllium or visible contamination with beryllium, Alternative #8 would require PPE only for employees exposed above the TWA PEL or STEL;
—Medical Surveillance: Whereas the proposed standard's medical surveillance provisions require employers to offer medical surveillance to employees with signs or symptoms of beryllium-related health effects regardless of their exposure level, Alternative #8 would require surveillance only for those employees exposed above the TWA PEL or STEL.

To estimate the cost savings for this alternative, OSHA re-estimated the group of workers that would fall under the above provisions and the changes to their scope. Combining these various adjustments along with associated unit costs, OSHA estimates that, under this regulatory alternative, the costs for the proposed rule would decline from $37.6 million to $18.9 million using a 3 percent discount rate and from $39.1 million to $20.0 million using a 7 percent discount rate.

The Agency has not quantified the impact of this alternative on the benefits of the rule. However, ancillary provisions that offer protective measures to workers exposed below the proposed TWA PEL, such as personal protective clothing and equipment, beryllium work areas, hygiene areas, housekeeping requirements, and hazard communication, all serve to reduce the risks to beryllium-exposed workers beyond that which the proposed TWA PEL and STEL could achieve. OSHA's preliminary conclusion is that the requirements triggered by the action level and other exposures below the proposed PELs will result in very real and necessary, but difficult to quantify, further reduction in risk beyond that provided by the PELs alone.

The remainder of this section discusses additional regulatory alternatives that apply to individual ancillary provisions. At this time, OSHA is not able to quantify the effects of these regulatory alternatives on benefits. The Agency solicits comment on the effects of these regulatory alternatives on the benefits of the proposed rule.

b. Exposure Monitoring

Paragraph (d) of the proposed standard, Exposure Monitoring, requires annual monitoring where exposures are at or above the action level and at or below the TWA PEL. It does not require periodic monitoring where exposure levels have been determined to be below the action level, or above the TWA PEL. The rationale for this provision is provided in this preamble discussion of paragraph (a) in Section XVIII, Summary and Explanation of the Proposed Standard. Below is a brief summary, followed by a discussion of three alternatives.

Because of the variable nature of employee exposures to airborne concentrations of beryllium, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to beryllium at levels above the TWA PEL on days when no exposure measurements are made. Even when all measurements on a given day fall at or below the TWA PEL, if those measurements are still at or above the action level, there is a smaller safety margin and a greater chance that on another day, when exposures are not measured, the employee's exposure may exceed the TWA PEL. When exposure measurements are at or above the action level, the employer cannot be reasonably confident that employees have not been exposed to beryllium concentrations in excess of the TWA PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is met or exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring. The proposed action level that would trigger the exposure monitoring is one-half of the TWA PEL, which reflects the Agency's typical approach to setting action levels (see, *e.g.,* Inorganic arsenic (29 CFR 1910.1018), Ethylene oxide (29 CFR 1910.1047), Benzene (29 CFR 1910.1028), and Methylene Chloride (29 CFR 1910.1052)).

Certain other aspects of the proposed periodic monitoring requirements, which the Agency based on the stakeholders' recommended standard submitted by Materion and the United Steelworkers (Materion and USW, 2012), depart significantly from OSHA's usual exposure monitoring requirements. The proposed standard only requires annual monitoring, and does not require periodic monitoring when exposures are recorded above the TWA PEL, whereas most OSHA standards require monitoring at least every 6 months when exposure levels exceed the action level, and every 3 months when exposures are above the TWA PEL. For example, the standards for vinyl chloride (29 CFR 1910.1017), inorganic arsenic (29 CFR 1910.1018), lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), methylene chloride (29 CFR 1910.1052), acrylonitrile (29 CFR 1910.1045), ethylene oxide (29 CFR 1910.1047), and formaldehyde (29 CFR 1910.1048), all specify periodic monitoring at least every six months when exposures are at, or above, the action level. Monitoring is required every three months when exposures exceed the TWA PEL in the standards for methylene chloride, ethylene oxide, acrylonitrile, inorganic arsenic, lead, and vinyl chloride. In the standards for cadmium, 1,3-Butadiene, formaldehyde, benzene and asbestos (29 CFR 1910.1001), monitoring is required every six months when exposures exceed the TWA PEL. In these standards, monitoring workers exposed above the TWA PEL ensures that employers know workers' exposure levels in order to select appropriate respirators and other PPE, and that records of their exposures are available if needed for medical, legal, or epidemiological purposes.

OSHA has examined three regulatory alternatives that would modify the requirements of paragraph (d) to be more similar to OSHA's typical periodic monitoring requirements. Under Regulatory Alternative #9, employers would be required to perform periodic exposure monitoring every 180 days when exposures are at or above the action level or above the STEL, but at or below the TWA PEL. As shown in Table IX–22, Regulatory Alternative #9 would increase the annualized cost of the proposed rule by about $773,000 using either a 3 percent or 7 percent discount rate.

Under Regulatory Alternative #10, employers would be required to perform periodic exposure monitoring every 180 days when exposures are at or above the action level or above the STEL, including where exposures exceed the TWA PEL. As shown in Table IX–22, Regulatory Alternative #10 would increase the annualized cost of the proposed rule by about $929,000 using either a 3 percent or 7 percent discount rate.

Under Regulatory Alternative #11, employers would be required to perform periodic exposure monitoring every 180 days when exposures are at or above the action level, and every 90 days where exposures exceed the TWA PEL or STEL. This alternative is similar to the periodic monitoring requirements in the draft proposed rule presented to the SERs during the 2007 OSHA beryllium SBAR Panel process. Of the exposure monitoring alternatives, it is also the most similar to the exposure monitoring provisions of most other 6(b)(5) standards. As shown in Table IX–22, Regulatory Alternative #11 would increase the annualized cost of the proposed rule by about $1.07 million using either a 3 percent or 7 percent discount rate.

c. Regulated Areas

Proposed paragraph (e) requires employers to establish and maintain beryllium work areas wherever employees are exposed to airborne beryllium, regardless of the level of exposure, and regulated areas wherever airborne concentrations of beryllium exceed the TWA PEL or STEL. Employers are required to demarcate beryllium work areas and regulated areas and limit access to regulated areas to authorized persons.

The SBAR Panel report recommended that OSHA consider dropping or limiting the provision for regulated areas (SBAR, 2008). In response to this recommendation, OSHA examined Regulatory Alternative #12, which would eliminate the requirement that employers establish regulated areas. This alternative is meant only to eliminate the requirement to set up and demarcate specific physical areas: All ancillary provisions would be triggered by the same conditions as under the standard's definition of a ''regulated area.'' For example, under the current proposal, employees who work in regulated areas for at least 30 days annually are eligible for medical surveillance. If OSHA were to remove the requirement to establish regulated areas, the medical surveillance provisions would be altered so that employees who work more than 30 days annually in jobs or areas with exposures that exceed the TWA PEL or STEL are eligible for medical surveillance. This alternative would not eliminate the proposed requirement to establish beryllium work areas. As shown in Table IX–22, Regulatory Alternative #12 would decrease the annualized cost of the proposed rule by about $522,000 using a 3 percent discount rate, and by about $523,000 using a 7 percent discount rate.

d. Personal Protective Clothing and Equipment

Regulatory Alternative #13 would modify the requirements for personal protective equipment (PPE) by requiring appropriate PPE whenever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. This alternative would be broader, and thus more protective, than the PPE requirement in the proposed standard, which requires PPE to be used in three circumstances: (1) Where exposure exceeds the TWA PEL or STEL; (2) where employees' clothing or skin may become visibly contaminated with beryllium; and (3) where employees may have skin contact with soluble beryllium compounds. These PPE requirements were based on the stakeholders' recommended standard that Materion and the United Steelworkers submitted to the Agency (Materion and USW, 2012).

The proposed rule's requirement to use PPE where work clothing or skin may become "visibly contaminated" with beryllium differs from prior standards, which do not require contamination to be visible in order for PPE to be required. While OSHA's language regarding PPE requirements varies somewhat from standard to standard, previous standards tend to emphasize potential for contact with a substance that can trigger health effects via dermal exposure, rather than "visible contamination" with the substance. For example, the standard for chromium (VI) requires the employer to provide appropriate PPE where a hazard is present or is likely to be present from skin or eye contact with chromium (VI) (29 CFR 1910.1026). The lead and cadmium standards require PPE where employees are exposed above the PEL or where there is potential for skin or eye irritation, regardless of airborne exposure level. Under the Methylenedianiline (MDA) standard (29 CFR 1910.1050), PPE must be provided where employees are subject to dermal exposure to MDA, where liquids containing MDA can be splashed into the eyes, or where airborne concentrations of MDA are in excess of the PEL.

OSHA requests comment on the proposed PPE requirements in Regulatory Alternative #13, which would modify the proposed PPE requirements to be similar to the chromium (VI), lead, cadmium, and MDA standards. Because small beryllium particles can pass through intact or broken skin and cause sensitization, limiting the requirements for PPE based on surfaces that are "visibly contaminated" may not adequately protect workers from beryllium exposure. Submicron particles (less than 1 μg in diameter) are not visible to the naked eye and yet may pass through the skin and cause beryllium sensitization. Although solubility may play a role in the level of sensitization risk, the available evidence suggests that contact with insoluble, as well as soluble, beryllium can cause sensitization via dermal contact (see this preamble at Section V, Health Effects). Sensitized workers are at significant risk of developing CBD (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk).

To estimate the cost of Regulatory Alternative #13, OSHA assumed that all at-risk workers, except administrative occupations, would require protective clothing and a pair of work gloves that would need to be replaced annually. The economic analysis of the proposed standard already contained costs for protective clothing for all employees whose clothing might be contaminated by beryllium (the analysis assumed that all clothing contamination would be visible, or the clothing is already provided even if not required by this standard) and gloves for many jobs where workers were expected to be exposed to visible contamination or soluble beryllium; thus OSHA estimated the cost of this alternative as the cost of providing gloves for the remainder of the jobs where workers have potential for skin exposure even in the absence of visible contamination. As shown in Table IX–22, Regulatory Alternative #13 would increase the annualized cost of the proposed rule by about $138,000 using either a 3 percent or 7 percent discount rate.

e. Medical Surveillance

The proposed requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are exposed to beryllium in a regulated area (*i.e.,* above the proposed TWA PEL or STEL) for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and (2) CT scans for employees who were exposed above the proposed TWA PEL or STEL for more than 30 days in a 12-month period for 5 years or more. The proposed standard would require annual medical exams to be provided for employees exposed in a regulated area for 30 days or more per year and for employees showing signs or symptoms of CBD, while tests for beryllium sensitization and CT scans would be provided to eligible employees biennially.

OSHA estimated in Chapter V of the PEA that the medical surveillance requirements would apply to 4,528 workers in general industry, of whom 387 already receive that surveillance.[43] In Chapter V, OSHA estimated the costs of medical surveillance for the remaining 4,141 workers who would now have such protection due to the proposed standard. The Agency's preliminary analysis indicates that 4 workers with beryllium sensitization and 6 workers with CBD will be referred to pulmonary specialists annually as a result of this medical surveillance. Medical surveillance is particularly important for this rule because beryllium-exposed workers, including many workers exposed below the proposed PELs, are at significant risk of illness. OSHA did not estimate, and the benefits analysis does not include, monetized benefits resulting from early discovery of illness.

OSHA has examined eight regulatory alternatives (#14 through #21) that would modify the proposed rule's requirements for employee eligibility, the tests that must be offered, and the frequency of periodic exams. Medical surveillance was a subject of special concern to SERs during the SBAR Panel process, and the SBAR Panel offered many comments and recommendations related to medical surveillance for OSHA's consideration. Some of the Panel's concerns have been partially addressed in this proposal, which was modified since the SBAR Panel was convened (see this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, for more detailed discussion). Several of the regulatory alternatives presented here (#16, #18, and #20) also respond to recommendations by the SBAR Panel to reduce burdens on small businesses by dropping or reducing the frequency of medical surveillance requirements. OSHA is also considering several additional regulatory alternatives that would increase the frequency of surveillance or the range of employees covered by medical surveillance (#14, #15, #17, #19, and #21).

OSHA has preliminarily determined that a significant risk of beryllium sensitization, CBD, and lung cancer exists at exposure levels below the proposed TWA PEL and that there is evidence that beryllium sensitization can occur even from short-term exposures (see this preamble at Section V, Health Effects, and Section VIII,

[43] See current compliance rates for medical surveillance in Chapter V of the PEA, Table V–15.

Significance of Risk). The Agency therefore anticipates that more employees would develop adverse health effects without receiving the benefits of early intervention in the disease process because they are not eligible for medical surveillance (see this preamble at Section V, Health Effects).

OSHA is considering three regulatory alternatives that would expand eligibility for medical surveillance to a broader group of employees than those eligible under the proposed standard. Under Regulatory Alternative #14, medical surveillance would be available to employees who are exposed to beryllium above the proposed TWA PEL or STEL, including employees exposed for fewer than 30 days per year. Regulatory Alternative #15 would expand eligibility for medical surveillance to employees who are exposed to beryllium above the proposed action level, including employees exposed for fewer than 30 days per year. Regulatory Alternative #21 would extend eligibility for medical surveillance as set forth in proposed paragraph (k) to all employees in shipyards, construction, and general industry who meet the criteria of proposed paragraph (k)(1). However, all other provisions of the standard would be in effect only for employers and employees that fall within the scope of the proposed rule. Each of these alternatives would provide surveillance to fewer workers (and cost less to employers) than the draft proposed rule presented to SERs during the SBAR Panel process, which included skin contact as a trigger and would therefore cover most beryllium-exposed workers in general industry, construction, and maritime. These alternatives would provide more surveillance (and cost more to employers) than the medical surveillance requirements in the current proposal.

To estimate the cost of Regulatory Alternative #14, OSHA assumed that 1 person would enter regulated areas for less than 30 days a year for every 4 people working in regulated areas on a regular basis. Thus, this alternative includes costs for an incremental number of annual medical exams equal to 25 percent of the number of workers estimated to be working in regulated areas after the standard is promulgated. As shown in Table IX–22, Regulatory Alternative #14 would increase the annualized cost of the proposed rule by about $38,000 using either a 3 percent or 7 percent discount rate.

To estimate the cost of Regulatory Alternative #15, OSHA assumed that all workers exposed above the action level before the standard would continue to be exposed after the standard is promulgated. OSHA also assumed that 1 person would enter areas exceeding the action level for fewer than 30 days a year for every 4 people working in an area exceeding the action level on a regular basis. Thus, this alternative includes costs for medical exams for the number of workers exposed between the action level and the TWA PEL as well as an incremental 25 percent of all workers exposed above the action level. As shown in Table IX–22, Regulatory Alternative #15 would increase the annualized cost of the proposed rule by about $3.9 million using a discount rate of 3 percent, and by about $4.0 million using a discount rate of 7 percent.

For Alternative #21, OSHA is considering two different scenarios to estimate costs: One where the TWA PEL for the groups outside the scope of the proposed standard changes from 2 μg/m³ to 0.2 μg/m³, as in Regulatory Alternative #2; and one where the TWA PEL remains at the current level of 2.0 μg/m³. For costing purposes, these have been designated as Regulatory Alternative #21a and Regulatory Alternative #21b, respectively.

For Regulatory Alternative #21a, medical surveillance above the proposed TWA PEL of 0.2, OSHA estimated the cost of extending medical surveillance to workers in aluminum production, abrasive blasting in construction, maritime abrasive blasting, maritime welding, and coal fired power plants, assuming that all feasible controls are in place to reduce exposures to the proposed TWA PEL of 0.2 μg/m³ or lower. OSHA did not include control costs to achieve compliance with a TWA PEL of 0.2 μg/m³, as these costs were addressed in Regulatory Alternative #2. (For a summary of the estimates of affected workers and the exposure profile, see the discussion accompanying Regulatory Alternative # 2.) As shown in Table IX–22, Regulatory Alternative #21a would increase the annualized cost of the proposed rule by about $4.4 million using a 3-percent discount rate and $4.5 million using a 7-percent discount rate.

For Alternative #21b, medical surveillance above the current TWA PEL of 2.0 μg/m³, OSHA estimated that all abrasive blasters in construction and shipyards who are currently above the current TWA PEL of 2.0 μg/m³would be eligible for medical surveillance. As discussed under alternative #2, outside of abrasive blasting, OSHA has identified a small group of maritime welders who may be exposed to beryllium above the current TWA PEL in their work. Of these workers, 90 percent would be below the current TWA PEL if their employers instituted all feasible engineering and work practice controls to meet the existing standard. If they came into compliance with the current PELs, they would not be required to offer employees medical surveillance under Alternative #21b. OSHA estimated that the other 10 percent of these maritime welders, and 10 percent of workers in primary aluminum production and coal-fired power generation, with all feasible engineering controls and work practices in place, would still be exposed above the current TWA PEL and would be eligible for medical surveillance under Alternative #21b. OSHA's customary method in preparing an economic analysis of a new standard is to cost out the incremental cost of the new standard assuming full compliance with existing standards. Finally, OSHA estimated that 15 percent of the workers excluded from the scope of the proposed standard absent the alternative would show signs and symptoms of CBD or be exposed in emergencies, and so would be eligible for medical surveillance. As shown in Table IX–22, under these assumptions Regulatory Alternative #21b would increase the annualized cost of the proposed rule by about $3.0 million using a 3-percent discount rate and $3.1 million using a 7-percent discount rate. The Agency notes that, as abrasive blasters are the primary application group with beryllium exposure in construction and shipyards, it is unlikely that as many as 15 percent of other workers would show signs and symptoms of beryllium exposure or be exposed to beryllium in an emergency. Thus, OSHA believes the stated cost of about $3.0 million may overestimate the true costs for this alternative and invites comment on this issue.

In response to concerns raised during the SBAR Panel process about testing requirements, OSHA is considering two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. As shown in Table IX–22, this alternative would decrease the annualized cost of the proposed rule by about $710,000 using a discount rate of 3 percent, and by about $724,000 using a discount rate of 7 percent.

Regulatory Alternative #18 would eliminate the CT scan requirement from the proposed rule. This alternative would decrease the annualized cost of the proposed rule by about $472,000 using a discount rate of 3 percent, and by about $481,000 using a discount rate of 7 percent.

OSHA is considering several alternatives to the proposed frequency of sensitization testing, CT scans, and general medical examinations. The frequency of periodic medical surveillance is an important factor in the efficacy of the surveillance in protecting worker health. Regular, appropriately frequent medical surveillance promotes awareness of beryllium-related health effects and early intervention in disease processes among workers. In addition, the longer the time interval between when a worker becomes sensitized and when the worker's case is identified in the surveillance program, the more difficult it will be to identify and address the exposure conditions that led to sensitization. Therefore, reducing the frequency of sensitization testing would reduce the usefulness of the surveillance information in identifying problem areas and reducing risks to other workers. These concerns must be weighed against the costs and other burdens of surveillance.

Regulatory alternative #17 would require employers to offer annual testing for beryllium sensitization to eligible employees, as in the draft proposal presented to the SBAR Panel. As shown in Table IX–22, this alternative would increase the annualized cost of the proposed rule by about $392,000 using a discount rate of 3 percent, and by about $381,000 using a discount rate of 7 percent.

Regulatory Alternative #19 would similarly increase the frequency of periodic CT scans from biennial to annual scans, increasing the annualized cost of the proposed rule by about $459,000 using a discount rate of 3 percent, and by about $450,000 using a discount rate of 7 percent.

Finally, under Regulatory Alternative #20, employers would only have to provide all periodic components of the medical surveillance exams biennially to eligible employees. This alternative would decrease the annualized cost of the proposed rule by about $446,000 using a discount rate of 3 percent and by about $433,000 using a discount rate of 7 percent.

f. Medical Removal

Under paragraph (l) of the proposed standard, Medical Removal, employees in jobs with exposure at or above the action level become eligible for medical removal when they are diagnosed with CBD or confirmed positive for beryllium sensitization. When an employee chooses removal, the employer is required to remove the employee to comparable work in an environment where beryllium exposure is below the action level if such work is available and the employee is either already qualified or can be trained within one month. If comparable work is not available, paragraph (l) would require the employer to place the employee on paid leave for six months or until comparable work becomes available (whichever comes first). Or, rather than choosing removal, an eligible employee could choose to remain in a job with exposure at or above the action level and wear a respirator. The proposed medical removal protection (MRP) requirements are based on the stakeholders' recommended beryllium standard that representatives of the beryllium production industry and the United Steelworkers union submitted to OSHA in 2012 (Materion and USW, 2012).

The scientific information on effects of exposure cessation is limited at this time, but the available evidence suggests that removal from exposure can be beneficial for individuals who are sensitized or have early-stage CBD (see this preamble at Section VIII, Significance of Risk). As CBD progresses, symptoms become serious and debilitating. Steroid treatment is less effective at later stages, once fibrosis has developed (see this preamble at Section VIII, Significance of Risk). Given the progressive nature of the disease, OSHA believes it is reasonable to conclude that removal from exposure to beryllium will benefit sensitized employees and those with CBD. Physicians at National Jewish Health, one of the main CBD research and treatment sites in the US, ''consider it important and prudent for individuals with beryllium sensitization and CBD to minimize their exposure to airborne beryllium,'' and ''recommend individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry to have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour time-weighted average'' (NJMRC, 2013). However, OSHA is aware that MRP may prove costly and burdensome for some employers and that the scientific literature on the effects of exposure cessation on the development of CBD among sensitized individuals and the progression from early-stage to late-stage CBD is limited.

The SBAR Panel report included a recommendation that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (SBAR, 2008). In response to this recommendation, OSHA analyzed Regulatory Alternative #22, which would remove the proposed requirement that employers offer MRP. As shown in Table IX–22, this alternative would decrease the annualized cost of the proposed rule by about $149,000 using a discount rate of 3 percent, and by about $166,000 using a discount rate of 7 percent.

Table IX-22: Cost of Regulatory Alternatives Affecting Ancillary Provisions
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

3% Discount Rate	Total Cost	Incremental Cost Relative to Proposal	Benefits	Incremental Benefits Relative to the Proposal
Proposed Rule	$37,597,325	——	$575,826,633	——
Alternative 1b: Include Trace Contaminants; Offer Opt Out for Trace Contaminant Industries with Objective Data	$49,863,812	$12,266,488		
Alternative 7: Update Z table 1910.1000 only, (No ancillary provisions)	$9,789,873	-$27,807,451	$249,099,326	-$326,727,308
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	$18,917,028	-$18,680,297		
Alternative 9: semiannual monitoring when exposure between AL/STEL and PEL	$38,370,615	$773,291		
Alternative 10: semiannual monitoring when exposure above AL/STEL	$38,526,658	$929,333		
Alternative 11: semiannual monitoring when exposure above AL/STE, quarterly monitoring when exposure above PEL	$38,670,043	$1,072,719		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	$37,075,072	-$522,252		
Alternative 13: PPE wherever there is contact with beryllium or beryllium contaminated surfaces	$37,735,352	$138,027		
Alternative 14: No 30 day minimum for medical surveillance in regulated areas	$37,635,572	$38,248		
Alternative 15: No 30 day minimum for medical surveillance and triggered by AL	$41,466,339	$3,869,014		
Alternative 16: No BeLPTs in medical surveillance	$36,887,307	-$710,018		
Alternative 17: BeLPTs part of annual exam, rather than biannually.	$37,989,639	$392,314		
Alternative 18: No CT Scans	$37,124,958	-$472,367		
Alternative 19: Annual CT scans rather than biannual	$38,056,056	$458,732		
Alternative 20: All periodic components of medical surveillance are biannual	$37,150,975	-$446,349		
Alternative 21a: Medical Surveillance (PEL 0.2)	$42,042,633	$4,445,308		
Alternative 21b: Medical Surveillance (PEL 2.0)	$40,573,150	$2,975,826		
Alternative 22: No medical removal protection	$37,448,499	-$148,826		

Table IX-22: Cost of Regulatory Alternatives Affecting Ancillary Provisions, Continued
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

7% Discount Rate	Total Cost	Incremental Cost Relative to Proposal	Benefits	Incremental Benefits Relative to the Proposal
Proposed Rule	$39,147,434	—	$255,334,295	—
Alternative 1b: Include Trace Contaminants; Offer Opt Out for Trace Contaminant Industries with Objective Data	$51,781,738	$12,634,305		
Alternative 7: Update Z table 1910.1000 only, (No ancillary provisions)	$10,586,317	-$28,561,116	$110,383,499	-$144,950,796
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	$19,986,867	-$19,160,567		
Alternative 9: semiannual monitoring when exposure between AL/STEL and PEL	$39,920,724	$773,291		
Alternative 10: semiannual monitoring when exposure above AL/STEL	$40,076,767	$929,333		
Alternative 11: semiannual monitoring when exposure above AL/STE, quarterly monitoring when exposure above PEL	$40,220,152	$1,072,719		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	$38,624,295	-$523,139		
Alternative 13: PPE wherever there is contact with beryllium or beryllium contaminated surfaces	$39,285,461	$138,027		
Alternative 14: No 30 day minimum for medical surveillance in regulated areas	$39,185,910	$38,477		
Alternative 15: No 30 day minimum for medical surveillance and triggered by AL	$43,162,902	$4,015,468		
Alternative 16: No BeLPTs in medical surveillance	$38,423,316	-$724,117		
Alternative 17: BeLPTs part of annual exam, rather than biannually.	$39,528,226	$380,793		
Alternative 18: No CT Scans	$38,666,205	-$481,229		
Alternative 19: Annual CT scans rather than biannual	$39,597,303	$449,870		
Alternative 20: All periodic components of medical surveillance are biannual	$38,714,200	-$433,233		
Alternative 21a: Medical Surveillance (PEL 0.2)	$43,708,041	$4,560,608		
Alternative 21b: Medical Surveillance (PEL 2.0)	$42,198,735	$3,051,301		
Alternative 22: No medical removal protection	$38,981,379	-$166,054		

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

5. Timing

As proposed, the new standard would become effective 60 days following publication in the **Federal Register**. The majority of employer duties in the standard would become enforceable 90 days following the effective date. Change rooms, however, would not be required until one year after the effective date, and the deadline for engineering controls would be no later than two years after the effective date.

OSHA invites suggestions for alternative phase-in schedules for engineering controls, medical surveillance, and other provisions of the standard. Although OSHA did not explicitly develop or quantitatively analyze any other regulatory alternatives involving longer-term or more complex phase-ins of the standard (possibly involving more delayed implementation dates for small businesses), some general outcomes are likely. For example, a longer phase-in time would have several advantages, such as reducing initial costs of the standard or allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However, a longer phase-in would also postpone and reduce the benefits of the standard. Suggestions for alternatives may apply to specific industries (*e.g.,* industries where first-year or annualized cost impacts are highest), specific size-classes of employers (*e.g.,* employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule.

OSHA requests comments on all these regulatory alternatives, including the Agency's regulatory alternatives presented above, the Agency's analysis of these alternatives, and whether there are other regulatory alternatives the Agency should consider.

I. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended in 1996, requires the preparation of an Initial Regulatory Flexibility Analysis (IRFA) for proposed rules where there would be a significant economic impact on a substantial number of small entities. (5 U.S.C. 601–612). Under the provisions of the law, each such analysis shall contain:

1. A description of the impact of the proposed rule on small entities;
2. A description of the reasons why action by the agency is being considered;
3. A succinct statement of the objectives of, and legal basis for, the proposed rule;
4. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
5. A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
6. An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule;
7. A description and discussion of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities, such as:
(a) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
(b) The clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
(c) The use of performance rather than design standards; and
(d) An exemption from coverage of the rule, or any part thereof, for such small entities.

5 U.S.C. 603, 607. The Regulatory Flexibility Act further states that the required elements of the IRFA may be performed in conjunction with, or as part of, any other agenda or analysis required by any other law if such other analysis satisfies the provisions of the IRFA. 5 U.S.C. 605.

While a full understanding of OSHA's analysis and conclusions with respect to costs and economic impacts on small entities requires a reading of the complete PEA and its supporting materials, the IRFA summarizes the key aspects of OSHA's analysis as they affect small entities.

1. A Description of the Impact of the Proposed Rule on Small Entities

Section IX.F of this preamble summarized the impacts of the proposed rule on small entities. Table IX–9 showed costs as a percentage of profits and revenues for small entities, classified as small by the Small Business Administration, and Tables IX–10 showed costs as a percentage of revenues and profits for business entities with fewer than 20 employees. (The costs in these tables were annualized using a discount rate of 3 percent.)

2. A Description of the Reasons Why Action by the Agency Is Being Considered

Chronic beryllium disease (CBD) is a hypersensitivity, or allergic reaction, to beryllium that leads to a chronic inflammatory disease of the lungs. It takes months to years after initial beryllium exposure before signs and symptoms of CBD occur. Removing an employee with CBD from the beryllium source does not always lead to recovery. In some cases CBD continues to progress following removal from beryllium exposure. CBD is not a chemical pneumonitis but an immune-mediated granulomatous lung disease. OSHA's preliminary risk assessment, presented in Section VI of this preamble, indicates that there is significant risk of beryllium sensitization and chronic beryllium disease from a 45-year (working life) exposure to beryllium at the current TWA PEL of 2 μg/m³. The risk assessment further indicates that there is significant risk of lung cancer to workers exposed to beryllium at the current TWA PEL of 2 μg/m³. The proposed standard, with a lower PEL of .2 μg/m³, will help to address these health concerns.

For CBD to occur, an employee must first become sensitized (*i.e.,* allergic) to beryllium. Once an employee is sensitized, inhaled beryllium that deposits and persists in the lung may trigger a cell-mediated immune response (*i.e.,* hypersensitivity reaction) that results in the formation of a type of lung scarring known as a granuloma. The granuloma consists of a localized mass of immune and inflammatory cells that have formed around a beryllium particle lodged in the interstitium, which is tissue between the air sacs that can be affected by fibrosis or scarring. With time, the granulomas spread and can lead to chronic cough, shortness of breath (especially upon exertion), fatigue, abnormal pulmonary function, and lung fibrosis.

While CBD primarily affects the lungs, it can also involve other organs such as the liver, skin, spleen, and kidneys. As discussed in more detail in this preamble, some studies demonstrate that sensitization and CBD cases have occurred in workplaces that use a wide range of beryllium compounds, including several beryllium salts, refined beryllium metal, beryllium oxide, and the beryllium alloys. While water-soluble and insoluble beryllium compounds have the potential to cause sensitization, it has been suggested that CBD is the result of occupational exposure to beryllium oxide and other water-insoluble berylliums rather than exposure to water-soluble beryllium or beryllium ores. However, there are inadequate data, at this time, on employees selectively exposed to specific beryllium compounds to eliminate a potential CBD concern for any particular form of this metal. Regardless of the type of beryllium compound, in order to cause respiratory disease the inhaled beryllium must contain particulates that are small enough to reach the bronchoalveolar region of the lung where the disease takes place (OSHA, 2007).

Some research suggests that skin exposure to small beryllium particles or beryllium-containing solutions may also lead to sensitization (Tinkle et al., 2003). These additional risk factors may explain why some individuals with seemingly brief, low level exposure to airborne beryllium become sensitized while others with long-term high exposures do not. Other studies indicate that even though employees sensitized to beryllium do not exhibit clinical symptoms, their immune function is altered such that inhalation to previously safe levels of beryllium can now trigger serious lung disease (Kreiss *et al.,* 1996; Kreiss *et al.,* 1997; Kelleher *et al.,* 2001 and Rossman, 2001).

In the 1980s, the laboratory blood test known as the BeLPT was developed. The test substantially improved identification of beryllium-sensitized individuals and provides an opportunity to diagnose CBD at an early stage. The BeLPT measures the ability of immune cells (*i.e.,* peripheral blood lymphocytes) to react with beryllium. It has been reported that the BeLPT can identify 70 to 90 percent of those sensitized with a high specificity (approximately 1 to 3 percent false positives) (Newman *et al.,* 2001; Stange et al., 2004).

An employee with an abnormal BeLPT (*i.e.,* the individual is sensitized) can undergo fiber-optic bronchoscopy to obtain a lung biopsy sample from which granulomatous lung inflammation can be pathologically observed prior to the onset of symptoms. The combination of a confirmed abnormal BeLPT (that is, a second abnormal result from the BeLPT) and microscopic evidence of granuloma formation is considered diagnostic for CBD. The BeLPT assists in differentiating CBD from other granulomatous lung diseases (*e.g.,* sarcoidosis) with similar lung pathology. This pre-clinical diagnostic tool provides opportunities for early intervention that did not exist when diagnosis relied on clinical symptoms, chest x-rays, and abnormal pulmonary function (OSHA, 2007).

The BeLPT/lung biopsy diagnostic approach has been utilized in several occupational surveys and surveillance programs over the last fifteen years. The findings have expanded scientific awareness of sensitization and CBD prevalence among beryllium employees and provided a better understanding of its work-related risk factors. Some of the more informative studies come from nuclear weapons facilities operated by the Department of Energy (Viet *et al.,* 2000; Stange *et al.,* 2001; DOE/HSS Report, 2006), a beryllium ceramics plant in Arizona (Kreiss *et al.,* 1996; Henneberger *et al.,* 2001; Cummings *et al.,* 2007), a beryllium production plant in Ohio (Kreiss *et al.,* 1997; Kent *et al.,* 2001), a beryllium machining facility in Alabama (Kelleher *et al.,* 2001; Madl *et al.,* 2007), and a beryllium alloy plant (Shuler *et al.,* 2005) and another beryllium processing plant (Rosenman *et al.,* 2005), both in Pennsylvania. The prevalence of beryllium sensitization from these surveyed workforces generally ranged from 1 to 10 percent with a prevalence of CBD from 0.6 to 8 percent.

In most of the surveys discussed above, 36–100 percent of those workers who initially tested positive with the BeLPT were diagnosed with CBD upon pathological evaluation. Most of these workers diagnosed with CBD had worked four to10 years on the job, although some were diagnosed within several months of employment. Surveys that found a high proportion (*e.g.,* larger than 50 percent) of CBD among the sensitized employees were from facilities with a large number of employees who had been exposed to respirable beryllium for many years. It has been estimated from ongoing surveillance of sensitized individuals, with an average follow-up time of 4.5 years, that 37 percent of beryllium-exposed employees were estimated to progress to CBD (Newman *et al,* 2005). Another study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that only about 20 percent of sensitized individuals employed less than five years eventually were diagnosed with CBD while 40 percent of sensitized employees employed ten years or more developed CBD (Stange *et al.,* 2001). This observation, along with the study findings that CBD prevalence increases with cumulative exposure (described below), suggests that sensitized employees who acquire a higher lung burden of beryllium may be at greater risk of developing CBD than sensitized employees who have lesser amounts of beryllium in their lungs.

The greatest prevalence of sensitization and CBD were reported for production processes that involve heating beryllium metal (*e.g.,* furnace operations, hot wire pickling, and annealing) or generating and handling beryllium powder (*e.g.,* machining, forming, firing). For example, nearly 15 percent of machinists at the Arizona beryllium ceramics plant were sensitized, compared to just 1 percent of workers who never worked in machining (Kreiss *et al.,* 1996). A low prevalence of sensitization and CBD was reported among current employees at the Department of Energy (DOE) clean-up sites where beryllium was once used in the production of nuclear weapons (DOE/OSS, 2006). These sites have been subject to the DOE CBD-prevention programs since 1999. While the prevalence of sensitization and CBD in non-production jobs was less, cases of CBD were found among secretaries, office employees, and security guards. CBD cases have also been reported in downstream uses of beryllium such as dental laboratories and metal recycling (OSHA, 2007).

The potential importance of respirable and ultrafine beryllium particulates in the onset of CBD is illustrated in studies of employees at a large beryllium metal, alloy, and oxide production plant in Ohio. An initial cross-sectional survey reported that the highest prevalence of sensitization and CBD occurred among workers employed in beryllium metal production, even though the highest airborne total mass concentrations of beryllium were generally among employees operating the beryllium alloy furnaces in a different area of the plant (Kreiss *et al.,* 1997). Preliminary follow-up investigations of particle size-specific sampling at five furnace sites within the plant determined that the highest respirable (*e.g.,* particles less than10 μm in diameter) and alveolar-deposited (*e.g.,* particles less than1 μm in diameter) beryllium mass and particle number concentrations, as collected by a general area impactor device, were measured at the beryllium metal production furnaces rather than the beryllium alloy furnaces (Kent *et al.,* 2001; McCawley *et al.,* 2001). A statistically significant linear trend was reported between the above alveolar-deposited particle mass concentration and prevalence of CBD and sensitization in the furnace production areas. On the other hand, a linear trend was not found for CBD and sensitization prevalence and total beryllium mass concentration. The authors concluded that these findings suggest that alveolar-deposited particles may be a more relevant exposure metric for predicting the incidence of CBD or sensitization than the total mass concentration of airborne beryllium (OSHA, 2007).

Several epidemiological cohort studies have reported excess lung cancer mortality among workers employed in U.S. beryllium production and processing plants during the 1930s to 1960s. The largest and most comprehensive study investigated the mortality experience of over 9,000 workers employed in seven different beryllium processing plants over a 30 year period (Ward *et. al.,* 1992). The employees at the two oldest facilities (*i.e.,* Lorain, OH and Reading, PA) were found to have significant excess lung cancer mortality relative to the U.S. population. These two plants were believed to have the highest exposure levels to beryllium. A different analysis of the lung cancer mortality in this cohort using various local reference populations and alternate adjustments for smoking generally found smaller, non-significant, excess mortality among the beryllium employees (Levy *et al.,* 2002). All the cohort studies are limited by a lack of job history and air monitoring data that would allow investigation of mortality trends with beryllium exposure.

The weight of evidence indicates that beryllium compounds should be regarded as potential occupational lung carcinogens, and OSHA has regulated it since 1974. Other organizations, such as the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists (ACGIH) have reached similar conclusions with respect to the carcinogenicity of beryllium.

3. A Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The objective of the proposed beryllium standard is to reduce the number of fatalities and illnesses occurring among employees exposed to beryllium. This objective will be achieved by requiring employers to install engineering controls where appropriate and to provide employees with the equipment, respirators, training, medical surveillance, and other protective measures to perform their jobs safely. The legal basis for the rule is the responsibility given the U.S.

Department of Labor through the Occupational Safety and Health Act of 1970 (OSH Act). The OSH Act provides that, in promulgating health standards dealing with toxic materials or harmful physical agents, the Secretary ''shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' 29 U.S.C. 655(b)(5). See Section II of this preamble for a more detailed discussion.

4. A Description of, and an Estimate of, the Number of Small Entities to Which the Proposed Rule Will Apply

OSHA has completed a preliminary analysis of the impacts associated with this proposed rule, including an analysis of the type and number of small entities to which the proposed rule would apply. In order to determine the number of small entities potentially affected by this rulemaking, OSHA used the definitions of small entities developed by the Small Business Administration (SBA) for each industry.

The proposed standard would impact occupational exposures to beryllium in all forms, compounds, and mixtures in general industry. Based on the definitions of small entities developed by SBA for each industry, the proposal is estimated to potentially affect a total of 3,741 small entities as shown in Table IX–1 in Chapter IX of the PEA.

The Agency also estimated costs and conducted a screening analysis for very small employers (those with fewer than 20 employees). OSHA estimates that approximately 2,875 very small entities would be affected by the proposed standard, as shown in Table III–13 in Chapter III of the PEA.

5. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

Tables IX–23 and IX–24 show the average costs of the proposed standard by NAICS code and by compliance requirement (PEL/STEL or ancillary provisions) for, respectively, small entities (classified as small by SBA) and very small entities (those with fewer than 20 employees). Total costs are reported as N/A for NAICS codes with no affected entities in the relevant size classification. The weighted average cost per small entity for the proposed rule would be about $8,638 annually, with PEL/STEL compliance accounting for about 23 percent of the costs and ancillary provisions accounting for about 77 percent of the costs.

The weighted average cost per very small entity for the proposed rule would be about $2,212 annually, with PEL/STEL compliance accounting for about 39 percent of the costs and ancillary provisions accounting for about 61 percent of the costs.

Table IX-23
Average Costs for Small Entities Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL Compliance (Includes Respirators)	Ancillary Provisons	Total
Beryllium Production					
	331419	Primary Smelting and Refining of Nonferrous Metals	N/A	N/A	N/A
Beryllium Oxide Ceramics and Composites					
	327113a	Porcelain electrical supply manufacturing (primary)	$85,376	$10,438	$95,814
	327113b	Porcelain electrical supply manufacturing (secondary)	$5,478	$7,502	$12,979
	334220	Cellular telephones manufacturing	$5,901	$13,417	$19,319
	334310	Compact disc players manufacturing	$5,331	$11,438	$16,769
	334411	Electron Tube Manufacturing BeO traveling wave tubes	$6,721	$14,878	$21,599
	334415	Electronic resistor manufacturing	$5,812	$9,241	$15,052
	334419	Other electronic component manufacturing	$5,357	$7,625	$12,982
	334510	Electromedical equipment manufacturing	$5,268	$3,545	$8,812
	336322b	Other motor vehicle electrical & electronic equipment	$5,735	$12,681	$18,416
Nonferrous Foundries					
	331521	Aluminum die-casting foundries	$24,256	$14,141	$38,397
	331522	Nonferrous (except aluminum) die-casting foundries	$23,001	$12,013	$35,015
	331524	Aluminum foundries (except die-casting)	$25,338	$15,180	$40,518
	331525a	Copper foundries (except die-casting) (non-sand casting foundries)	$25,540	$15,755	$41,295
	331525b	Copper foundries (except die-casting) (sand casting foundries)	$27,012	$18,120	$45,132
Secondary Smelting, Refining, and Alloying					
	331314	Secondary smelting & alloying of aluminum	$22,432	$11,325	$33,757
	331421b	Copper rolling, drawing, and extruding	$22,432	$11,775	$34,206
	331423	Secondary smelting, refining, & alloying of copper	$23,335	$11,767	$35,102
	331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (Except Copper and Aluminum)	$11,155	$11,029	$22,183
Precision Machining					
	332721a	Precision turned product manufacturing (high beryllium content)	$8,643	$10,839	$19,482
	332721b	Precision turned product manufacturing (low beryllium content)	$2,904	$11,304	$14,208
Copper Rolling, Drawing and Extruding					
	331421a	Copper rolling, drawing, and extruding	$2,316	$116,815	$119,132
	331422	Copper wire (except mechanical) drawing	$2,867	$102,598	$105,465
Stamping, Spring, and Connector Manufacturing					
	332612	Light gauge spring manufacturing	$2,035	$5,242	$7,277
	332116	Metal stamping	$1,935	$6,460	$8,395
	334417	Electronic connector manufacturing	$1,905	$3,860	$5,765
	336322a	Other motor vehicle electrical & electronic equipment	$2,032	$8,017	$10,049
Arc and Gas Welding					
	331111	Iron and Steel Mills	$3,613	$6,764	$10,377
	331221	Rolled Steel Shape Manufacturing	$3,879	$8,663	$12,541
	331513	Steel Foundries (except Investment)	$2,472	$6,185	$8,657
	332117	Powder Metallurgy Part Manufacturing	$2,113	$6,166	$8,278
	332212	Hand and Edge Tool Manufacturing	$2,234	$4,803	$7,037

Table IX-23, continued

Average Costs for Small Entities Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL Compliance (Includes Respirators)	Ancillary Provisons	Total
	332312	Fabricated Structural Metal Manufacturing	$2,111	$3,964	$6,076
	332313	Plate Work Manufacturing	$2,597	$4,783	$7,379
	332322	Sheet Metal Work Manufacturing	$2,459	$4,552	$7,010
	332323	Ornamental and Architectural Metal Work Manufacturing	$2,289	$4,258	$6,548
	332439	Other Metal Container Manufacturing	$1,975	$3,883	$5,858
	332919	Other Metal Valve and Pipe Fitting Manufacturing	$1,927	$4,374	$6,301
	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$2,376	$4,407	$6,782
	333111	Farm Machinery and Equipment Manufacturing	$1,304	$2,594	$3,899
	333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	$1,933	$3,836	$5,769
	333911	Pump and Pumping Equipment Manufacturing	$1,455	$3,002	$4,457
	333922	Conveyor and Conveying Equipment Manufacturing	$2,370	$4,439	$6,809
	333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	$3,116	$6,006	$9,122
	333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$1,820	$3,463	$5,282
	336211	Motor Vehicle Body Manufacturing	$3,201	$5,854	$9,055
	336214	Travel Trailer and Camper Manufacturing	$1,490	$2,914	$4,404
	336399a	All Other Motor Vehicle Parts Manufacturing	$3,302	$6,143	$9,445
	336510	Railroad Rolling Stock	$4,298	$8,685	$12,983
	336999	All Other Transportation Equipment Manufacturing	$1,291	$3,048	$4,339
	337215	Showcase, Partition, Shelving, and Locker Manufacturing	$2,253	$4,713	$6,966
	811310	Commercial and Industrial Machinery and Equipment Repair	$1,880	$3,565	$5,445
Resistance Welding					
	333411	Air Purification Equipment Manufacturing	$0	$8,363	$8,363
	333412	Industrial and Commercial Fan and Blower Manufacturing	$0	$11,780	$11,780
	333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	$0	$10,186	$10,186
	333415	Air-Conditioning, Warm Air Heating, and Industrial Refrigeration Equipment Manufacturing	$0	$18,247	$18,247
	335211	Electric Housewares and Household Fan Manufacturing	$0	$15,789	$15,789
	335212	Household Vacuum Cleaner Manufacturing	$0	$17,638	$17,638
	335221	Household Cooking Appliance Manufacturing	$0	$15,870	$15,870
	335222	Household Refrigerator and Home Freezer Manufacturing	$0	$16,548	$16,548
	335224	Household Laundry Equipment Manufacturing	$0	$8,274	$8,274
	335228	Other Major Household Appliance Manufacturing	$0	$1,740	$1,740
	336311	Carburetor, Piston, Piston Ring, and Valve Manufacturing	$0	$5,227	$5,227
	336312	Gasoline Engine and Engine Parts Manufacturing	$0	$16,015	$16,015
	336321	Vehicular Lighting Equipment Manufacturing	$0	$6,084	$6,084
	336322c	Other Motor Vehicle Electrical and Electronic Equipment Manufacturing	$0	$16,355	$16,355
	336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$0	$17,707	$17,707
	336340	Motor Vehicle Brake System Manufacturing	$0	$18,828	$18,828
	336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$0	$18,037	$18,037
	336360	Motor Vehicle Seating and Interior Trim Manufacturing	$0	$6,586	$6,586

Table IX-23, continued

Average Costs for Small Entities Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL Compliance (Includes Respirators)	Ancillary Provisions	Total
	336370	Motor Vehicle Metal Stamping	$0	$8,894	$8,894
	336391	Motor Vehicle Air-Conditioning Manufacturing	$0	$16,715	$16,715
	336399b	All Other Motor Vehicle Parts Manufacturing	$0	$17,568	$17,568
Dental Laboratories					
	339116	Dental laboratories	$494	$900	$1,394
	621210	Offices of dentists	$577	$1,053	$1,630
		Weighted Average	**$1,969**	**$6,669**	**$8,638**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Table IX-24

Average Costs for Very Small Entities (<20 employees) Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL Compliance (Includes Respirators)	Ancillary Provisions	Total
Beryllium Production					
	331419	Primary Smelting and Refining of Nonferrous Metals (Brush Wellman)	N/A	N/A	N/A
Beryllium Oxide Ceramics and Composites					
	327113a	Porcelain electrical supply manufacturing (primary)	N/A	N/A	N/A
	327113b	Porcelain electrical supply manufacturing (secondary)	$5,176	$1,670	$6,846
	334220	Cellular telephones manufacturing	$5,182	$1,091	$6,273
	334310	Compact disc players manufacturing	$5,202	$3,181	$8,383
	334411	Electron Tube Manufacturing BeO traveling wave tubes	$5,172	$1,258	$6,430
	334415	Electronic resistor manufacturing	$5,176	$1,673	$6,849
	334419	Other electronic component manufacturing	$5,179	$1,783	$6,962
	334510	Electromedical equipment manufacturing	$5,171	$1,099	$6,271
	336322b	Other motor vehicle electrical & electronic equipment	$5,198	$1,170	$6,368
Nonferrous Foundries					
	331521	Aluminum die-casting foundries	N/A	N/A	N/A
	331522	Nonferrous (except aluminum) die-casting foundries	N/A	N/A	N/A
	331524	Aluminum foundries (except die-casting)	N/A	N/A	N/A
	331525a	Copper foundries (except die-casting) (non-sand casting foundries)	N/A	N/A	N/A
	331525b	Copper foundries (except die-casting) (sand casting foundries)	N/A	N/A	N/A
Secondary Smelting, Refining, and Alloying					
	331314	Secondary smelting & alloying of aluminum	N/A	N/A	N/A
	331421b	Copper rolling, drawing, and extruding	N/A	N/A	N/A
	331423	Secondary smelting, refining, & alloying of copper	$19,724	$1,864	$21,589
	331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (Except Copper and Aluminum)	$9,626	$1,430	$11,055
Precision Machining					
	332721a	Precision turned product manufacturing (high beryllium content)	$3,033	$3,849	$6,882
	332721b	Precision turned product manufacturing (low beryllium content)	$1,023	$4,022	$5,046
Copper Rolling, Drawing and Extruding					
	331421a	Copper rolling, drawing, and extruding	$1,133	$4,550	$5,684
	331422	Copper wire (except mechanical) drawing	$1,304	$6,379	$7,682
Stamping, Spring, and Connector Manufacturing					
	332612	Light gauge spring manufacturing	$1,839	$1,471	$3,310
	332116	Metal stamping	$1,846	$1,697	$3,543
	334417	Electronic connector manufacturing	$1,841	$1,173	$3,014
	336322a	Other motor vehicle electrical & electronic equipment	$1,851	$1,157	$3,007
Arc and Gas Welding					
	331111	Iron and Steel Mills	N/A	N/A	N/A
	331221	Rolled Steel Shape Manufacturing	N/A	N/A	N/A
	331513	Steel Foundries (except Investment)	N/A	N/A	N/A
	332117	Powder Metallurgy Part Manufacturing	N/A	N/A	N/A
	332212	Hand and Edge Tool Manufacturing	$782	$2,389	$3,171

Table IX-24, continued

Average Costs for Very Small Entities (<20 employees) Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL Compliance (Includes Respirators)	Ancillary Provisions	Total
	332312	Fabricated Structural Metal Manufacturing	$715	$1,584	$2,299
	332313	Plate Work Manufacturing	$935	$1,956	$2,891
	332322	Sheet Metal Work Manufacturing	$834	$1,786	$2,620
	332323	Ornamental and Architectural Metal Work Manufacturing	$1,032	$2,121	$3,153
	332439	Other Metal Container Manufacturing	$726	$1,745	$2,471
	332919	Other Metal Valve and Pipe Fitting Manufacturing	$834	$3,469	$4,302
	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$812	$1,748	$2,560
	333111	Farm Machinery and Equipment Manufacturing	$715	$1,584	$2,299
	333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	$732	$1,805	$2,536
	333911	Pump and Pumping Equipment Manufacturing	$727	$1,750	$2,477
	333922	Conveyor and Conveying Equipment Manufacturing	$717	$1,619	$2,335
	333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	$750	$2,011	$2,761
	333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$715	$1,583	$2,298
	336211	Motor Vehicle Body Manufacturing	$715	$1,583	$2,298
	336214	Travel Trailer and Camper Manufacturing	$715	$1,585	$2,300
	336399a	All Other Motor Vehicle Parts Manufacturing	$723	$1,702	$2,424
	336510	Railroad Rolling Stock	N/A	N/A	N/A
	336999	All Other Transportation Equipment Manufacturing	$764	$2,174	$2,938
	337215	Showcase, Partition, Shelving, and Locker Manufacturing	$771	$2,264	$3,035
	811310	Commercial and Industrial Machinery and Equipment Repair	$1,327	$2,623	$3,949
Resistance Welding			$0	$0	$0
	333411	Air Purification Equipment Manufacturing	$0	$2,506	$2,506
	333412	Industrial and Commercial Fan and Blower Manufacturing	$0	$2,401	$2,401
	333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	$0	$2,321	$2,321
	333415	Air-Conditioning, Warm Air Heating, and Industrial Refrigeration Equipment Manufacturing	$0	$1,094	$1,094
	335211	Electric Housewares and Household Fan Manufacturing	$0	$1,151	$1,151
	335212	Household Vacuum Cleaner Manufacturing	N/A	N/A	N/A
	335221	Household Cooking Appliance Manufacturing	$0	$1,056	$1,056
	335222	Household Refrigerator and Home Freezer Manufacturing	N/A	N/A	N/A
	335224	Household Laundry Equipment Manufacturing	N/A	N/A	N/A
	335228	Other Major Household Appliance Manufacturing	N/A	N/A	N/A
	336311	Carburetor, Piston, Piston Ring, and Valve Manufacturing	$0	$1,395	$1,395
	336312	Gasoline Engine and Engine Parts Manufacturing	$0	$1,331	$1,331
	336321	Vehicular Lighting Equipment Manufacturing	$0	$1,056	$1,056
	336322c	Other Motor Vehicle Electrical and Electronic Equipment Manufacturing	$0	$1,452	$1,452
	336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$0	$1,056	$1,056
	336340	Motor Vehicle Brake System Manufacturing	$0	$1,056	$1,056
	336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$0	$1,056	$1,056
	336360	Motor Vehicle Seating and Interior Trim Manufacturing	$0	$1,056	$1,056

Table IX-24, continued

Average Costs for Very Small Entities (<20 employees) Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL Compliance (Includes Respirators)	Ancillary Provisions	Total
	336370	Motor Vehicle Metal Stamping	$0	$1,329	$1,329
	336391	Motor Vehicle Air-Conditioning Manufacturing	$0	$1,056	$1,056
	336399b	All Other Motor Vehicle Parts Manufacturing	$0	$1,267	$1,267
Dental Laboratories			$0	$0	$0
	339116	Dental laboratories	$325	$598	$923
	621210	Offices of dentists	$518	$947	$1,465
		Weighted Average	**$862**	**$1,350**	**$2,212**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

6. Federal Rules Which May Duplicate, Overlap or Conflict With the Proposed Rule

Section 4(b)(1) of the OSH Act exempts the working conditions for certain Federal and non-Federal employees from the provisions of the OSH Act to the extent that other Federal agencies exercise statutory authority to prescribe and enforce occupational safety and health standards. The Department of Energy (DOE) issued a regulation in 1999 entitled Chronic Beryllium Disease Prevention Program (CBDPP) (10 CFR part 850, 64 FR 68854–68914, December 8, 1999). Additionally, DOE issued 10 CFR part

851, Worker Safety and Health Program (71 FR 6931–6948, February 9, 2006), which establishes requirements for worker safety and health for DOE contractors at DOE sites. The CBDPP establishes a beryllium program for DOE employees and DOE contractor employees. Therefore, under Section 4(b)(1) of the OSH Act, OSHA's beryllium standard would not apply to work subject to the CBDPP. DOE has included in its regulations a requirement for compliance with any more stringent PEL established by OSHA in rulemaking (10 CFR 850.22). OSHA requests comment on the potential overlap of DOE's rule with OSHA's proposed rule. (See I. Issues and Alternatives in this preamble).

There is also a Federal statute addressing the compensation of some employees with beryllium related illnesses—The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 and its subsequent amendments. The EEOICPA creates a Federal employees' compensation program that covers beryllium-related health effects for DOE employees and its contractor employees, including many private companies that work away from DOE sites. Several of the private companies whose employees are covered by the OSH Act, either directly in amendments to the OSH Act or identified in subsequent Department of Labor regulations on that Act, would be covered by an OSHA occupational health standard for beryllium and EEOICPA.

There would be no conflict or duplication, however, between an OSHA standard and the EEOICPA. In general, the OSHA standard would have requirements to protect employee health in the future, and the EEOICPA provides compensation for employees who have developed beryllium-related illness. There is some overlap between the two in that they may both require similar medical examinations, or require employers to provide some compensation to employees, but the proposed OSHA standard specifically contemplates and addresses that overlap to avoid conflict and duplication. The explanation for proposed paragraph (k) in Section XVIII of this preamble, Summary and Explanation, notes that employers may satisfy the both examination requirements with a single examination, and the proposed standard specifies that the amount of an employer's financial obligations will be reduced by the amount of EEOICPA payments received by that employee (see proposed paragraph (l)(4)).

7. Alternatives to the Proposed Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

This section first discusses several provisions in the proposed standard that OSHA has adopted or modified based on comments from small entity representatives (SERs) during the SBREFA process or on recommendations made by the SBAR Panel as potentially alleviating impacts on small entities. Then, the Agency presents various regulatory alternatives to the proposed OSHA beryllium standard.

a. Elements of the Proposed Rule To Reduce Impacts on Small Entities

During the SBAR Panel, SERs requested a clearer definition of the triggers for medical surveillance. This concern was rooted in the cost of BeLPTs and the trigger of potential skin contact. For the proposed rule, the Agency has removed skin contact as a trigger for medical surveillance along with providing four clearly defined trigger mechanisms. The newly defined medical surveillance provision reduces the number of employees requiring a BeLPT, particularly for small businesses with low exposures.

Some of the SERs in low-exposure industries wanted to be ''shielded'' from ''expensive'' compliance with a standard they perceive to be unnecessary and suggested a PEL-only standard that triggered provisions on the PEL. The alternative of a PEL-only standard and ancillary provisions triggered only by the PEL are discussed in Chapter 8 of the PEA (and is repeated in the following section).

Some SERs were already applying many of the protective controls and practices that would be required by the ancillary provisions of the standard. However, many SERs objected to the requirements regarding hygiene facilities. For this proposed rule, OSHA has preliminarily concluded that all affected employers currently have hand washing facilities. OSHA has also preliminarily concluded that no affected employers will be required to install showers. The Agency has determined that the long-term rental of modular units was representative of costs for a range of reasonable approaches to comply with the change room part of the provision. Alternatively, employers could renovate and rearrange their work areas in order to meet the requirements of this provision.

b. Regulatory Alternatives

For the convenience of those persons interested only in OSHA's regulatory flexibility analysis, this section repeats the discussion of the various regulatory alternatives to the proposed OSHA beryllium standard presented in Chapter VIII of the PEA, but only for the regulatory alternatives to the proposed OSHA beryllium standard that lower costs. OSHA believes that this presentation of specific regulatory alternatives explores the possibility of less costly ways (than the proposed rule) to provide an adequate level of worker protection from exposure to beryllium.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's preliminary findings of significant risk and feasibility. As noted above, for this chapter on the Initial Regulatory Flexibility Analysis, the Agency is only presenting regulatory alternatives that reduce costs for small entities. (See Chapter VIII for the full list of all alternatives analysed.) There are eight regulatory alternatives and an informational alternative that reduce costs for small entities (and for all businesses in total). Using the numbering scheme from Chapter VIII, these are Regulatory Alternatives #5, #6, #7, #8. #12, #16, #18, and #22. To facilitate comment, OSHA has organized these potentially less costly regulatory alternatives (and a general discussion of possible phase-ins of the rule) into four categories: (1) Exposure limits; (2) methods of compliance; (3) ancillary provisions; and (4) timing.

(1) Exposure limit (TWA PEL, STEL, and ACTION LEVEL) alternatives

Regulatory Alternative #5, which would set a TWA PEL at 0.5 μg/m³ and an action level at 0.25 μg/m³, both higher than in the proposal, responds to an issue raised during the Small Business Advocacy Review (SBAR) process conducted in 2007 to consider a draft OSHA beryllium proposed rule that culminated in an SBAR Panel report (SBAR, 2008). That report included a recommendation that OSHA consider both the economic impact of a low TWA PEL and regulatory alternatives that would ease cost burden for small entities. OSHA has provided a full analysis of the economic impact of its proposed PELs (see Chapter VI of the PEA), and Regulatory Alternative #5 addresses the second half of that recommendation. However, the higher 0.5 μg/m³ TWA PEL does not appear to be consistent with the Agency's mandate under the OSH Act to promulgate a lower PEL if it is feasible and could prevent additional fatalities and non-fatal illnesses. The data presented in Table IX–25 below indicate that the lower TWA PEL would prevent additional fatalities and non-fatal illnesses, but nevertheless the Agency solicits comments on this alternative and OSHA's analysis of the costs and benefits associated with it.

Table IX–25 below presents, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed TWA PEL of 0.2 μg/m³ and for the regulatory alternative of a TWA PEL of 0.5 μg/m³ (Regulatory Alternative #5), using alternative discount rates of 3 percent and 7 percent. Table IX–25 also breaks out costs by provision and benefits by type of disease and by morbidity/mortality. As Table IX–25 shows, going from a TWA PEL of 0.5 μg/m³ to a TWA PEL of 0.2 μg/m³ would prevent, annually, an additional 29 beryllium-related fatalities and an additional 15 non-fatal illnesses.

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Table IX-25: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of 0.5 μg/m3 PEL Alternative
Millions ($2010)

	Proposed PEL (PEL = 0.2 μg/m^3, AL = 0.10 μg/m^3)			Alternative 5 Incremental Costs/Benefits			Alternative 5 (PEL = 0.5 μg/m^3, AL = 0.25 μg/m^3)		
Discount Rate		**3%**	**7%**		**3%**	**7%**		**3%**	**7%**
Annualized Costs									
Control Costs		$9.5	$10.3		-$3.6	-$3.9		$6.0	$6.5
Respirators		$0.2	$0.3		-$0.1	-$0.1		$0.1	$0.1
Exposure Assessment		$2.2	$2.4		-$0.3	-$0.3		$1.9	$2.1
Regulated areas and Beryllium Work Areas		$0.6	$0.7		-$0.3	-$0.3		$0.3	$0.4
Medical Surveillance		$2.9	$3.0		-$0.1	-$0.1		$2.8	$2.9
Medical Removal		$0.1	$0.2		-$0.1	-$0.1		$0.1	$0.1
Exposure Control Plan		$1.8	$1.8		$0.0	$0.0		$1.8	$1.8
Protective Clothing and Equipment		$1.4	$1.4		$0.0	$0.0		$1.4	$1.4
Hygiene Areas and Practices		$0.4	$0.4		$0.0	$0.0		$0.4	$0.4
Housekeeping		$12.6	$12.9		$0.0	$0.0		$12.6	$12.9
Training		$5.8	$5.8		$0.0	$0.0		$5.8	$5.8
Total Annualized Costs (point estimate)		**$37.6**	**$39.1**		**-$4.4**	**-$4.8**		**$33.2**	**$34.4**
Annual Benefits: Number of Cases Prevented	**Cases**			**Cases**			**Cases**		
Fatal Lung Cancers (midpoint estimate)	4			0			4		
Fatal Chronic Beryllium Disease	92			-29			63		
Beryllium-Related Mortality	96	$573.0	$253.7	-28	-$171.8	-$76.1	67	$401.2	$177.7
Beryllium Morbidity	50	$2.8	$1.6	-15	-$0.9	-$0.5	34	$2.0	$1.1
Monetized Annual Benefits (midpoint estimate)		**$575.8**	**$255.3**		**-$172.7**	**-$76.6**		**$403.1**	**$178.8**
Net Benefits		**$538.2**	**$216.2**		**-$168.2**	**-$71.9**		**$370.0**	**$144.4**

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

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Informational Alternative Featuring Unchanged PEL but Full Ancillary Provisions

An Informational Analysis: This proposed regulation has the somewhat unusual feature for an OSHA substance-specific health standard that most of the quantified benefits would come from the ancillary provisions rather than from meeting the PEL with engineering controls. OSHA decided to analyze for informational purposes the effect of retaining the existing PEL but applying all of the ancillary provisions, including respiratory protection. Under this approach, the TWA PEL would remain at 2.0 micrograms per cubic meter, but all of the other proposed provisions (including respiratory protection, which OSHA does not consider an ancillary provision) would be required with their triggers remaining the same as in the proposed rule—either the presence of airborne beryllium at any level (*e.g.,* initial monitoring, written exposure control plan), at certain kinds of dermal exposure (PPE), at the action level of 0.1 $\mu g/m^3$ (*e.g.,* periodic monitoring, medical removal), or at 0.2 $\mu g/m^3$ (*e.g.,* regulated areas, respiratory protection, medical surveillance).

Given the record regarding beryllium exposures, this approach is not one OSHA could legally adopt because the absence of a more protective requirement for engineering controls would not be consistent with section 6(b)(5) of the OSH Act, which requires OSHA to ''set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' For that reason, this additional analysis is provided strictly for informational purposes. EO 12866 and EO 13563 direct agencies to identify approaches that maximize net benefits, and this analysis is purely for the purpose of exploring whether this approach would hold any real promise to maximize net benefits if it was permissible under the OSH Act. It does not appear to hold such promise because an ancillary-provisions-only approach would not be as protective and thus offers fewer benefits than one that includes a lower PEL and engineering controls, and OSHA estimates the costs would be about the same (or slightly lower, depending on certain assumptions) under that approach as under the traditional proposed approach.

On an industry by industry basis, OSHA found that some industries would have lower costs if they could adopt the ancillary-provisions-only approach. Some employers would use engineering controls where they are cheaper, even if they are not mandatory. OSHA does not have sufficient information to do an analysis of the employer-by-employer situations in which there exist some employers for whom the ancillary-provisions-only approach might be cheaper. In the majority of affected industries, the Agency estimates there are no costs saving to the ancillary-provisions-only approach. However, OSHA estimates a total of $2,675,828 per year in costs saving for entire industries where the ancillary-provisions-only approach would be less expensive.

The above discussion does not account for the possibility that the lack of engineering controls would result in higher beryllium exposures for workers in adjacent (non-production) work areas due to the increased level of beryllium in the air. Because of a lack of data, and because the issue did not arise in the other regulatory alternatives OSHA considered (all of which have a PEL of less than 2.0 $\mu g/m^3$), OSHA did not carefully examine exposure levels in non-production areas for either cost or benefit purposes. To the extent such exposure levels would be above the action level, there would be additional costs for respiratory protection.

The ancillary-provisions-only approach adds uncertainty to the benefits analysis such that the benefits of the rule as proposed may exceed, and perhaps greatly exceed, the benefits of this ancillary-provisions-only approach:

(1) Most exposed individuals would be in respirators, which OSHA considers less effective than engineering controls in preventing employee exposure to beryllium. OSHA last did an extensive review of the evidence on effectiveness of respirators for its APFs rulemaking in 2006 (71 FR 50128–45 Aug 24, 2006). OSHA has not in the past tried to quantify the size of this effect, but it could partially negate the estimated benefits of 92 CBD deaths prevented per year and 4 lung cancer cases prevented per year by the proposed standard.

(2) As noted above, in the proposal OSHA did not consider benefits caused by reductions in exposure in non-production areas. Unless employers act to reduce exposures in the production areas, the absence of a requirement for such controls would largely negate such benefits from reductions in exposure in the non-productions areas.

(3) OSHA believes that there is a strong possibility that the benefits of the ancillary provisions (a midpoint estimate of eliminating 45 percent of all remaining cases of CBD) would be partially or wholly negated in the absence of engineering controls that would reduce both airborne and surface dust levels. The measured reduction in benefits from ancillary provision was in a facility with average exposure levels of less than 0.2 $\mu g/m^3$.

Based on these considerations, OSHA believes that the ancillary-provisions-only approach is not one that is likely to maximize net benefits. The costs saving, if any, are estimated to be small, and the difficult-to-measure declines in benefits could be substantial.

(2) A Method-of-compliance Alternative

Paragraph (f)(2) of the proposed rule contains requirements for the implementation of engineering and work practice controls to minimize beryllium exposures in beryllium work areas. For each operation in a beryllium work area, employers must ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure: Material and/or process substitution; ventilated enclosures; local exhaust ventilation; or process controls, such as wet methods and automation. Employers are exempt from using engineering and work practice controls only when they can show that such controls are not feasible or where exposures are below the action level based on two exposure samples taken seven days apart.

These requirements, which are based on the stakeholders' recommended beryllium standard that beryllium industry and union stakeholders submitted to OSHA in 2012 (Materion and USW, 2012), address a concern associated with the proposed TWA PEL. OSHA expects that day-to-day changes in workplace conditions, such as workers' positioning or patterns of airflow, may cause frequent exposures above the TWA PEL in workplaces where periodic sampling indicates exposures are between the action level and the TWA PEL. As a result, the default under the standard is that the controls are required until the employer can demonstrate that exposures have not exceeded the action level from at least two separate measurements taken seven days apart.

OSHA believes that substitution or engineering controls such as those outlined in paragraph (f)(2)(i) provide the most reliable means to control variability in exposure levels. However, OSHA also recognizes that the requirements of paragraph (f)(2)(i) are not typical of OSHA standards, which usually require engineering controls only where exposures exceed the TWA PEL or STEL. The Agency is therefore considering Regulatory Alternative #6, which would drop the provisions of (f)(2)(i) from the proposed standard and make conforming edits to paragraphs (f)(2)(ii) and (iii). This regulatory alternative does not eliminate the need for engineering controls to comply with the proposed TWA PEL and STEL, but does eliminate the requirement to use one or more of the specified engineering or work practice controls where exposures equal or exceed the action level. As shown in Table IX–26, Regulatory Alternative #6 would decrease the annualized cost of the proposed rule by about $457,000 using a discount rate of 3 percent and by about $480,000 using a discount rate of 7 percent. OSHA has not been able to estimate the change in benefits resulting from Regulatory Alternative #6 at this time and invites public comment on this issue.

Table IX-26: Cost of Regulatory Alternatives, Alternative 6
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

3% Discount Rate	Total Cost	Incremental Cos Relative to Propos
Proposed Rule	$37,597,325	——
Alternative 6: Eliminate (f)(2) controls	$37,140,020	-$457,304

7% Discount Rate	Total Cost	Incremental Cos Relative to Propos
Proposed Rule	$39,147,434	——
Alternative 6: Eliminate (f)(2) controls	$38,667,896	-$479,538

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

(3) Regulatory Alternatives That Affect Ancillary Provisions

The proposed standard contains several ancillary provisions (provisions other than the exposure limits), including requirements for exposure assessment, medical surveillance, medical removal, training, and regulated areas or access control. As reported in Chapter V of the PEA, these ancillary provisions account for $27.8 million (about 72 percent) of the total annualized costs of the rule ($37.6 million) using a 3 percent discount rate, or $28.6 million (about 73 percent) of the total annualized costs of the rule ($39.1 million) using a 7 percent discount rate. The most expensive of the ancillary provisions are the requirements for housekeeping and training, with annualized costs of $12.6 million and $5.8 million, respectively, at a 3 percent discount rate ($12.9 million and $5.8 million, respectively, at a 7 percent discount rate).

OSHA's reasons for including each of the proposed ancillary provisions are explained in Section XVIII of this preamble, Summary and Explanation of the Standards. In particular, OSHA is proposing the requirements for exposure assessment to provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is especially important because workers exposed above the proposed TWA PEL, as well as many workers exposed below the proposed TWA PEL, are at significant risk of death and illness. Medical surveillance would allow for identification of beryllium-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA is proposing regulated areas and access control because they serve to limit exposure to beryllium to as few employees as possible. OSHA is proposing worker training to ensure that employers inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize their exposure to beryllium. Worker training on beryllium-related work practices is particularly important in controlling beryllium exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA has examined a variety of regulatory alternatives involving changes to one or more of the proposed ancillary provisions. The incremental cost of each of these regulatory alternatives and its impact on the total costs of the proposed rule is summarized in Table IX–27 at the end of this section. OSHA has preliminarily determined that several of these ancillary provisions will increase the benefits of the proposed rule, for example, by helping to ensure the TWA PEL is not exceeded or by lowering the risks to workers given the significant risk remaining at the proposed TWA PEL. However, except for Regulatory Alternative #7 (involving the elimination of all ancillary provisions), OSHA did not estimate changes in monetized benefits for the regulatory alternatives that affect ancillary provisions. Two regulatory alternatives that involve all ancillary provisions are presented below (#7 and #8), followed by regulatory alternatives for regulated areas (#12), for medical surveillance (#16 and #18), and for medical removal (#22).

(a) All Ancillary Provisions

The SBAR Panel recommended that OSHA analyze a PEL-only standard as a regulatory alternative. The Panel also recommended that OSHA consider not applying ancillary provisions of the standard where exposure levels are low so as to minimize costs for small businesses (SBAR, 2008). In response to these recommendations, OSHA analyzed Regulatory Alternative #7, a PEL-only standard, and Regulatory Alternative #8, which would apply ancillary provisions of the beryllium standard only where exposures exceed the proposed TWA PEL of 0.2 μg/m^3 or the proposed STEL of 2 μg/m^3.

Regulatory Alternative #7 would solely update 1910.1000 Tables Z–1 and Z–2, so that the proposed TWA PEL and STEL would apply to all workers in general industry. This alternative would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, medical removal, PPE, housekeeping, training, and regulated areas or access control. Under this regulatory alternative, OSHA estimates that the costs for the proposed ancillary provisions of the rule (estimated at $27.8 million annually at a 3 percent discount rate) would be eliminated. In order to meet the PELs, employers would still commonly need to do monitoring, train workers on the use of controls, and set up some kind of regulated areas to indicate where respirator use would be required. It is also likely that, under this alternative, many employers would follow the recommendations of Materion and the United Steelworkers to provide medical surveillance, PPE, and other protective measures for their workers (Materion and USW, 2012). OSHA has not attempted to estimate the extent to which these ancillary-provision costs would be incurred if they were not formally required or whether any of these costs under Regulatory Alternative #7 would reasonably be attributable to the proposed rule. OSHA welcomes comment on the issue.

OSHA has also estimated the effect of this regulatory alternative on the benefits of the rule. As a result of eliminating all of the ancillary provisions, annualized benefits are estimated to decrease 57 percent, relative to the proposed rule, from $575.8 million to $249.1 million, using a 3 percent discount rate, and from $255.3 million to $110.4 million using a 7 percent discount rate. This estimate follows from OSHA's analysis of benefits in Chapter VII of the PEA, which found that about 57 percent of the benefits of the proposed rule, evaluated at their mid-point value, were attributable to the combination of the ancillary provisions. As these estimates show, OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to beryllium. The stakeholders' recommended standard that representatives of the primary beryllium manufacturing industry and the United Steelworkers union provided to OSHA confirms the importance of ancillary provisions in protecting workers from the harmful effects of beryllium exposure (Materion and USW, 2012). Ancillary provisions such as personal protective clothing and equipment, regulated areas, medical surveillance, hygiene areas, housekeeping requirements, and hazard communication all serve to reduce the risks to beryllium-exposed workers beyond that which the proposed TWA PEL alone could achieve.

Moreover, where there is continuing significant risk at the TWA PEL, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (D.C. Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. Nevertheless, OSHA requests comment on this alternative.

Under Regulatory Alternative #8, several ancillary provisions that the current proposal would require under a variety of exposure conditions (*e.g.,* dermal contact, any airborne exposure, exposure at or above the action level) would instead only apply where exposure levels exceed the TWA PEL or STEL. Regulatory Alternative #8 affects the following provisions of the proposed standard:

— Exposure monitoring: Whereas the proposed standard requires annual monitoring when exposure levels are at or above the action level and at or below the TWA PEL, Regulatory Alternative #8 would require annual exposure monitoring only where exposure levels exceed the TWA PEL or STEL;
—Written exposure control plan: Whereas the proposed standard requires written exposure control plans to be maintained in any facility covered by the standard, Regulatory Alternative #8 would require only facilities with exposures above the TWA PEL or STEL to maintain a plan;
— Housekeeping: Whereas the proposed standard's housekeeping requirements apply across a wide variety of beryllium exposure conditions, Alternative #8 would limit housekeeping requirements to areas and employees with exposures above the TWA PEL or STEL;
— PPE: Whereas the proposed standard requires PPE for employees under a variety of conditions, such as exposure to soluble beryllium or visible contamination with beryllium, Alternative #8 would require PPE only for employees exposed above the TWA PEL or STEL;
— Medical Surveillance: Whereas the proposed standard's medical surveillance provisions require employers to offer medical surveillance to employees with signs or symptoms of beryllium-related health effects regardless of their exposure level, Alternative #8 would require surveillance only for those employees exposed above the TWA PEL or STEL.

To estimate the cost savings for this alternative, OSHA re-estimated the group of workers that would fall under the above provisions and the changes to their scope. Combining these various adjustments along with associated unit costs, OSHA estimates that, under this regulatory alternative, the costs for the proposed rule would decline from $37.6 million to $18.9 million using a 3 percent discount rate and from $39.1 million to $20.0 million using a 7 percent discount rate.

The Agency has not quantified the impact of this alternative on the benefits of the rule. However, ancillary provisions that offer protective measures to workers exposed below the proposed TWA PEL, such as personal protective clothing and equipment, beryllium work areas, hygiene areas, housekeeping requirements, and hazard communication, all serve to reduce the risks to beryllium-exposed workers beyond that which the proposed TWA PEL and STEL could achieve. OSHA's preliminary conclusion is that the requirements triggered by the action level and other exposures below the proposed PELs will result in very real and necessary, but difficult to quantify, further reduction in risk beyond that provided by the PELs alone.

The remainder of this section discusses additional regulatory alternatives that apply to individual ancillary provisions. At this time, OSHA is not able to quantify the effects of these regulatory alternatives on benefits. The Agency solicits comment on the effects of these regulatory alternatives on the benefits of the proposed rule.

(b) Regulated Areas

Proposed paragraph (e) requires employers to establish and maintain beryllium work areas wherever employees are exposed to airborne beryllium, regardless of the level of exposure, and regulated areas wherever airborne concentrations of beryllium exceed the TWA PEL or STEL. Employers are required to demarcate beryllium work areas and regulated areas and limit access to regulated areas to authorized persons.

The SBAR Panel report recommended that OSHA consider dropping or limiting the provision for regulated areas (SBAR, 2008). In response to this recommendation, OSHA examined Regulatory Alternative #12, which would eliminate the requirement that employers establish regulated areas. This alternative is meant only to eliminate the requirement to set up and demarcate specific physical areas: All ancillary provisions would be triggered by the same conditions as under the standard's definition of a ''regulated area.'' For example, under the current proposal, employees who work in regulated areas for at least 30 days annually are eligible for medical surveillance. If OSHA were to remove the requirement to establish regulated areas, the medical surveillance provisions would be altered so that employees who work more than 30 days annually in jobs or areas with exposures that exceed the TWA PEL or STEL are eligible for medical surveillance. This alternative would not eliminate the proposed requirement to establish beryllium work areas. As shown in Table IX–27, Regulatory Alternative #12 would decrease the annualized cost of the proposed rule by about $522,000 using a 3 percent discount rate, and by about $523,000 using a 7 percent discount rate.

(e) Medical Surveillance

The proposed requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are exposed to beryllium in a regulated area (*i.e.,* above the proposed TWA PEL or STEL) for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and (2) CT scans for employees who were exposed above the proposed TWA PEL or STEL for more than 30 days in a 12-month period for 5 years or more. The proposed standard would require annual medical exams to be provided for employees exposed in a regulated area for 30 days or more per year and for employees showing signs or symptoms of CBD, while tests for beryllium sensitization and CT scans would be provided to eligible employees biennially.

OSHA estimated in Chapter V of the PEA that the medical surveillance requirements would apply to 4,528 workers in general industry, of whom 387 already receive that surveillance.[44] In Chapter V, OSHA estimated the costs of medical surveillance for the remaining 4,141 workers who would now have such protection due to the proposed standard. The Agency's preliminary analysis indicates that four workers with beryllium sensitization and six workers with CBD will be referred to pulmonary specialists annually as a result of this medical surveillance. Medical surveillance is particularly important for this rule because beryllium-exposed workers, including many workers exposed below the proposed PELs, are at significant risk of illness. OSHA did not estimate, and the benefits analysis does not include, monetized benefits resulting from early discovery of illness.

Medical surveillance was a subject of special concern to SERs during the SBAR Panel process, and the SBAR Panel offered many comments and recommendations related to medical surveillance for OSHA's consideration. Some of the Panel's concerns have been partially addressed in this proposal, which was modified since the SBAR Panel was convened (see this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, for more detailed discussion). The regulatory alternatives presented in this sub-section (#16, #18, and #20) also respond to recommendations by the SBAR Panel to reduce burdens on small businesses by dropping or reducing the frequency of medical surveillance requirements. OSHA has preliminarily determined that a significant risk of beryllium sensitization, CBD, and lung cancer exists at exposure levels below the proposed TWA PEL and that there is evidence that beryllium sensitization can occur even from short-term exposures (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk). The Agency therefore anticipates that more employees would develop adverse health effects without receiving the benefits of early intervention in the disease process because they are not eligible for medical surveillance (see this preamble at Section V, Health Effects).

In response to concerns raised during the SBAR Panel process about testing requirements, OSHA is considering two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. As shown in Table IX–27, this alternative would decrease the annualized cost of the proposed rule by about $710,000 using a discount rate of 3 percent, and by about $724,000 using a discount rate of 7 percent.

Regulatory Alternative #18 would eliminate the CT scan requirement from the proposed rule. This alternative would decrease the annualized cost of the proposed rule by about $472,000 using a discount rate of 3 percent, and by about $481,000 using a discount rate of 7 percent.

OSHA is considering several alternatives to the proposed frequency of sensitization testing, CT scans, and general medical examinations. The frequency of periodic medical surveillance is an important factor in the efficacy of the surveillance in protecting worker health. Regular, appropriately frequent medical surveillance promotes awareness of beryllium-related health effects and early intervention in disease processes among workers. In addition, the longer the time interval between when a worker becomes sensitized and when the worker's case is identified in the surveillance program, the more difficult it will be to identify and address the exposure conditions that led to sensitization. Therefore, reducing the frequency of sensitization testing would reduce the usefulness of the surveillance information in identifying problem areas and reducing risks to other workers. These concerns must be weighed against the costs and other burdens of surveillance.

Finally, under Regulatory Alternative #20, employers would only have to provide all periodic components of the medical surveillance exams biennially to eligible employees. This alternative would decrease the annualized cost of the proposed rule by about $446,000 using a discount rate of 3 percent and by about $433,000 using a discount rate of 7 percent.

[44] See current compliance rates for medical surveillance in Chapter V of the PEA, Table V–15.

(d) Medical Removal

Under paragraph (l) of the proposed standard, Medical Removal, employees in jobs with exposure at or above the action level become eligible for medical removal when they are diagnosed with CBD or confirmed positive for beryllium sensitization. When an employee chooses removal, the employer is required to remove the employee to comparable work in an environment where beryllium exposure is below the action level if such work is available and the employee is either already qualified or can be trained within one month. If comparable work is not available, paragraph (l) would require the employer to place the employee on paid leave for six months or until comparable work becomes available (whichever comes first). Or, rather than choosing removal, an eligible employee could choose to remain in a job with exposure at or above the action level and wear a respirator. The proposed medical removal protection (MRP) requirements are based on the stakeholders' recommended beryllium standard that representatives of the beryllium production industry and the United Steelworkers union submitted to OSHA in 2012 (Materion and USW, 2012).

The scientific information on effects of exposure cessation is limited at this time, but the available evidence suggests that removal from exposure can be beneficial for individuals who are sensitized or have early-stage CBD (see this preamble at Section VIII, Significance of Risk). As CBD progresses, symptoms become serious and debilitating. Steroid treatment is less effective at later stages, once fibrosis has developed (see this preamble at Section VIII, Significance of Risk). Given the progressive nature of the disease, OSHA believes it is reasonable to conclude that removal from exposure to beryllium will benefit sensitized employees and those with CBD. Physicians at National Jewish Health, one of the main CBD research and treatment sites in the US, ''consider it important and prudent for individuals with beryllium sensitization and CBD to minimize their exposure to airborne beryllium,'' and ''recommend individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry to have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour time-weighted average'' (NJMRC, 2013). However, OSHA is aware that MRP may prove costly and burdensome for some employers and that the scientific literature on the effects of exposure cessation on the development of CBD among sensitized individuals and the progression from early-stage to late-stage CBD is limited.

The SBAR Panel report included a recommendation that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (SBAR, 2008). In response to this recommendation, OSHA analyzed Regulatory Alternative #22, which would remove the proposed requirement that employers offer MRP. As shown in Table IX–27, this alternative would decrease the annualized cost of the proposed rule by about $149,000 using a discount rate of 3 percent, and by about $166,000 using a discount rate of 7 percent.

Table IX-27: Cost of Regulatory Alternatives Affecting Ancillary Provisions
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

3% Discount Rate	Total Cost	Incremental Cost Relative to Proposal	Benefits	Incremental Benefits Relative to the Proposal
Proposed Rule	$37,597,325	——	$575,826,633	——
Alternative 7: Update Z table 1910.1000 only, (No ancillary provisions)	$9,789,873	-$27,807,451	$249,099,326	-$326,727,308
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	$18,917,028	-$18,680,297		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	$37,075,072	-$522,252		
Alternative 16: No BeLPTs in medical surveillance	$36,887,307	-$710,018		
Alternative 18: No CT Scans	$37,124,958	-$472,367		
Alternative 20: All periodic components of medical surveillance are biannual	$37,150,975	-$446,349		
Alternative 22: No medical removal protection	$37,448,499	-$148,826		

Table IX-27: Cost of Regulatory Alternatives Affecting Ancillary Provisions, Continued
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

7% Discount Rate	Total Cost	Incremental Cost Relative to Proposal	Benefits	Incremental Benefits Relative to the Proposal
Proposed Rule	$39,147,434	——	$255,334,295	——
Alternative 7: Update Z table 1910.1000 only, (No ancillary provisions)	$10,586,317	-$28,561,116	$110,383,499	-$144,950,796
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	$19,986,867	-$19,160,567		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	$38,624,295	-$523,139		
Alternative 16: No BeLPTs in medical surveillance	$38,423,316	-$724,117		
Alternative 18: No CT Scans	$38,666,205	-$481,229		
Alternative 20: All periodic components of medical surveillance are biannual	$38,714,200	-$433,233		
Alternative 22: No medical removal protection	$38,981,379	-$166,054		

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

(5) Timing

As proposed, the new standard would become effective 60 days following publication in the **Federal Register**. The majority of employer duties in the standard would become enforceable 90 days following the effective date. Change rooms, however, would not be required until one year after the effective date, and the deadline for engineering controls would be no later than two years after the effective date.

OSHA invites suggestions for alternative phase-in schedules for engineering controls, medical surveillance, and other provisions of the standard. Although OSHA did not explicitly develop or quantitatively analyze any other regulatory alternatives involving longer-term or more complex phase-ins of the standard (possibly involving more delayed implementation dates for small businesses), some general outcomes are likely. For example, a longer phase-in time would have several advantages, such as reducing initial costs of the standard or allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However, a longer phase-in would also postpone and reduce the benefits of the standard. Suggestions for alternatives may apply to specific industries (*e.g.,* industries where first-year or annualized cost impacts are highest), specific size-classes of employers (*e.g.,* employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule.

OSHA requests comments on all these regulatory alternatives, including the Agency's regulatory alternatives presented above, the Agency's analysis of these alternatives, and whether there are other regulatory alternatives the Agency should consider.

SBAR Panel

Table IX–28 lists all of the SBAR Panel recommendations and OSHA's response to those recommendations.

TABLE IX–28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES

Panel recommendation	OSHA response
The Panel recommends that OSHA evaluate carefully the costs and technological feasibility of engineering controls at all PEL options, especially those at the lowest levels.	OSHA has reviewed its cost estimates and the technological feasibility of engineering controls at various PEL levels. These issues are discussed in the Regulatory Alternatives Chapter of the PEA.
The Panel recommends that OSHA consider alternatives that would alleviate the need for monitoring in operations with exposures far below the PEL. The Panel also recommends that OSHA consider explaining more clearly how employers may use "objective data" to estimate exposures. Although the draft proposal contains a provision allowing employers to initially estimate exposures using "objective data" (*e.g.,* data showing that the action level is unlikely to be exceeded for the kinds of process or operations an employer has), the SERs did not appear to have fully understood how this alternative may be used.	OSHA has removed the initial exposure monitoring requirement for workers likely to be exposed to beryllium by skin or eye contact through routine handling of beryllium powders or dusts or contact with contaminated surfaces. The periodic monitoring requirement presented in the SBAR Panel report required monitoring every 6 months for airborne levels at or above the action level but below the PEL, and every 3 months for exposures at or above the PEL. The proposed standard requires annual exposure monitoring for levels at or above the action level and at or below the PEL. By reducing the frequency of periodic monitoring from every 6 months (version submitted to the SBAR panel) to annually where exposure levels are at or below the PEL (the proposed standard), the Agency has lessened the need for monitoring in small business operations with exposures at or below the PEL. In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring. OSHA is also considering whether to create a guidance product on the use of objective data. These issues are discussed in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (d): Exposure Monitoring.
The Panel recommends that OSHA consider providing some type of guidance to describe how to use objective data to estimate exposures in lieu of conducting personal sampling. Using objective data could provide significant regulatory relief to several industries where airborne exposures are currently reported by SERs to be well below even the lowest PEL option. In particular, since several ancillary provisions, which may have significant costs for small entities may be triggered by the PEL or an action level, OSHA should consider encouraging and simplifying the development of objective data from a variety of sources.	In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring. OSHA is also considering whether to create a guidance product on the use of objective data to satisfy the requirements of the proposed rule. These issues are discussed in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (d): Exposure Monitoring.
The Panel recommends that OSHA revisit its analysis of the costs of regulated areas if a very low PEL is proposed. Drop or limit the provision for regulated areas: SERs with very low exposure levels or only occasional work with beryllium questioned the need for separating areas of work by exposure level. Segregating machines or operations, SERs said, would affect productivity and flexibility. Until the health risks of beryllium are known in their industries, SERs challenged the need for regulated areas.	SERs with very low exposure levels or only occasional work with beryllium will not be required to have regulated areas unless exposures are above the proposed PEL of 0.2 μg/m³. The proposed standard requires the employer to establish and maintain a regulated area wherever employees are, or can be expected to be exposed to airborne beryllium at levels above a PEL of 0.2 μg/m³.
The Panel recommends that OSHA revisit its cost model for hygiene areas to reflect SERs' comments that estimated costs are too low and more carefully consider the opportunity costs of using space for hygiene areas where SERs report they have no unused space in their physical plant for them. The Panel also recommends that OSHA consider more clearly defining the triggers (skin exposure and contaminated surfaces) for the hygiene areas provisions. In addition, the Panel recommends that OSHA consider alternative requirements for hygiene areas dependent on airborne exposure levels or types of processes. Such alternatives might include, for example, hand washing facilities in lieu of showers in particular cases or different hygiene area triggers where exposure levels are very low.	The Agency has removed skin exposure as a trigger for the hygiene provision. The requirement for washing facilities applies to each employee working in a beryllium work area. A beryllium work area means any work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium. OSHA has preliminarily concluded that all affected employers currently have handwashing facilities. OSHA has also preliminarily concluded that no affected employers will be required to install showers. Change rooms have only been costed for regulated areas or where employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the PEL. The Agency has determined that the long-term rental of modular units was representative of costs for a range of reasonable approaches to comply with the change room part of the provision. Alternatively, employers could renovate and rearrange their work areas in order to meet the requirements of this provision.

TABLE IX–28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

Panel recommendation	OSHA response
The Panel recommends that OSHA consider clearly explaining the purpose of the housekeeping provision and describing what affected employers must do to achieve it. For example, OSHA should consider explaining more specifically what surfaces need to be cleaned and how frequently they need to be cleaned. The Panel recommends that the Agency consider providing guidance in some form so that employers understand what they must do. The Panel also recommends that once the requirements are clarified that the Agency re-analyzes its cost estimates. The Panel also recommends that OSHA reconsider whether the risk and cost of all parts of the medical surveillance provisions are appropriate where exposure levels are very low. In that context, the Panel recommends that OSHA should also consider the special problems and costs to small businesses that up until now may not have had to provide or manage the various parts of an occupational health standard or program.	In this preamble, OSHA has clarified the purpose of the housekeeping provision. However, due to the variety of work settings in which beryllium is used, OSHA has preliminarily concluded that a highly specific directive on what surfaces need to be cleaned, and how frequently, would not provide effective guidance to businesses. Instead, at the suggestion of industry and union stakeholders (Materion and USW, 2012), OSHA's proposed standard includes a more flexible requirement for employers to develop a written exposure control plan specific to their facilities. The written exposure control plan must include documentation of operations and jobs with beryllium exposure and housekeeping procedures, including surface cleaning and beryllium migration control. OSHA requests suggestions for examples of specific guidance that could be helpful to employers preparing written exposure control plans. These issues are discussed in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (f) Methods of Compliance and (j) Housekeeping. Regulatory Alternative #20 would reduce the frequency of physical examinations from annual to biennial, matching the frequency of BeLPT testing in the proposed rule. These alternatives for medical surveillance are discussed in the Regulatory Alternatives Chapter and in this preamble at section XVIII, Summary and Explanation of the Proposed Standard, (k) Medical Surveillance.
The Panel recommends that OSHA consider that small entities may lack the flexibility and resources to provide alternative jobs to employees who test positive for the BeLPT, and whether MRP achieves its intended purpose given the course of beryllium disease. The Panel also recommends that if MRP is implemented, that its effects on the viability of very small firms with a sensitized employee be considered carefully.	Under the proposed standard, employees are only eligible for medical removal if they are sensitized or have been diagnosed with CBD; skin exposure is not a trigger for medical removal (unlike the version submitted by the SBAR Panel). After becoming eligible for medical removal an employee may choose to remain in a job with exposure at or above the action level, provided that the employee wears a respirator in accordance with the Respiratory Protection standard (29 CFR 1910.134). If the employee chooses removal, the employer is only required to place the employee in comparable work with exposure below the action level if such work is available; if such work is not available, the employer may place the employee on paid leave for six months or until such work becomes available. OSHA discusses the basis of the provision and requests comments on it in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (l) Medical Removal Protection. OSHA provides an analysis of costs and economic impacts of the provision in the PEA in Chapter 5 and Chapter 6, respectively.
The Panel recommends that OSHA consider more clearly defining the trigger mechanisms for medical surveillance and also consider additional or alternative triggers—such as limiting the BeLPT to a narrower range of exposure scenarios and reducing the frequency of BeLPT tests and physical exams. The Panel also recommends that OSHA reconsider whether the risk and cost of all parts of the medical surveillance provisions are appropriate where exposure levels are very low. In that context, the Panel recommends that OSHA should also consider the special problems and costs to small businesses that up until now may not have had to provide or manage the various parts of an occupational health standard or program.	As stated above, the triggers for medical surveillance in the proposed standard have changed from those presented to the SBAR Panel. Whereas the draft standard presented at the SBAR Panel required medical surveillance for employees with skin contact—potentially applying to employees with any level of airborne exposure—the proposed standard ties medical surveillance to exposures above the proposed PEL of 0.2 $\mu g/m^3$ (or signs or symptoms of beryllium-related health effects, or emergency exposure). Thus, small businesses with exposures below the proposed PEL would not need to provide or manage medical surveillance for their employees unless employees develop signs or symptoms of beryllium-related health effects or are exposed in emergencies. These issues are discussed in this preamble at section XVIII, Summary and Explanation of the Proposed Standard, (k) Medical Surveillance.
The Panel recommends that the Agency, in evaluating the economic feasibility of a potential regulation, consider not only the impacts of estimated costs on affected establishments, but also the effects of the possible outcomes cited by SERs: loss of market demand, the loss of market to foreign competitors, and of U.S. production being moved abroad by U.S. firms. The Panel also recommends that OSHA consider the potential burdens on small businesses of dealing with employees who have a positive test from the BeLPT. OSHA may wish to address this issue by examining the experience of small businesses that currently provide the BeLPT.	OSHA has reviewed the possible effects of the proposed regulation on market demand and/or foreign production, in addition to the Agency's usual measures of economic impact (costs as a fraction of revenues and profits). This discussion can be found in Chapter VI of the PEA (entitled Economic Feasibility Analysis and Regulatory Flexibility Determination).

TABLE IX–28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

Panel recommendation	OSHA response
The Panel recommends that OSHA consider seeking ways of minimizing costs for small businesses where the exposure levels may be very low. Clarifying the use of objective data, in particular, may allow industries and establishments with very low exposures to reduce their costs and involvement with many provisions of a standard. The Panel also recommends that the Agency consider tiering the application of ancillary provisions of the standard according to exposure levels and consider a more limited or narrowed scope of industries.	The provisions in the standard presented in the SBAR panel report applied to all employees, whereas the proposed standard's ancillary provisions are only applied to employees in work areas who are, or can reasonably be expected to be, exposed to airborne beryllium. In addition, the scope of the proposed standard includes several limitations. Whereas the standard presented in the SBAR panel report covered beryllium in all forms and compounds in general industry, construction, and maritime, the scope of the proposed standard (1) applies only to general industry; (2) does not apply to beryllium-containing articles that the employer does not process; and (3) does not apply to materials that contain less than 0.1 percent beryllium by weight. In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring (Section XVIII, Summary and Explanation of this Proposed Standard, (d) Exposure Monitoring). OSHA is also considering whether to create a guidance product on the use of objective data to comply with the requirements of this proposed standard. OSHA is considering two Regulatory Alternatives that would reduce the impact of ancillary alternatives on employers, including small businesses. Regulatory Alternative #7, a PEL-only standard, would drop all ancillary provisions from the standard. Regulatory Alternative #8 would limit the application of several ancillary provisions, including Exposure Monitoring, the written exposure control plan section of Method of Compliance, PPE, Housekeeping, and Medical Surveillance, to operations or employees with exposure levels exceeding the TWA PEL or STEL. These alternatives are discussed in the Regulatory Alternatives Chapter and in this preamble at Section I, Issues and Alternatives.
The Panel recommends that OSHA provide an explanation and analysis for all health outcomes (and their scientific basis) upon which it is regulating employee exposure to beryllium. The Panel also recommends that OSHA consider to what extent a very low PEL (and lower action level) may result in increased costs of ancillary provisions to small entities (without affecting airborne employee exposures). Since in the draft proposal the PEL and action level are critical triggers, the Panel recommends that OSHA consider alternate action levels, including an action level set at the PEL, if a very low PEL is proposed.	The explanation and analysis for all health outcomes (and their scientific basis) are discussed in this preamble at Section V, Health Effects, and Section VI, Preliminary Risk Assessment. They are also reviewed in this preamble at Section VIII, Significance of Risk, and the Benefits Chapter of the PEA. OSHA requests comment on these health outcomes. As discussed above, OSHA is considering Regulatory Alternatives #7 and #8, which would eliminate or reduce the impact of ancillary provisions on employers, respectively. These alternatives are discussed in the Regulatory Alternatives Chapter of the PEA and in this preamble at Section I, Issues and Alternatives. OSHA seeks comment on other ways to avoid costs of ancillary provisions when they are not necessary to protect employees from exposure to beryllium.
The Panel recommends that OSHA consider more clearly and thoroughly defining the triggers for ancillary provisions, particularly the skin exposure trigger. In addition, the Panel recommends that OSHA clearly explain the basis and need for small entities to comply with ancillary provisions. The Panel also recommends that OSHA consider narrowing the trigger related to skin and contamination to capture only those situations where surfaces and surface dust may contain beryllium in a concentration that is significant enough to pose any risk—or limiting the application of the trigger for some ancillary provisions.	OSHA has removed skin exposure as a trigger for several ancillary provisions in this proposed standard, including Exposure Monitoring, Hygiene Areas and Practices, and Medical Surveillance. In addition, the language of this proposed standard regarding skin exposure has changed: for some ancillary provisions, including PPE and Housekeeping, the requirements are triggered by visible contamination with beryllium or dermal contact with soluble beryllium compounds. These requirements are discussed in this preamble at Section XVIII, Summary and Explanation of this Proposed Standard. The Agency has also explained the basis and need for compliance with ancillary provisions in this preamble at Section XVIII, Summary and Explanation.
Several SERs said that OSHA should first assume the burden of describing the exposure level in each industry rather than employers doing so. Others said that the Agency should accept exposure determinations made on an industry-wide basis, especially where exposures were far below the PEL options under consideration. As noted above, the Panel recommends that OSHA consider alternatives that would alleviate the need for monitoring in operations or processes with exposures far below the PEL. The use of objective data is a principal method for industries with low exposures to satisfy compliance with a proposed standard. The Panel recommends that OSHA consider providing some guidance to small entities in the use of objective data.	In the Technological Feasibility Analysis presented in the PEA, OSHA has described the exposure level in each industry or application group. In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring (section XVIII, Summary and Explanation of this Proposed Standard, (d) Exposure Monitoring). Industry-wide data may be used as objective data to support an employer's case that exposures at its facilities are far below the PEL. OSHA is also considering whether to create a guidance product on the use of objective data to comply with requirements in the proposed standard.

TABLE IX–28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

Panel recommendation	OSHA response
The Panel recommends that OSHA consider more fully evaluating whether the BeLPT is suitable as a test for beryllium sensitization in an OSHA standard and respond to the points raised by the SERs about its efficacy. In addition, the Agency should consider the availability of other tests under development for detecting beryllium sensitization and not limit either employers' choices or new science and technology in this area. Finally, the Panel recommends that OSHA re-consider the trigger for medical surveillance where exposures are low and consider if there are appropriate alternatives.	OSHA has provided discussion of the BeLPT in Appendix A to the regulatory text; in this preamble at section V, Health Effects; and in this preamble at section XVIII, Summary and Explanation, (k) Medical Surveillance. In the regulatory text, OSHA has clarified that a test for beryllium sensitization other than the BeLPT may be used in lieu of the BeLPT if a more reliable and accurate diagnostic test is developed. In this preamble at Section I, Issues and Alternatives, the Agency requests comments on the BeLPT and on the reliability and accuracy of alternate tests. As stated above, the triggers for medical surveillance in this proposed standard have changed from those presented to the SBAR Panel. Whereas the draft standard presented during the SBREFA process required medical surveillance for employees with skin contact—potentially applying to employees with any level of airborne exposure—this proposed standard ties medical surveillance to exposures above the proposed PEL of 0.2 $\mu g/m^3$ (or signs or symptoms of beryllium-related health effects, or emergency exposure). The triggers for medical surveillance are discussed in this preamble at section XVIII, Summary and Explanation, (k) Medical Surveillance. OSHA is considering Regulatory Alternative #16, which would eliminate BeLPT testing requirements from this proposed standard. This alternative is discussed in the Regulatory Alternatives Chapter and in in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (k) Medical Surveillance.
Seeking ways of minimizing costs to low risk processes and operations: OSHA should consider alternatives for minimizing costs to industries, operations, or processes that have low exposures. Such alternatives may include, but not be limited to: encouraging the use of objective data by such mechanisms as providing guidance for objective data; assuring that triggers for skin exposure and surface contamination are clear and do not pull in low risk operations; providing guidance on least-cost ways for low risk facilities to determine what provisions of the standard they need to comply with; and considering ways to limit the scope of 28 the standard if it can be ascertained that certain processes do not represent a significant risk.	The standard presented in the SBAR panel report had skin exposure as a trigger. The only skin exposure trigger in this proposed standard is the requirement for PPE when employees' skin is potentially exposed to soluble beryllium compounds. OSHA uses an exposure profile to determine which workers will be affected by the standard. As a result, this proposed standard establishes regulated work areas and exposure monitoring only with respect to employees who are, or can reasonably be expected to be, exposed to airborne beryllium. In addition, the scope of this proposed standard includes several limitations. Whereas the standard presented in the SBAR panel report covered beryllium in all forms and compounds in general industry, construction, and maritime, the scope of this proposed standard (1) applies only to general industry; (2) does not apply to beryllium-containing articles that the employer does not process; and (3) does not apply to materials that contain less than 0.1 percent beryllium by weight. In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring (Section XVIII, Summary and Explanation of this Proposed Standard, (d) Exposure Monitoring). OSHA is also considering whether to create a guidance product on the use of objective data.
PEL-only standard: One SER recommended a PEL-only standard. This would protect employees from airborne exposure risks while relieving the beryllium industry of the cost of the ancillary provisions. The Panel recommends that OSHA, consistent with its statutory obligations, analyze this alternative.	OSHA is considering Regulatory Alternative #7, a PEL-only standard. This alternative is discussed in the Regulatory Alternatives Chapter of the PEA and in this preamble at Section I, Issues and Alternatives.
Alternative triggers for ancillary provisions: The Panel recommends that OSHA clarify and consider eliminating or narrowing the triggers for ancillary provisions associated with skin exposure or contamination. In addition, the Panel recommends that OSHA should consider trying ancillary provisions dependent on exposure rather than have these provisions all take effect with the same trigger. If OSHA does rely on a trigger related to skin exposure, OSHA should thoroughly explain and justify this approach based on an analysis of the scientific or research literature that shows a risk of sensitization via exposure to skin. If OSHA adopts a relatively low PEL, OSHA should consider the effects of alternative airborne action levels in pulling in many low risk facilities that may be unlikely to exceed the PEL—and consider using only the PEL as a trigger at very low levels.	OSHA has removed skin exposure as a trigger for several ancillary provisions in this proposed standard, including Exposure Monitoring, Hygiene Areas and Practices, and Medical Surveillance. In addition, the language of this proposed standard regarding skin exposure has changed: for some ancillary provisions, including PPE and Housekeeping, the requirements are triggered by visible contamination with beryllium or skin contact with soluble beryllium compounds. These requirements are discussed in this preamble at Section XVIII, Summary and Explanation. OSHA has explained the scientific basis for minimizing skin exposure to beryllium in this preamble at Section V, Health Effects, and explains the basis for specific ancillary provisions related to skin exposure in this preamble at Section XVIII, Summary and Explanation.

TABLE IX–28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

Panel recommendation	OSHA response
	In this proposed standard, the application of ancillary provisions is dependent on exposure, and not all provisions take effect with the same trigger. A number of requirements are triggered by exposures (or a reasonable expectation of exposures) above the PEL or action level (AL). As discussed above, OSHA is considering Regulatory Alternatives #7 and #8, which would eliminate or reduce the impact of ancillary provisions on employers, respectively. These alternatives are discussed in the Regulatory Alternatives Chapter of the PEA and in this preamble at Section I, Issues and Alternatives.
Revise the medical surveillance provisions, including eliminating the BeLPT: The BeLPT was the most common complaint from SERs. The Panel recommends that OSHA carefully examine the value of the BeLPT and consider whether it should be a requirement of a medical surveillance program. The Panel recommends that OSHA present the scientific evidence that supports the use of the BeLPT as several SERs were doubtful of its reliability. The Panel recommends that OSHA also consider reducing the frequency of physicals and the BeLPT, if these provisions are included in a proposal. The Panel recommends that OSHA also consider a performance-based medical surveillance program, permitting employers in consultation with physicians and health experts to develop appropriate tests and their frequency.	Responding to comments from SERs, OSHA has revised the medical surveillance provision and removed the skin exposure trigger for medical surveillance. As a result, OSHA estimates that the number of small-business employees requiring a BeLPT will be substantially reduced. OSHA has provided discussion of the BeLPT in Appendix A to the regulatory text; in this preamble at section V, Health Effects; and in this preamble at section XVIII, Summary and Explanation, (k) Medical Surveillance. In the regulatory text, OSHA has clarified that a test for beryllium sensitization other than the BeLPT may be used in lieu of the BeLPT if a more reliable and accurate diagnostic test is developed. In this preamble at Section I, Issues and Alternatives, the Agency requests comments on the BeLPT and on the reliability and accuracy of alternate tests. The frequency of periodic BeLPT testing in this proposed standard is biennial, whereas annual testing was included in the draft standard presented to the SBAR Panel. Regulatory Alternative #20 would reduce the frequency of physical examinations from annual to biennial, matching the frequency of BeLPT testing in this proposed rule. In response to the suggestion to allow performance-based medical surveillance, OSHA is considering two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Regulatory Alternative #16 would eliminate BeLPT testing requirements from this proposed standard. Regulatory Alternative #18 would eliminate the CT scan requirement from this proposed standard. These alternatives are discussed in the Regulatory Alternatives Chapter and in this preamble at Section XVIII, Summary and Explanation, (k) Medical Surveillance.
No medical removal protection (MRP): OSHA's draft proposed standard did not include any provision for medical removal protection, but OSHA did ask the SERs to comment on MRP as a possibility. Based on the SER comments, the Panel recommends that if OSHA includes an MRP provision, the agency provide a thorough analysis of why such a provision is needed, what it might accomplish, and what its full costs and economic impacts on those small businesses that need to use it might be.	This proposed standard includes an MRP provision. OSHA discusses the basis of the provision and requests comments on it in this preamble at Section XVIII, Summary and Explanation, (l) Medical Removal Protection. OSHA provides an analysis of costs and economic impacts of the provision in the PEA in Chapter V and Chapter VI, respectively. The Agency is considering Alternative #22, which would eliminate the MRP requirement from the standard. This alternative is discussed in the Regulatory Alternatives Chapter and in in this preamble at section XVIII, Summary and Explanation, (l) Medical Removal Protection.

X. OMB Review Under the Paperwork Reduction Act of 1995

A. Overview

The proposed general industry standard for occupational exposure to beryllium contains collection of information (paperwork) requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA–95), 44 U.S.C. 3501 *et seq.,* and OMB's regulations at 5 CFR part 1320. PRA–95 defines *''collection of information''* to mean, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format'' (44 U.S.C. 3502(3)(A)).

Under PRA–95, a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it, and the agency displays a currently valid OMB control number. In addition, the public is not required to respond to a collection of information unless the collection of information displays a currently valid OMB control number. Also, notwithstanding any other provision of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number.

B. Solicitation of Comments

OSHA prepared and submitted an Information Collection Request (ICR) for the collection of information requirements identified in this NPRM to OMB for review in accordance with 44 U.S.C. 3507(d). The Agency solicits comments on the proposed collection of information requirements and the estimated burden hours and costs associated with these requirements, including comments on the following items:

- Whether the proposed collection of information requirements are necessary for the proper performance of the

Agency's functions, including whether the information is useful;

• The accuracy of OSHA's estimate of the burden (time and cost) of the information collection requirements, including the validity of the methodology and assumptions used;

• The quality, utility and clarity of the information collected; and

• Ways to minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information.

C. Proposed Collection of Information Requirements

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(1), the following paragraphs provide information about this ICR.

1. *Title:* Occupational Exposure to Beryllium

2. *Description of the ICR:* The proposed Beryllium standard contains collection of information requirements which are essential components of the occupational safety and health standard that will assist both employers and their employees in identifying the exposures to beryllium and beryllium compounds, the medical effects of such exposures, and the means to reduce the risk of overexposures to beryllium and beryllium compounds.

3. Brief Summary of the Collection of Information Requirements

Below is a summary of the collection of information requirements identified in the Beryllium proposal. Specific details contained in the following collections of information requirements are discussed in Section XVIII: *Summary and Explanation of the Proposed Standard.*

§ 1910.1024(d) Exposure Monitoring

Under paragraph (d)(5)(i) of the proposed standard, within 15 working days after receiving the results of any exposure monitoring completed under this standard, employers must notify each employee whose exposure is characterized by the monitoring in writing. Employers must either notify each of these employees individually in writing, or post the exposure monitoring results in an appropriate location accessible to all of these employees. In this proposed standard, the following provisions require exposure monitoring: § 1910.1024(d)(1), General; § 1910.1024(d)(2), Initial Exposure Monitoring; § 1910.1024(d)(3), Periodic Exposure Monitoring; § 1910.1024(d)(4), Additional Monitoring.

Proposed paragraph (d)(5)(ii) details additional information an employer would need to include in the written notification in (d)(5)(i), should beryllium exposure exceed the TWA PEL or STEL: a description of the suspected or known sources of exposure, and the corrective action(s) the employer has taken or will take to reduce the employee's exposure to or below the applicable PEL.

§ 1910.1024(e)(2)(i) & (ii) Demarcation of Beryllium Work Areas

Proposed paragraph (e)(2)(i) would require employers to identify each beryllium work area through signs or any other methods that adequately establish and inform each employee of the boundaries of each beryllium work area. Paragraph (e)(2)(ii) would require employers to identify each regulated area in accordance with paragraph (m)(2).

§ 1910.1024(f)(1)(i), (ii), and (iii) Written Exposure Control Plan

Proposed paragraph (f)(1)(i) would require employers to establish, implement, and maintain a written exposure control plan for beryllium work areas. The plan must contain: (A) An inventory of operations and job titles reasonably expected to have exposure; (B) an inventory of operations and job titles reasonably expected to have exposure at or above the action level; (C) an inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL; (D) procedures for minimizing cross-contamination, including but not limited to preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas; (E) procedures for keeping surfaces in the beryllium work area as free as practicable of beryllium; (F) procedures for minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace; (G) an inventory of engineering and work practice controls; and (H) procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators.

Proposed paragraph (f)(1)(ii) would require employers to update their exposure control plans whenever any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in new or additional exposures to beryllium. Paragraph (f)(1)(ii) also requires employers to update their plans when an employee is confirmed positive for beryllium sensitization, is diagnosed with CBD, or shows other signs or symptoms related to beryllium exposure. In addition, this paragraph requires employers to update their plans if the employer has any reason to believe that new or additional exposures are occurring or will occur. Proposed paragraph (f)(1)(iii) would require employers to make a copy of the exposure control plan accessible to each employee who is or can reasonably be expected to be exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)).

§ 1910.1024(g) Respiratory Protection

Proposed paragraph (g)(1) would require employers to provide at no cost and ensure that each employee uses respiratory protection during certain periods or operations. Where the proposed standard requires an employee to use respiratory protection, proposed paragraph (g)(2) requires such use to be in accordance with the Respiratory Protection Standard (29 CFR 1910.134).

The Respiratory Protection Standard's collection of information requirements indicate that employers must: develop a written respirator program; obtain and maintain employee medical evaluation records; provide the physician or other licensed health care professional (PLHCP) with information about the employee's respirator and the conditions under which the employee will use the respirator; administer fit tests for employees who will use negative- or positive-pressure, tight-fitting facepieces; and establish and retain written information regarding medical evaluations, fit testing, and the respirator program.

§ 1910.1024(h) Personal Protective Clothing and Equipment

§ 1910.1024(h)(2)(v) Removal and Storage

Proposed paragraph (h)(2)(v) would require employers to ensure that any protective clothing or equipment required by the standard which is removed from the workplace for laundering, cleaning, maintenance, or disposal is labeled in accordance with paragraph (m)(3) of the proposed standard and the Hazard Communication standard at 29 CFR 1910.1200.

§ 1910.1024(h)(3)(iii) Cleaning and Replacement

Proposed paragraph (h)(3)(iii) would require employers to inform in writing the persons or the business entities who launder, clean or repair the protective clothing or equipment required by this standard of the potentially harmful effects of exposure to airborne beryllium and contact with soluble beryllium compounds and how the protective clothing and equipment must be handled in accordance with the standard.

§ 1910.1024(j)(3) Housekeeping

Proposed paragraph (j)(3)(i) requires waste, debris, and materials visibly contaminated with beryllium and consigned for disposal to be disposed of in sealed, impermeable enclosures. Proposed paragraph (j)(3)(ii) requires these enclosures to be labeled in accordance with proposed paragraph (m)(3) of the standard.

Proposed paragraph (j)(3)(iii) requires materials designated for recycling that are visibly contaminated with beryllium to be cleaned to remove the visible particulate or placed in sealed, impermeable enclosures that are labeled in accordance with proposed paragraph (m)(3) of the standard.

§ 1910.1024(k) Medical Surveillance

§ 1910.1024(k)(1), (2), and (3) Employee Medical Surveillance

Proposed paragraph (k)(1) details when and under what conditions an employer must make medical surveillance available to its employees. Paragraph (k)(2) of the proposed standard specifies the frequency of medical examinations that are to be offered to those employees covered by the medical surveillance program, and proposed paragraph (k)(3) details the content of the medical examinations.

§ 1910.1024(k)(4) Information Provided to the PLHCP

Proposed paragraph (k)(4) would require employers to provide a copy of this standard and its appendices to the examining PLHCP. In addition, the proposed paragraph would require employers to provide the following information, if known, to the PLHCP: (A) A description of the employee's former and current duties that relate to the employee's occupational exposure; (B) the employee's former and current levels of occupational exposure; (C) a description of any protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that protective clothing and equipment; and (D) information from records of employment-related medical examinations previously provided to the employee, currently within the control of the employer, after obtaining a medical release from the employee.

§ 1910.1024(k)(5)(i), (ii), and (iii) Licensed Physician's Written Medical Opinion

Under proposed paragraph (k)(5)(i), the employer must obtain a written medical opinion from the licensed physician within 30 days of the employee's medical examination. The written medical opinion must contain the following information: (A) The licensed physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of CBD from further exposure; (B) any recommended limitations on the employee's exposure, including the use and limitations of protective clothing or equipment, including respirators; and (C) a statement that the PLHCP has explained the results of the medical examination to the employee, including any tests conducted, any medical conditions related to exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

Proposed paragraph (k)(5)(ii) would require the employer to ensure that neither the licensed physician nor any other PLHCP reveals to the employer findings or diagnoses which are unrelated to beryllium exposure.

Proposed paragraph (k)(5)(iii) would require the employer to provide a copy of the licensed physician's written medical opinion to the employee within two weeks after receiving it.

§ 1910.1024(k)(7) Beryllium Sensitization Test Results Research

Proposed paragraph (k)(7) would require employers, upon request by OSHA, to convey employees' beryllium sensitization test results to OSHA for evaluation and analysis.

§ 1910.1024(m) Communication of Hazards

Proposed paragraph (m)(1)(i) would require chemical manufacturers, importers, distributors, and employers to comply with all applicable requirements of the Hazard Communication Standard (HCS) for beryllium (29 CFR 1910.1200). Proposed paragraph (m)(1)(ii) requires that when classifying the hazards of beryllium, the employer must address at least the following: cancer; lung effects (chronic beryllium disease and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation.

Proposed paragraph (m)(1)(iii) would require employers to include beryllium in the hazard communication program established to comply with the HCS, and ensure that each employee has access to labels on containers and safety data sheets for beryllium.

Proposed paragraph (m)(2)(i) would require employers to post warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area. Proposed paragraph (m)(2)(ii) would require these signs to be legible and readily visible, and contains language that would be required to appear on each warning sign.

Proposed paragraph (m)(3) would require employers to label each bag and container of clothing, equipment, and materials visibly contaminated with beryllium consistent with the Hazard Communication standard at 29 CFR 1910.1200. Proposed paragraph (m)(3) also contains language that would be required to appear on every such label.

Proposed paragraph (m)(4)(iv) would require employers to make copies of the standard and its appendices readily available at no cost to each employee and designated employee representative.

§ 1910.1024(m)(4)(iv) Employee Information

Paragraph (m)(4)(iv) requires that employers make copies of the standard and its appendices readily available at no cost to each employee and designated employee representative.

§ 1910.1024(n) Recordkeeping

§ 1910.1024(n)(1)(i), (ii), and (iii) Exposure Measurements.

Proposed paragraph (n)(1)(i) would require employers to keep records of all measurements taken to monitor employee exposure to beryllium as required by paragraph (d) of the standard.

Proposed paragraph (n)(1)(ii) would require employers to include at least the following information in the records: (A) The date of measurement for each sample taken; (B) the operation that is being monitored; (C) the sampling and analytical methods used and evidence of their accuracy; (D) the number, duration, and results of samples taken; (E) the type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and, (F) the name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

Proposed paragraph (n)(1)(iii) would require employers to maintain employee exposure monitoring records in accordance with 29 CFR 1910.1020(d)(1)(ii).

§ 1910.1024(n)(2)(i), (ii), and (iii) Historical Monitoring Data

Proposed paragraph (n)(2)(i) would require employers to establish an accurate record of any historical monitoring data used to satisfy the initial monitoring requirements in paragraph (d)(2) of the proposed standard. Paragraph (n)(2)(ii) would require the employer to demonstrate that the data comply with the requirements of paragraph (d)(2) of the standard. Paragraph (n)(2)(iii) would require the employer to maintain historical monitoring data in accordance with 29 CFR 1910.1020.

§ 1910.1024(n)(3)(i), (ii), and (iii) Objective Data

Proposed paragraph (n)(3)(i) would require employers to establish accurate records of any objective data relied upon to satisfy the requirement for initial monitoring in proposed paragraph (d)(2). Proposed paragraph (n)(3)(ii) would require employers to have at least the following information in such records: (A) The data relied upon; (B) the beryllium-containing material in question; (C) the source of the objective data; (D) a description of the operation exempted from initial monitoring and how the data support the exemption; and (E) other information demonstrating that the data meet the requirements for objective data contained in paragraph (d)(2)(ii) of the proposed standard. Proposed paragraph (n)(3)(iii) would require employers to maintain objective data records in accordance with 29 CFR 1910.1020.

§ 1910.1024(n)(4)(i), (ii), & (iii) Medical Surveillance

Proposed paragraph (n)(4)(i) would require employers to establish accurate records for each employee covered by the medical surveillance requirements in proposed paragraph (k). Proposed paragraph (n)(4)(ii) would require employers to include in employee medical records the following information about the employee: (A) Name, social security number, and job classification; (B) a copy of all licensed physicians' written opinions; and (C) a copy of the information provided to the PLHCP as required by paragraph (k)(4) of the proposed standard. Proposed paragraph (n)(4)(iii) would require employers to maintain medical records in accordance with 29 CFR 1910.1020.

§§ 1910.1024(n)(5)(i) & (ii) Training

Proposed paragraph (n)(5)(i) would require employers to prepare an employee training record at the completion of any training required by the proposed standard. The training record must contain the following information: The name, social security number, and job classification of each employee trained; the date the training was completed; and the topic of the training. Proposed paragraph (n)(5)(ii) would require employers to maintain employee training records for three years after the completion of training. This record maintenance requirement would also apply to records of annual retraining or additional training as described in paragraph (m)(4) of the proposed standard.

§ 1910.1024(n)(6) Access to Records

Under proposed paragraph (n)(6), employers must make all records maintained as a requirement of the standard available for examination and copying to the Assistant Secretary, the Director of NIOSH, each employee, and each employee's designated representative(s) in accordance with the *Access to employee exposure and medical records* standard (29 CFR 1910.1020).

§ 1910.1024(n)(7) Transfer of Records

Paragraph (n)(7) of the proposed standard would require employers to comply with the transfer requirements contained in the *Access to employee exposure and medical records* standard (29 CFR 1910.1020(h)). That existing standard requires employers either to transfer records to successor employers or, if there is no successor employer, to inform employees of their access rights at least three months before the cessation of the employer's business.

4. *Affected Public:* Business or other for-profit. This standard applies to employers in general industry who have employees that may have occupational exposures to any form of beryllium, including compounds and mixtures, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of the proposed standard. This standard does not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process. Also, this standard does not apply to materials containing less than 0.1% beryllium by weight.

5. *Number of respondents:* Employers in general industry that have employees working in jobs affected by beryllium exposure (4,088 employers).

6. *Frequency of responses:* Frequency of response varies depending on the specific collection of information.

7. *Number of responses:*155,818.

8. *Average time per response:* Varies from 5 minutes (.08 hours) for a clerical worker to generate and maintain an employee medical record, to 8 hours for a human resource manager to develop and implement a written exposure control plan.

9. *Estimated total burden hours:* 80,776.

10. *Estimated cost (capital-operation and maintenance):* $10,900,579.

D. Submitting Comments

Members of the public who wish to comment on the paperwork requirements in this proposal must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, OSHA (RIN–1218–AB76), Office of Management and Budget, Room 10235, Washington, DC 20503, Fax: 202–395–5806 (this is not a toll-free numbers), email: *OIRA_submission@omb.eop.gov*. The Agency encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket (Docket Number OSHA–H005C–2006–0870), along with their comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES**.

E. Docket and Inquiries

To access the docket to read or download comments and other materials related to this paperwork determination, including the complete Information Collection Request (ICR) (containing the Supporting Statement with attachments describing the paperwork determinations in detail) use the procedures described under the section of this notice titled ADDRESSES. You also may obtain an electronic copy of the complete ICR by visiting the Web page at *http://www.reginfo.gov/public/do/PRAMain*, scroll under ''Currently Under Review'' to ''Department of Labor (DOL)'' to view all of the DOL's ICRs, including those ICRs submitted for proposed rulemakings. To make inquiries, or to request other information, contact Mr. Todd Owen, Directorate of Standards and Guidance, OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

XI. Federalism

The Agency reviewed the proposed beryllium rule according to the Executive Order (E.O.) on Federalism (E.O. 13132, 64 FR 43255, Aug. 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that would restrict States' policy options and take such actions only when clear constitutional authority exists and the problem is of national scope. The E.O. allows Federal agencies to preempt State law only with the expressed consent of Congress; in such cases, Federal agencies must limit preemption of State law to the extent possible.

Under Section 18 of the Occupational Safety and Health Act (the ''Act'' or ''OSH Act,'' 29 U.S.C. 667), Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as ''State-Plan States.'' (29 U.S.C. 667). Occupational safety and health standards developed by State-Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards.

While OSHA drafted this proposed rule to protect employees in every State, Section 18(c)(2) of the OSHA Act permits State-Plan States to develop and enforce their own standards, provided the requirements in these standards are at least as safe and healthful as the requirements specified in this proposed rule if it is promulgated.

In summary, this proposed rule complies with E.O. 13132. In States without OSHA-approved State plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards; in these States, this rule limits State policy options in the same manner as every standard promulgated by the Agency. In States with OSHA-approved State plans, this rulemaking does not significantly limit State policy options.

XII. State-Plan States

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the 27 State and U.S. territories with their own OSHA-approved occupational safety and health plans (''State-Plan States'') must revise their standards to reflect the new standard or amendment. The State standard must be at least as effective as the Federal standard or amendment, and must be promulgated within six months of the publication date of the final Federal rule. 29 CFR 1953.5(a).

The State may demonstrate that a standard change is not necessary because, for example, the State standard is already the same as or at least as effective as the Federal standard change. In order to avoid delays in worker protection, the effective date of the State standard and any of its delayed provisions must be the date of State promulgation or the Federal effective date, whichever is later. The Assistant Secretary may permit a longer time period if the State makes a timely demonstration that good cause exists for extending the time limitation. 29 CFR 1953.5(a).

Of the 27 States and territories with OSHA-approved State plans, 22 cover public and private-sector employees: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. The five states and territories whose OSHA-approved State plans cover only public-sector employees are: Connecticut, Illinois, New Jersey, New York, and the Virgin Islands.

This proposed beryllium rule applies to general industry. If adopted as proposed, all State Plan States would be required to revise their general industry standard appropriately within six months of Federal promulgation.

XIII. Unfunded Mandates Reform Act

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1532, an agency must prepare a written ''qualitative and quantitative assessment'' of any regulation creating a mandate that ''may result in the expenditure by the State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more'' in any one year before issuing a notice of proposed rulemaking. OSHA's proposal does not place a mandate on State or local governments, for purposes of the UMRA, because OSHA cannot enforce its regulations or standards on State or local governments (*see* 29 U.S.C. 652(5)). Under voluntary agreement with OSHA, some States enforce compliance with their State standards on public sector entities, and these agreements specify that these State standards must be equivalent to OSHA standards. The OSH Act also does not cover tribal governments in the performance of traditional governmental functions, though it does when tribal governments engage in commercial activity. However, the proposal would not require tribal governments to expend, in the aggregate, $100,000,000 or more in any one year for their commercial activities. Thus, although OSHA may include compliance costs for affected governmental entities in its analysis of the expected impacts associated with a proposal, the proposal does not trigger the requirements of UMRA based on its impact on State, local, or tribal governments.

Based on the analysis presented in the Preliminary Economic Analysis (see Section IX above), OSHA concludes that the proposal would impose a Federal mandate on the private sector in excess of $100 million in expenditures in any one year. The Preliminary Economic Analysis constitutes the written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits required under Section 202(a) of the UMRA (2 U.S.C. 1532).

XIV. Protecting Children From Environmental Health and Safety Risks

E.O.13045 (66 FR 19931 (Apr. 23, 2003)) requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to E.O. 12866 (58 FR 51735 (Oct. 4, 1993)) must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. E.O.13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under E.O. 12866 (*i.e.,* a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term ''environmental health risks and safety risks'' means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.,* through air, food, water, soil, product use).

The proposed beryllium rule is economically significant under E.O. 12866 (see Section IX of this preamble). However, after reviewing the proposed beryllium rule, OSHA has determined that the rule would not impose environmental health or safety risks to children as set forth in E.O. 13045. The proposed rule would require employers to limit employee exposure to beryllium and take other precautions to protect employees from adverse health effects associated with exposure to beryllium. OSHA is not aware of any studies showing that exposure to beryllium disproportionately affects children or that employees under 18 years of age who may be exposed to beryllium are disproportionately affected by such exposure. Based on this preliminary determination, OSHA believes that the proposed beryllium rule does not constitute a covered regulatory action as defined by E.O. 13045. However, if such conditions exist, children who are exposed to beryllium in the workplace would be better protected from exposure to beryllium under the proposed rule than they are currently.

XV. Environmental Impacts

OSHA has reviewed the beryllium proposal according to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). Based on that review, OSHA does not expect that the proposed rule, in and of itself, would create additional environmental issues. OSHA has made a preliminary determination that the proposed standard will have no impact on air, water, or soil quality; plant or animal life; the use of land or aspects of the external environment. Therefore, OSHA concludes that the proposed beryllium standard would have no significant environmental impacts.

XVI. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed this proposed rule in accordance with E.O. 13175 on Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000), and determined that it does not have ''tribal implications'' as defined in that order. The rule, if promulgated, would not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

XVII. Public Participation

OSHA encourages members of the public to participate in this rulemaking by submitting comments on the proposal.

Written Comments. OSHA invites interested persons to submit written data, views, and arguments concerning this proposal. In particular, OSHA encourages interested persons to comment on the issues raised at the end of each section. When submitting comments, persons must follow the procedures specified above in the sections titled **DATES** and **ADDRESSES**.

Informal public hearings. The Agency will schedule an informal public hearing on the proposed rule if requested during the comment period.

XVIII. Summary and Explanation

Introduction

This section of the preamble explains the requirements that OSHA proposes to control occupational exposure to beryllium, including the purpose of these requirements and how they will protect workers from hazardous beryllium exposures.

OSHA believes, based on currently available information, that the proposed requirements are necessary and appropriate to protect workers exposed to beryllium. In developing this proposed rule, OSHA has considered many sources of data and information, including responses to the Request for Information (RFI) for ''Occupational Exposure to Beryllium'' (OSHA, 2002); the responses from Small Entity Representatives (SERs) who participated in the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*) process (OSHA, 2007a); recommendations of the Small Business Advocacy Review (SBAR) Panel (OSHA, 2008b); the Department of Energy (DOE) Chronic Beryllium Disease Prevention Program rule (DOE, 1999); and numerous scientific studies, professional journal articles, and other data obtained by the Agency.

The provisions in the proposed standard are generally consistent with other recent OSHA health standards, such as chromium (VI)(29 CFR 1910.1026) and cadmium (29 CFR 1910.1027). Using a similar approach across health standards, when possible, makes them more understandable and easier for employers to follow, and helps to facilitate uniformity of interpretation. This approach is also consistent with section 6(b)(5) of the OSH Act, which states that health standards shall consider ''experience gained under this and other health and safety laws'' (29 U.S.C. 655(b)(5)). However, to the extent that protecting workers from occupational exposure to beryllium requires different or unique approaches, the Agency has formulated proposed requirements to address the specific hazards and working conditions associated with beryllium exposure.

Also pursuant to section 6(b)(5), OSHA has expressed the proposed requirements in performance-based language, where possible, to provide employers with greater flexibility in determining the most effective strategies for controlling beryllium hazards in their workplaces. OSHA believes this approach allows employers to incorporate changes and advancements in control strategy, technology, and industry practice, thereby reducing the need to revise the rule when those changes occur.

(a) Scope and Application

In paragraph (a)(1), OSHA proposes to apply this standard to occupational exposure to beryllium in all forms, compounds, and mixtures in general industry.

For the purpose of the proposed rule, OSHA is treating beryllium generally, instead of individually addressing specific compounds, forms, and mixtures. Based on a review of scientific studies, OSHA has preliminarily determined that the toxicological effects of beryllium exposure on the human body are similar regardless of the form of beryllium (see the Health Effects section of this preamble at V.B.5; V.G). OSHA is not aware of any information that would lead the Agency to conclude that exposure to different forms of beryllium necessitates different regulatory approaches or requirements.

OSHA has preliminarily decided to limit the scope of the rulemaking to general industry. This proposal is modeled on a suggested rule that was crafted by two major stakeholders in general industry, Materion Brush and the United Steelworkers Union (Materion and USW, 2012). In the course of developing this proposal, they provided OSHA with data on exposure and control measures and information on their experiences with handling beryllium in general industry settings. At this time, the information available to OSHA on beryllium exposures outside of general industry is limited, but suggests that most operations in other sectors are unlikely to involve beryllium exposure. The Agency hopes to expedite the rulemaking process by limiting the scope of this proposal to general industry and relying on already existing standards to protect workers in those operations outside of general industry where beryllium exposure may exist.

The proposed rule would not apply to marine terminals, longshoring, or agriculture. OSHA has not found evidence indicating that beryllium is used or handled in these sectors in a way that might result in beryllium exposure. The proposed rule also excludes the construction and shipyard sectors. OSHA believes that occupational exposures to beryllium in the construction and shipyard sectors occur primarily in abrasive blasting operations.

Abrasive blasters and ancillary abrasive blasting workers are exposed to beryllium from coal slag and other abrasive blast material that may contain beryllium as a trace contaminant. Airborne concentrations of beryllium have been measured above the current TWA PEL of 2 μg/m³ when blast material containing beryllium is used as intended (see Appendix IV–C in the PEA, OSHA 2014). Abrasive blasters, pot tenders, and cleanup workers have the potential for significant airborne exposure during blasting operations and during cleanup of spent material that may contain beryllium as a trace contaminant.

To address high concentrations of various hazardous chemicals in abrasive blasting material, employers must already be using engineering and work practice controls to limit workers' exposures and must be supplementing these controls with respiratory protection when necessary. For example, abrasive blasters in the construction industry fall under the protection of the Ventilation standard (29 CFR 1926.57). The Ventilation standard includes an abrasive blasting subsection (29 CFR 1926.57(f)), which requires that abrasive blasting respirators be worn by all abrasive blasting operators when working inside blast-cleaning rooms (29 CFR 1926.57(f)(5)(ii)(A)), or when using silica sand in manual blasting operations where the nozzle and blast are not physically separated from the operator in an exhaust-ventilated enclosure (29 CFR 1926.57(f)(5)(ii)(B)), or when needed to protect workers from exposures to hazardous substances in excess of the limits set in § 1926.55 (29 CFR 1926.57(f)(5)(ii)(C); ACGIH, 1971)). For maritime, standard 29 CFR 1915.34(c) covers similar requirements for respiratory protection needed in blasting operations. Due to these requirements, OSHA believes that abrasive blasters already have controls in place and wear respiratory protection during blasting operations. Thus, in estimating costs for Regulatory Alternatives #2a and #2b, OSHA judged that the reduction of the TWA PEL would not impose costs for additional engineering controls or respiratory protection in abrasive blasting (see Appendix VIII–C in this chapter for details). OSHA requests comment on this issue—in particular, whether abrasive blasters using blast material that may contain beryllium as a trace contaminant are already using all feasible engineering and work practice controls, respiratory protection, and PPE that would be required by Regulatory Alternatives #2a and #2b.

OSHA requests comment on the limitation of the scope to general industry, as well as information on beryllium exposures in all industry sectors. The Agency requests information on whether employees in the construction, maritime, longshoring, shipyard, and agricultural sectors are exposed to beryllium in any form and, if so, their levels of exposure and what types of exposure controls are currently in place. In particular, OSHA requests comment on whether abrasive blasters using blast material that may contain beryllium as a trace contaminant are already using all feasible engineering and work practice controls, respiratory protection, and PPE. OSHA also requests comment on Regulatory Alternatives #2a and #2b, presented at the end of this section, that would provide protection to workers in sectors outside of general industry. Regulatory Alternative #2a would expand the scope of the proposed standard to include employers in construction and maritime. Regulatory #2b would change the Z tables in 29 CFR 1910.1000 and 29 CFR 1915.1000, and Appendix A of 29 CFR 1926.55, to lower the permissible exposure limits for beryllium for workers in all beryllium-exposed occupations. Another regulatory alternative that would impact the scope of affected industries, extending eligibility for medical surveillance to employees in shipyards, construction, and parts of general industry excluded from the scope of the proposed standard, is discussed along with other medical surveillance alternatives (see this preamble at Section XVIII, paragraph (k), Regulatory Alternative #21). Depending on the nature of the data and comments provided, OSHA envisions possible expansions of its regulation of beryllium either as part of this rulemaking or at a later time.

Paragraph (a)(2) specifies that the proposed rule would not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process. The HCS defines an article as ''a manufactured item other than a fluid or particle: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities *e.g.,* minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.'' For example, items or parts containing beryllium that employers assemble where the physical integrity of the item is not compromised are unlikely to release more than a very small quantity of beryllium that would not pose a physical or health hazard for workers. These items would be considered articles that are exempt from the scope of the proposed standard. Similarly, finished or processed items or parts containing beryllium that employers are simply packing in containers or affixing with shipping tags or labels are unlikely to release more than a minute or trace amount of beryllium. These items would also come within the proposed exemption. By contrast, if an employer performs operations such as machining, grinding, blasting, sanding, or other processes that physically alter an item, these operations would not fall within the exemption in proposed paragraph (a)(2) because they involve processing of the item and could result in significant exposure to beryllium-containing material.

Paragraph (a)(3) specifies that the proposed rule would not apply to materials containing less than 0.1% beryllium by weight. A similar exemption is included in several previously promulgated standards, including Benzene (29 CFR 1910.1028), Methylenedianiline (MDA) (29 CFR 1910.1050), and 1,3-Butadiene (BD) (29 CFR 1910.1051). These exemptions were established to limit the regulatory burden on employers who do not use materials containing 0.1 percent or more of the substance in question, on the premise that workers in exempted industries are not exposed at levels of concern. In the preamble to the MDA standard, OSHA states that the Agency relied on data showing that worker exposure to mixtures or materials of MDA containing less than 0.1 percent MDA did not create any hazards other than those expected from worker exposure beneath the action level (57 FR 35630, 35645–46, August 10, 1992). The exemption in the BD standard does not apply where airborne concentrations generated by such mixtures can exceed the action level or STEL. The exemption in the Benzene standard was based on indications that exposures resulting from substances containing trace amounts of benzene would generally be below the exposure limit, and on OSHA's belief that the exemption would encourage employers to reduce the concentration of benzene in certain substances (43 FR 27962, 27968, June 27, 1978).

OSHA is aware of two industries in the general industry sector that would be exempted from the proposed standard under proposed paragraph (a)(3): Coal-fired electric power generation and primary aluminum production. As discussed in the PEA, Chapter IV, Appendices A and B, most employees' TWA exposures in these industries do not exceed the proposed action level of 0.1 μg/m³. However, exposures above the proposed PEL of 0.2 μg/m³ have been found in some jobs and in facilities with poor housekeeping and work practices. In coal-fired electric power generation, these higher exposures are associated with intermittent exposure to fly ash during maintenance work in and around baghouses and boilers. Fly ash contains less than 0.01% beryllium; however, exposures between 0.1 and 0.4 μg/m³ were observed among workers maintaining boilers. Exposures for baghouse cleaning frequently exceeded the current PEL, reaching as high as 13 μg/m³. In aluminum production, the bauxite ore used as a raw material contains naturally occurring beryllium in the part per million range (*i.e.* <0.0001%); however, a study of four smelters showed that the arithmetic mean exposure was slightly above the proposed PEL, and the 95th percentile exposure (of 965 samples) was above 1 μg/m³. BeLPT testing in a group of 734 aluminum workers found two cases of confirmed beryllium sensitization (0.27%) and an additional few abnormal results that could not be confirmed, either because the worker was not retested or the retest appeared normal (Taiwo et al., 2008).

OSHA requests comment on the exemption proposed for the beryllium standard. Is it appropriate to include an exemption for operations where beryllium exists only as a trace contaminant, but some workers can nevertheless be significantly exposed? Should the Agency consider dropping the exemption, or constraining it to operations where exposures are below the proposed action level and STEL? OSHA requests additional data describing the levels of airborne beryllium in workplaces that fall under this exemption and comments on regulatory alternatives, discussed at the end of this section, that would eliminate or modify the exemption.

A number of stakeholders, including SERs who participated in the SBREFA process, urged OSHA to exempt certain industries or processes and activities from the proposed standard. In support of this request, SERs from the stamping industry argued that their exposures are low, below 0.2 μg/m³ (OSHA, 2007a). In addition, some SERs requested exemptions from particular requirements. SERs from the dental laboratory industry requested exemptions from all requirements other than training and the permissible exposure limit (PEL). In support of this request, they also argued that their exposures are very low, around 0.02 μg/m³ when ventilation is used. They indicated that they already have sufficient engineering and work practice controls in place to keep exposures low (OSHA, 2008b). The SBREFA Panel recommended that OSHA consider a more limited scope of industries (OSHA, 2008b).

The Panel's recommendation is addressed in part in this proposed standard, which has a much more limited scope than the draft standard reviewed by the SBREFA Panel. Whereas the draft reviewed by the Panel covered beryllium in all forms and compounds in general industry, construction, and maritime, the scope of the current beryllium proposal includes general industry only, and does not apply to employers in construction and maritime. In addition, it provides an exemption for those working with materials that contain beryllium only as a trace contaminant (less than 0.1 percent composition by weight).

Although much narrower than the scope in the SBREFA draft, the current proposal's scope includes industries of concern for some SERs. OSHA's preliminary feasibility analysis indicates that worker exposures in both dental laboratories and stamping facilities exceed or have the potential to exceed the proposed TWA PEL where appropriate controls are not in place (see section IX of this preamble, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis). Accordingly, OSHA has not exempted them from the proposed standard. However, if employers in these industries have historical or objective data that meet the requirements set forth in proposed paragraph (d)(2) demonstrating that they have no exposures or that exposures are below the action level and at or below the STEL, these employers may be able to satisfy many of their obligations under this proposed standard by reference to these data.

Some stakeholders, including employers who do stripping operations, urged that OSHA exempt them from the proposed rule because any beryllium exposures generated in their facilities were comprised of larger-sized particles, which they contended were not as harmful as smaller ones (OSHA, 2008b). OSHA has decided not to exempt operations based on particle size. As discussed in this preamble at section V, Health Effects, there is not sufficient evidence to demonstrate that particle size has a significant bearing on health outcomes.

While acknowledging the concerns raised by SERs that the scope of the standard might be too broad, OSHA is concerned that the scope of the current proposal might be too narrow. Exposures have the potential to exceed the proposed PEL in some blasting operations in construction and maritime, and in some general industry operations where beryllium exists as a trace contaminant. Abrasive blasters and ancillary abrasive blasting workers are exposed to beryllium from coal slags and other abrasive blast material, which contain beryllium in amounts less than 0.1 percent. Airborne concentrations of beryllium have been measured above the current TWA PEL of 2 μg/m³ when the blast material is used as intended. Abrasive blasters, pot tenders, and cleanup workers working primarily in construction and shipyards have the potential for significant airborne exposure during blasting operations and during cleanup of spent blast material. Coal fly ash in coal powered utility facilities is also known to contain trace amounts of beryllium, which may become airborne during furnace and bag house operations and result in exposures exceeding the current PELs. Similarly, beryllium exists as a contaminant in aluminum ore and may result in exposures above the proposed PELs during aluminum refining and production.

OSHA invites comment on the proposed scope of the standard and on Regulatory Alternatives 1 and 2 below, which would increase protection for workers in maritime and construction industries and in occupations dealing with beryllium as a trace contaminant.

Regulatory Alternatives 1a and 1b

Regulatory Alternative #1a would modify the proposed scope to eliminate the exemption for materials containing less than 0.1 percent beryllium by weight. Under this alternative, the scope of the rule would cover employers in general industry, including industries or occupations where beryllium exists as a trace contaminant. Regulatory Alternative #1a would expand the scope of the proposed standard to include all operations in general industry where beryllium exists only as a trace contaminant; that is, where the materials used contain no more than 0.1 percent beryllium by weight. Regulatory

Alternative #1b is similar to Regulatory Alternative #1a, but exempts operations where the employer can show that employees' exposures will not meet or exceed the action level or exceed the STEL. Where the employer has objective data demonstrating that a material containing beryllium or a specific process, operation, or activity involving beryllium cannot release beryllium in concentrations at or above the proposed action level or above the proposed STEL under any expected conditions of use, the specific process, operation, or activity would be exempt from the proposed standard except for recordkeeping requirements pertaining to the objective data. Alternative #1a and Alternative #1b, like the proposed rule, would not cover employers or employees in construction or shipyards.

Regulatory Alternatives 2a and 2b

These two alternatives would increase protections for workers in the construction and maritime sectors. Regulatory alternative #2a would expand the scope of the proposed standard to also include employers in construction and maritime. For example, this alternative would cover abrasive blasters, pot tenders, and cleanup staff working in construction and shipyards who have the potential for airborne beryllium exposure during blasting operations and during cleanup of spent media. Regulatory alternative #2b would amend 29 CFR 1910.1000 Table Z–1, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A to replace the current permissible exposure limits for beryllium and beryllium compounds (and the reference in 1910.1000 Table Z–1 to Table Z–2) with the TWA PEL and STEL adopted through this rulemaking. This alternative would also delete the entry for beryllium and beryllium compounds in 29 CFR 1910.1000 Table Z–2 because the entry would instead be listed in Table Z–1 as described above. Note that OSHA is proposing an 8-hour TWA PEL of 0.2 $\mu g/m^3$ and a 15-minute STEL of 2 $\mu g/m^3$, and is also considering alternative TWA PELs of 0.1 $\mu g/m^3$ and 0.5 $\mu g/m^3$, and alternative STELs of 0.5 $\mu g/m^3$, 1 $\mu g/m^3$, and 2.5 $\mu g/m^3$. This alternative would limit permissible airborne beryllium exposures for workers in all beryllium-exposed occupations including construction, maritime and other industries where beryllium is a trace contaminant.

The Z Tables and 1926.55 Appendix A do not incorporate ancillary provisions such as exposure monitoring, medical surveillance, medical removal, and PPE. However, many of the occupations excluded from the scope of the proposed beryllium standard receive some ancillary provision protections from other rules, such as Personal Protective Equipment (1910 Subpart I, 1915 Subpart I, 1926.28, also 1926 Subpart E), Ventilation (1926.57), Hazard Communication (1910.1200), and specific provisions for welding (1910 Subpart Q, 1915 Subpart D, 1926 Subpart J) and abrasive blasting (1910.109, 1926 Subpart U).

(b) Definitions

Proposed paragraph (b) includes definitions of key terms used in the proposed standard. To the extent possible, OSHA uses the same terms and definitions in the proposed standard as the Agency has used in other OSHA health standards. Using similar terms across health standards, when possible, makes them more understandable and easier for employers to follow. In addition, using similar terms and definitions helps to facilitate uniformity of interpretation.

''*Action level''* means an airborne concentration of beryllium of 0.1 micrograms per cubic meter of air ($\mu g/m^3$) calculated as an eight-hour time-weighted average (TWA). Exposures at or above the action level but below the TWA PEL trigger the proposed requirements for periodic exposure monitoring (see paragraph (d)(3)). In addition, paragraph (f)(1)(i)(B) requires employers to list as part of their Written Exposure Control Plan the operations and job titles reasonably expected to have exposure at or above the action level. Paragraph (f)(2)(i) requires employers to ensure that at least one of the controls listed in paragraph (f)(2)(i)(A) is in place unless employers can demonstrate for each operation or process either that such controls are not feasible, or that employee exposures do not exceed the action level based on at least two representative personal breathing zone samples taken seven days apart. Furthermore, whenever an employer allows employees to consume food or beverages in a beryllium work area, the employer must ensure that no employee is exposed to beryllium at or above the action level (paragraph (i)(4)(ii)). The action level is also relevant to the proposed medical removal requirements. Employees eligible for removal can chose to remain in environments with exposures above the action level provided they wear respirators (paragraph (l)(2)(ii)). These employees may also choose to be transferred to comparable work in environments with exposures below the action level (or if comparable work is not available, they may choose to be placed on paid leave for a period of at least six months (paragraph (l)(3)).

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed TWA PEL (see this preamble at section VI, Significance of Risk). When there is a continuing exposure risk at the PEL, the courts have ruled that OSHA has the legal authority to impose additional requirements, such as action levels, on employers to further reduce risk when those requirements will result in a greater than minimal incremental benefit to workers' health (*Asbestos II,* 838 F.2d at 1274). OSHA's preliminary conclusion is that an action level for beryllium exposure will result in a further reduction in risk beyond that provided by the PEL alone.

Another important reason for proposing an action level involves the variable nature of employee exposures to beryllium. Because of this fact, OSHA believes that maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to beryllium above the TWA PEL on days when no exposure measurements are made. This consideration is discussed later in this section of the preamble regarding proposed paragraph (d)(3).

OSHA's decision to propose an action level of one-half of the TWA PEL is consistent with previous standards, including those for inorganic arsenic (29 CFR 1910.1018), chromium (VI) (29 CFR 1910.1026), benzene (29 CFR 1910.1028), ethylene oxide (29 CFR 1910.1047), and methylene chloride (29 CFR 1910.1052).

''*Assistant Secretary*'' means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee. Proposed paragraph (k)(7) requires employers to report employee BeLPT results to OSHA for evaluation and analysis if requested by the Assistant Secretary. Proposed paragraph (n)(6) requires employers to make all records required under this section available, if requested, to the Assistant Secretary for examination and copying.

''*Beryllium lymphocyte proliferation test (BeLPT)*'' means the measurement of blood lymphocyte proliferation in a laboratory test when lymphocytes are challenged with a soluble beryllium salt. A confirmed positive test result indicates the person has beryllium sensitization. For additional explanation of the BeLPT, see the Health Effects section of this preamble (section V), and Appendix A of this proposed standard. Under paragraph (f)(1)(ii)(B), employers must update the exposure control plan when an employee is confirmed positive. The BeLPT could be used to determine whether an employee is confirmed positive (see definition of confirmed positive in paragraph (b) of this proposed standard). Paragraph (k)(3)(ii)(E) requires the BeLPT unless a more reliable and accurate test becomes available (see section I of this preamble, Issues and Alternatives, for discussion and request for comment regarding how OSHA should determine whether a test is more reliable and accurate than the BeLPT). Under paragraph (k)(7), employers must convey the results of medical tests such as the BeLPT to OSHA if requested.

''*Beryllium work area*'' means any work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure. OSHA notes both a distinction and some overlap between the definitions of beryllium work area and regulated area in this proposal. Beryllium work areas are areas where employees are or can reasonably be expected to be exposed to airborne beryllium *at any level,* whereas an area is a regulated area only if employees are or can reasonably be expected to be exposed *above the TWA PEL or STEL.* Therefore, while not all beryllium work areas are regulated areas, all regulated areas are beryllium work areas because they are areas with exposure to beryllium. Accordingly, all requirements for beryllium work areas also apply in all regulated areas, but requirements specific to regulated areas apply only to regulated areas and not to beryllium work areas where exposures do not exceed the TWA PEL or STEL.

The presence of a beryllium work area triggers a number of the requirements in this proposal. Under paragraphs (d)(1)(ii) and (iii), employers must determine exposures for each beryllium work area. Furthermore, paragraphs (e)(1)(i) and (e)(2)(i) require employers to establish, maintain, identify, and demarcate the boundaries of each beryllium work area. Under paragraph (f)(1)(i), employers must establish and maintain a written exposure control plan for beryllium work areas. And paragraph (f)(2)(i) requires employers to implement at least one of the controls listed in (f)(2)(i)(A)(1) through (4) for each operation in a beryllium work area unless one of the exemptions in (f)(2)(i)(B) applies. In addition, paragraph (i)(1) requires employers to provide readily accessible washing facilities to employees working in a beryllium work area, and to instruct employees to use these facilities when necessary. Where employees are allowed to eat or drink in beryllium work areas, employers must ensure that surfaces in these areas are as free as practicable of beryllium, that exposures are below the action level, and that these areas comply with the Sanitation standard (29 CFR 1910.141) (paragraph (i)(4)). Employers must maintain surfaces in all beryllium work areas as free as practicable of beryllium (paragraph (j)(1)(i)). Paragraph (j)(2) requires certain practices and prohibits other practices for cleaning surfaces in beryllium work areas.

''*CBD Diagnostic Center*'' means a medical facility that has the capability of performing an on-site clinical evaluation for the presence of chronic beryllium disease (CBD) that includes bronchoalveolar lavage, transbronchial biopsy and interpretation of the biopsy pathology, and the beryllium bronchoalveolar lavage lymphocyte proliferation test (BeBALLPT). For purposes of this proposal, the term ''CBD Diagnostic Center'' refers to any medical facility that meets these criteria, whether or not the medical facility formally refers to itself as a CBD diagnostic center. For example, if a hospital has all of the capabilities required by this proposal for CBD diagnostic centers, the hospital would be considered a CBD diagnostic center for purposes of this proposal.

Proposed paragraph (k)(6) requires employers to offer employees who have been confirmed positive a referral to a CBD diagnostic center for a clinical evaluation.

''*Chronic beryllium disease (CBD)*'' means a chronic lung disease associated with exposure to airborne beryllium. The Health Effects section of this preamble, section V, contains more information on CBD. CBD is relevant to several provisions of this proposal. Paragraph (f)(1)(ii)(B) requires employers to update the exposure control plan whenever an employee is diagnosed with CBD. Under paragraph (k)(1)(i)(B), employers must make medical surveillance available at no cost to employees who show signs and symptoms of CBD. Paragraph (k)(3)(ii)(B) requires medical examinations conducted under this standard to emphasize screening for respiratory conditions, which would include CBD. Under paragraph (k)(5)(i)(A), the licensed physician's opinion must advise the employee on whether or not the employee has any detected medical condition that would place the employee at an increased risk of CBD from further exposure to beryllium. Furthermore, CBD is a criterion for medical removal under paragraph (l)(1). Under paragraph (m)(1)(ii), employers must address CBD in classifying beryllium hazards under the HCS. Employers must also train employees on the signs and symptoms of CBD (see paragraph (m)(4)(ii)(A)).

''*Confirmed positive*'' means two abnormal test results from consecutive BeLPTs or a second abnormal BeLPT result within a two-year period of the first abnormal result. The definition of confirmed positive also includes a single result of a more reliable test indicating that a person has been identified as sensitized to beryllium. OSHA recognizes that diagnostic tests for beryllium sensitization could eventually be developed that would not require a second test to confirm sensitization. OSHA requests comment on how best to determine whether a new method is more reliable and accurate than the BeLPT for detecting beryllium sensitization (see section I of this preamble, Issues and Alternatives).

Paragraph (f)(1)(ii)(B) requires employers to update the exposure control plan whenever an employee is confirmed positive or is diagnosed with CBD. Under proposed paragraph (k)(3)(ii)(E), employers are required to ensure that a BeLPT is offered to each eligible employee at the employee's first medical examination under this proposed standard, and every two years from the date of the first examination unless the employee receives an abnormal BeLPT result. If the employee's first BeLPT result is abnormal, the employer must provide the employee a second test within one month of the first test. If the employee's second BeLPT result is also abnormal, the employee is considered confirmed positive for purposes of this proposed standard. OSHA requests comment on the methods used to determine when a BeLPT test result is abnormal, and on standardizing the use and interpretation of the BeLPT (see section I of this preamble, Issues and Alternatives).

A confirmed positive result will indicate to the licensed physician that the employee is sensitized to beryllium and is at increased risk of developing CBD (see paragraph (k)(5)(i)(A)). Employees who are confirmed positive are eligible for medical removal under proposed paragraph (l)(1).

''*Director*'' means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee. The proposed recordkeeping requirements mandate that, upon request, employers make all records required by this standard available to the Director (as well as the Assistant Secretary) for examination and copying (see paragraph (n)(6)). Typically, the Assistant Secretary sends representatives to review workplace safety and health records. However, the

Director may also review these records while conducting studies such as Health Hazard Evaluations of workplaces, or for other purposes.

''*Emergency*'' means any uncontrolled release of airborne beryllium. An emergency could result from equipment failure, rupture of containers, or failure of control equipment, among other causes.

Emergencies trigger several requirements of this proposed standard. Under paragraph (g)(1)(iv), respiratory protection is required during emergencies to protect employees from potential overexposures. Emergencies also trigger clean-up requirements under paragraph (j)(1)(ii), and medical surveillance under paragraph (k)(1)(i)(C). In addition, under paragraph (m)(4)(ii)(D), employers must train employees in applicable emergency procedures.

''*Exposure*'' and *''exposure to beryllium*'' mean the exposure to airborne beryllium that would occur if the employee were not using a respirator. This definition is consistent with the term ''employee exposure'' in other OSHA standards such as Asbestos (29 CFR 1910.1001), Benzene (29 CFR 1910.1028), Chromium (VI) (29 CFR 1910.1026), Butadiene (29 CFR 1910.1051), and Methylene chloride (29 CFR 1910.1052). Many OSHA standards establish action levels and permissible exposure limits based on quantitative airborne exposures, and many of these standards' requirements are tied to exposures at or above the applicable action level, or above the applicable permissible exposure limit(s). This definition is also consistent with OSHA's hierarchy of controls policy, which requires employers to implement engineering and work practices controls to control exposure before resorting to respiratory protection. For additional discussion of OSHA's hierarchy of controls policy, see the discussion of paragraph (f) in this section of the preamble.

''*High-efficiency particulate air (HEPA) filter*'' means a filter that is at least 99.97 percent effective in removing particles 0.3 micrometers in diameter (see Department of Energy Technical Standard DOE–STD–3020–2005). HEPA filtration is an effective means of removing hazardous beryllium particles from the air. The proposed standard requires beryllium-contaminated surfaces to be cleaned by HEPA vacuuming or other methods that minimize the likelihood of exposure (see paragraphs (j)(2)(i) and (ii)). Other OSHA health standards also require the use of vacuum systems equipped with HEPA filtration (see Chromium (VI) (29 CFR 1910.1026) and Lead in construction (29 CFR 1926.62)).

''*Physician or other licensed health care professional (PLHCP)*'' means an individual whose legally permitted scope of practice, such as license, registration, or certification, allows the person to independently provide or be delegated the responsibility to provide some or all of the health care services required in proposed paragraph (k). The Agency recognizes that personnel qualified to provide medical surveillance may vary from State to State, depending on State licensing requirements. Whereas all licensed physicians would meet this proposed definition of PLHCP, not all PLHCPs must be physicians.

Under paragraph (k)(5) of the proposed standard, the written medical opinion must be completed by a licensed physician. However, other requirements of paragraph (k) may be performed by a PLHCP under the supervision of a licensed physician (see paragraphs (k)(1)(ii), (k)(3)(i), (k)(3)(ii)(G), (k)(5)(i)(C), and (k)(5)(ii)). The proposed standard also identifies what information must be given to the PLHCP providing the services listed in this standard, and requires that employers maintain a record of this information (see paragraphs (k)(4) and (n)(4)(ii)(C)).

Allowing a PLHCP to provide some of the services required under this rule is consistent with other recent OSHA health standards, such as bloodborne pathogens (29 CFR 1910.1030), respiratory protection (29 CFR 1910.134), and methylene chloride (29 CFR 1910.1052).

''*Regulated area*'' means an area that the employer must demarcate where employee exposure to airborne concentrations of beryllium exceeds, or can reasonably be expected to exceed, either the TWA PEL or STEL. These areas include temporary work areas where maintenance or non-routine tasks are performed. For an explanation of the distinction and overlap between beryllium work areas and regulated areas, see the explanation of beryllium work areas earlier in this section of the preamble. The requirements triggered by regulated areas are discussed below.

Paragraphs (e)(1)(ii) and (e)(2)(ii) require employers to establish and demarcate regulated areas. Note that the demarcation requirements for regulated areas are more specific than those for other beryllium work areas (see also proposed paragraph (m)). Paragraph (e)(3) requires employers to restrict access to regulated areas to authorized persons, and paragraph (e)(4) requires employers to provide all employees in regulated areas appropriate respiratory protection and personal protective clothing and equipment, and to ensure that these employees use the required respiratory protection and protective clothing and equipment. Proposed paragraph (i)(5)(i) prohibits employers from allowing employees to eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

Under proposed paragraph (k)(1)(i)(A), employees who have worked in a regulated area for more than 30 days in the previous 12 months are eligible for medical surveillance. In addition, proposed paragraph (m)(2) requires warning signs associated with regulated areas to meet certain specifications. Proposed paragraph (m)(4) requires employers to train employees in the written exposure control plan required by paragraph (f)(1), including the location of regulated areas.

This proposed definition of regulated areas is consistent with other substance-specific health standards, such as Cadmium (29 CFR 1910.1027), Butadiene (29 CFR 1910.1051), and Methylene Chloride (29 CFR 1910.1052).

''*This standard*'' means this beryllium standard, 29 CFR 1910.1024.

(c) Permissible Exposure Limits (PELs)

Paragraph (c) of the proposed standard establishes two permissible exposure limits (PELs) for beryllium in all forms, compounds, and mixtures: An 8-hour time-weighted average (TWA) PEL of 0.2 μg/m^3 (proposed paragraph (c)(1)), and a 15-minute short-term exposure limit (STEL) of 2.0 μg/m^3 (proposed paragraph (c)(2)).

The TWA PEL section of the proposed standard requires employers to ensure that each employee's exposure to beryllium, averaged over the course of an 8-hour work shift, does not exceed 0.2 μg/m^3. The STEL section of the proposed standard requires employers to ensure that each employee's exposure sampled over any 15-minute period during the work shift does not exceed 2.0 μg/m^3. The existing Air Contaminants standard (29 CFR 1910.1000 Table Z–2) has two PELs for ''beryllium and beryllium compounds'': (1) a 2 μg/m^3 TWA PEL, and (2) a ceiling concentration of 5 μg/m^3 that employers must ensure is not exceeded during the 8-hour work shift, except for a maximum peak of 25 μg/m^3 over a 30-minute period in an 8-hour work shift. OSHA adopted the current PELs in 1972 pursuant to section 6(a) of the OSH Act (29 U.S.C. 655(a)). Section 6(a) permitted OSHA, during the first two years after the OSH Act became effective, to adopt as OSHA standards any established Federal standard or national consensus standard. The existing PELs were based on the American National Standards Institute (ANSI) Beryllium and Beryllium Compounds standard (ANSI, 1970), which in turn was based on a 1949 U.S. Atomic Energy Commission adoption of a threshold limit for beryllium of 2.0 μ/m³ and was included in the 1971 American Conference of Governmental Industrial Hygienists Documentation of the Threshold Limit Values for Substances in Workroom Air (ACGIH, 1971).

TWA PEL. OSHA is proposing the new TWA PEL because published studies and more recent exposure data submitted in the record from industrial facilities involved in beryllium work provide evidence that occupational exposure to a variety of beryllium compounds at levels below the current PELs pose a significant risk to workers (see this preamble at section VIII, Significance of Risk). OSHA's preliminary risk assessment, presented in section VI of this preamble, indicates that there is significant risk of beryllium sensitization [45] and CBD from a 45-year (working life) exposure to beryllium at the current TWA PEL of 2 μg/m³. The risk assessment further indicates that there is significant risk of lung cancer to workers exposed to beryllium at the current TWA PEL of 2 μg/m³.

OSHA believes this proposed PEL would be feasible across all affected industry sectors (see section IX.D of this preamble, Technological Feasibility) and that compliance with the proposed PEL would substantially reduce employees' risks of beryllium sensitization, CBD, and lung cancer (see section VI of this preamble, Preliminary Beryllium Risk Assessment). OSHA's confidence in the feasibility of the proposed PEL is high, based both on the preliminary results of the Agency's feasibility analysis and on the recommendation of the proposed PEL by Materion Corporation and the United Steelworkers. Materion is the sole beryllium producer in the U.S., and its facilities include some of the processes where OSHA expects it will be most challenging to control beryllium exposures. As with several other provisions of the proposed standard, OSHA's proposal for the TWA PEL follows the draft recommended standard submitted to the Agency by Materion and the Steelworkers Union (see this preamble at section III, Events Leading to the Proposed Standard).

OSHA's preliminary risk assessment indicates that the risks remaining at the proposed TWA PEL—while much lower than risks at the current PEL—are still significant (see this preamble at section VIII, Significance of Risk). In addition to the proposed PEL, the Agency is considering an alternative PEL of 0.1 μg/m³ that would reduce risks to workers further than the proposed PEL would, although significant risk remains at 0.1 μg/m³ as well (see section VIII of this preamble, Significance of Risk, and Regulatory Alternatives presented at the end of this discussion). Compared with the proposed PEL, OSHA has less confidence in the feasibility of a PEL of 0.1 μg/m³. In some industry sectors it is difficult to determine whether a PEL of 0.1 μg/m³ could be achieved in most operations, most of the time. However, OSHA believes this uncertainty could be resolved with additional information on current exposure levels and exposure control technologies. OSHA requests additional data and information to inform its final determinations on feasibility (see section IX.D of this preamble, Technological Feasibility) and the alternative PELs under consideration.

Because significant risks of sensitization and CBD remain at both 0.1 μg/m³ and 0.2 μg/m³, OSHA is also proposing a variety of ancillary provisions to help reduce risk to workers. These ancillary provisions include implementation of feasible engineering controls in beryllium work areas, respiratory protection, personal protective clothing and equipment, exposure monitoring, regulated areas, medical surveillance, medical removal, hygiene areas, housekeeping requirements, and hazard communication. The Agency believes these provisions will reduce the risk beyond that which the proposed TWA PEL alone could achieve. These provisions are discussed later in this section of the preamble.

Other federal agencies and organizations have recommended occupational exposure limits for beryllium. As mentioned in this preamble at section III, Events Leading to the Proposed Standard, in 1999 the Department of Energy (DOE) issued its Chronic Beryllium Disease Prevention Program rule (10 CFR part 850). The DOE rule established a beryllium action level of 0.2 μg/m³. This action level triggers many of the same requirements found in OSHA's proposed standard such as regulated areas, periodic exposure monitoring, hygiene facilities and practices, respiratory protection, and protective clothing and equipment (10 CFR 850.23(b)). Although the DOE rule retained OSHA's current TWA PEL, it also stated that employers would be required to ensure that employees are not exposed above any ''more stringent TWA PEL'' that OSHA may promulgate (10 CFR 850.22; 64 FR 68873 and 68906, December 8, 1999).

NIOSH has published a Recommended Exposure Limit (REL) of 0.5 μg/m³ as a Ceiling Limit and a NIOSH Alert on preventing CBD and beryllium sensitization (NIOSH, 1977; NIOSH, 2011). The NIOSH Alert provides guidance to workers and employers on the hazards of exposure to beryllium and ways to reduce or minimize exposure. In 2009, ACGIH adopted a revised Threshold Limit Value (TLV) for beryllium that lowered the TWA to 0.05 μg/m³ from 2 μg/m³ (ACGIH, 2009).

The SERs who participated in the SBREFA process had few comments about the proposed PELs (OSHA, 2008b). The major concerns about a reduced TWA PEL were economic impact and belief that beryllium-related health effects did not frequently occur in their industries (OSHA, 2008b). The Panel recommended that OSHA consider to what extent a very low PEL may result in increased costs to small entities. In section V of the Preliminary Economic Analysis (OSHA, 2014), OSHA considers the costs of the proposed PEL and ancillary provisions triggered by the PEL to all affected entities. In addition, the Agency is considering an alternative PEL of 0.5 μg/m³ (see Regulatory Alternative 5 below). The Agency seeks comment on whether different PELs should be considered and the justification for the PELs.

STEL. OSHA is also proposing a STEL of 2.0 μg/m³, as determined over a sampling period of 15 minutes. Where a significant risk of material impairment of health remains at the TWA PEL, OSHA has the authority to impose a STEL if doing so would further reduce risk and is feasible to implement. *Pub. Citizen Health Research Grp.* v. *Tyson, 796 F.2d 1479, 1505 (D.C. Cir. 1986) (Ethylene Oxide).*

As discussed in section VIII of this preamble, Significance of Risk, significant risk of CBD remains at the proposed TWA PEL of 0.2 μg/m³ and the proposed alternative TWA PEL of 0.1 μg/m³. OSHA believes the proposed STEL would further reduce this risk. The goal of a STEL is to protect employees from the risk of harm that can occur as a result of brief exposures that exceed the TWA PEL. Without a STEL, the only protection workers would have from high short-duration

[45] As discussed in section VIII of this preamble, Significance of Risk, beryllium sensitization is a necessary precursor to developing CBD.

exposures is that, when those exposures are factored in, they cannot exceed the cumulative 8-hour exposure at the proposed 0.2 μg/m³ TWA PEL (*i.e.,* 1.6 μg/m³). Since there are 32 15-minute periods in an 8-hour work shift, exposures could be as high as 6.4 μg/m³ (32×0.2 μg/m³) for 15 minutes under the proposed TWA PEL without a STEL, if exposures during the remainder of the 8-hour work shift are non-detectable. A STEL serves to minimize high task-based exposures by requiring feasible controls in these situations, and has the added effect of further reducing the TWA exposure.

OSHA believes a STEL for beryllium will help reduce the risk of sensitization and CBD in beryllium-exposed employees. As discussed in this preamble at section V, Health Effects, beryllium sensitization is the initial step in the development of CBD. Sensitization has been observed in some workers that were only exposed to beryllium for a few months (see section V.D.1 of this preamble), and tends to be more strongly associated with 'peak' and highest-job-worked exposure metrics than cumulative exposure (see section V.D.5 of this preamble). Short-term exposures to beryllium have been shown to contribute to the development of lung disease in experimental animals. Beagle dogs that were administered a single short-term perinasal exposure to aerosolized beryllium oxide developed a granulomatous lung inflammation similar to CBD, accompanied by an abnormal BeLPT response (Haley *et al.,* 1989). These study findings indicate that adverse effects to the lung may occur from beryllium exposures of relatively short duration. OSHA believes that a STEL in combination with a TWA PEL adds further protection from risk of harm than that afforded by the proposed 0.2 μg/m³ TWA PEL alone.

STEL exposures are typically associated with, and need to be measured during, the highest-exposure operations that an employee performs (see proposed paragraph (d)(1)(iii)). OSHA has preliminarily determined that the proposed STEL of 2.0 μg/m³ can be measured for this brief period of time using OSHA's available sampling and analytical methodology, and feasible means exist to maintain 15-minute short-term exposures at or below the proposed STEL (see section IX.D of this preamble, Technological Feasibility).

The current entry for beryllium and beryllium compounds (as Be) in 29 CFR 1910.1000 Table Z–1 directs the reader to the entry for beryllium and beryllium compounds in 29 CFR 1910.1000 Table Z–2. Table Z–2's entry for beryllium and beryllium compounds includes the current TWA PEL of 2 μg/m³, an acceptable ceiling concentration of 5 μg/m³, and an acceptable maximum peak above the acceptable ceiling concentration of 25 μg/m³, allowable for 30 minutes in an 8-hour shift. Table Z in 29 CFR 1915.1000, and 29 CFR 1926.55 Appendix A each include the current TWA PEL of 2 μg/m³ beryllium and beryllium compounds for construction and maritime industries, but no ceiling or peak exposure limit.

As discussed in this Summary and Explanation section of the preamble regarding paragraph (a), the scope of the proposed rule is limited to general industry. In addition, it provides an exemption for those working with materials that contain beryllium only as a trace contaminant (less than 0.1 percent composition by weight). The proposal would amend the entry for beryllium and beryllium compounds (as Be) in 29 CFR 1910.1000 Table Z–1, to add a cross reference to the new standard for operations or sectors that fall within the scope of the proposed standard, and note that industries not covered under the proposed standard would continue to be covered by the entry in 29 CFR 1910.1000 Table Z–2. The TWA, ceiling, and maximum peak exposure limits in 29 CFR 1910.1000 Table Z–2 would still apply to general industry applications and sectors exempted from the proposed standard. Under the proposed standard, the exposure limits in the current 29 CFR 1915.1000 Table Z and 29 CFR 1926.55 Appendix A would continue to apply in construction and maritime industries. As discussed previously in this preamble at Section I, Issues and Alternatives, and Section XVIII, paragraph (a), OSHA is considering Regulatory Alternative #2b, which would update 29 CFR 1915.1000 Tables Z–1 and Z–2, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A to the PEL and STEL adopted through this rulemaking to the general industry, construction, and maritime sectors and applications that do not fall within the scope of the proposed rule. Note that OSHA is proposing a TWA PEL of 0.2 μg/m³ and a STEL of 2 μg/m³, and OSHA is also considering alternative TWA PELs of .1 μg/m³ and .5 μg/m³, and alternative STELs of .5 μg/m³, 1 μg/m³, and 2.5 μg/m³.

OSHA invites comment on the proposed TWA PEL and STEL and on Regulatory Alternatives 3, 4, and 5 below, which specify a lower STEL, a lower TWA PEL, and a higher TWA PEL than those proposed, respectively. OSHA also requests comments and data on the range of TWA and short-term exposures in covered industries and the types of operations and engineering or work practice controls in place where these exposures are occurring.

Regulatory Alternative 3

This alternative would modify the proposed STEL to be five times the TWA PEL, rather than ten times the TWA PEL. Thus, if OSHA promulgates the proposed TWA PEL of 0.2 μg/m³, the STEL would be 1 μg/m³; if OSHA promulgates the alternative TWA PEL of 0.1 μg/m³, the STEL would be 0.5 μg/m³; and if OSHA promulgates the alternative TWA PEL of 0.5 μg/m³; the STEL would be 2.5 μg/m³.

As discussed above, OSHA has preliminarily determined that short-term exposures to beryllium can cause beryllium sensitization, and that therefore a STEL in combination with a TWA PEL adds further protection from risk of harm than that afforded by the proposed 0.2 μg/m³ TWA PEL alone.

When OSHA regulations in the past have included a STEL, it is typically five times the PEL. For example, OSHA's standard for methylene chloride (29 CFR 1910.1052) specifies an 8-hour TWA PEL of 25 ppm, and a short-term limit of 125 ppm averaged over 15 minutes. The standard for acrylonitrile (29 CFR 1910.1045) sets an 8-hour TWA PEL of 2 ppm, and a short-term limit of 10 ppm averaged over 15 minutes. The final standards for benzene (29 CFR 1910.1028), for ethylene oxide (29 CFR 1910.1047) and for 1,3-Butadiene (29 CFR 1910.1051) specify an 8-hour time-weighted average TWA PEL of 1 ppm and short-term limits of 5 ppm averaged over 15 minutes. OSHA has occasionally deviated from its usual practice of setting a STEL at five times the TWA PEL, as in the cases of formaldehyde (29 CFR 1910.1048) (TWA PEL 0.75 ppm, STEL 2 ppm) and methylenedianiline (29 CFR 1910.1050) (TWA PEL 10 ppb, STEL 100 ppb). OSHA requests comment on whether the beryllium standard should set a STEL at ten times the TWA PEL, as suggested by the Materion-USW joint proposed rule and specified in this proposal, or should it maintain its more usual practice of setting a STEL at five times the PEL.

Regulatory Alternative 4

This alternative would modify the proposed TWA PEL to be 0.1 μg/m³. As discussed above, OSHA believes a PEL of 0.1 μg/m³ would better protect workers from significant risk of CBD and lung cancer than the proposed TWA PEL of 0.2 μg/m³. OSHA's preliminary risk assessment indicates that the risk of CBD and lung cancer remaining at the proposed TWA PEL are significant, and that an alternative PEL of 0.1 μg/m³ would reduce these risks to workers further than the proposed PEL would. However, compared with the proposed PEL, OSHA has less confidence in the feasibility of a PEL of 0.1 μg/m³ (see section IX.D of this preamble, Technological Feasibility). This alternative would also lower the action level from 0.1 μg/m³ to .05 μg/m³.

Regulatory Alternative 5

This alternative would modify the proposed TWA PEL to be 0.5 μg/m³. This alternative would also raise the proposed action level to 2.5 μg/m³. As discussed above, the SBREFA Panel recommended that OSHA consider the economic impact of a reduced PEL and consider regulatory alternatives that would ease cost burden for small entities. The economic impact of a reduced PEL is considered in section VIII of the Preliminary Economic Analysis (OSHA, 2014). However, OSHA's preliminary risk assessment indicates significant risk to workers exposed at a PEL of 0.5 μg/m³, and OSHA's preliminary feasibility analysis indicates that a lower PEL is feasible. Unless OSHA receives new evidence showing that a PEL lower than 0.5 μg/m³ is not feasible or not needed to reduce significant risk, OSHA cannot adopt this alternative PEL due to its statutory obligation to set the PEL at the lowest feasible level to reduce or eliminate significant risk.

(d) Exposure Monitoring

Paragraph (d) of the proposed standard imposes monitoring requirements pursuant to section 6(b)(7) of the OSH Act (29 U.S.C. 655(b)(7)), which mandates that any standard promulgated under section 6(b) shall, where appropriate, ''provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees.''

The purposes of requiring assessment of employee exposures to beryllium include determination of the extent and degree of exposure at the worksite; identification and prevention of employee overexposure; identification of the sources of exposure to beryllium; collection of exposure data so that the employer can select the proper control methods to be used; and evaluation of the effectiveness of those selected methods. Exposure assessment enables employers to meet their legal obligation to ensure that their employees are not exposed to beryllium in excess of the permissible exposure limits and to notify employees of their exposure levels, including any overexposures as required by section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)). In addition, the availability of exposure data enables PLHCPs performing medical examinations to be informed of the extent of an employee's occupational exposures.

Paragraph (d)(1) contains proposed general requirements for exposure monitoring. Under paragraph (d)(1)(i), the monitoring requirements apply whenever there is actual exposure to airborne beryllium at any level, or a reasonable expectation of such exposure. As reflected in the definition of ''exposure'' in paragraph (b) of this standard, exposure monitoring results must reflect the amount of beryllium an employee would be exposed to without the use of a respirator.

Under paragraph (d)(1)(ii), monitoring to determine employee time-weighted average exposures must represent the employee's average exposure to airborne beryllium over an eight-hour workday. Under paragraph (d)(1)(iii), short term exposures must be characterized by sampling periods of 15 minutes for each operation likely to produce exposures above the STEL.[46] Samples taken pursuant to paragraphs (d)(1)(ii) and (d)(1)(iii) must reflect the exposure of employees on each work shift, for each job classification, in each beryllium work area. Samples must be taken within an employee's breathing zone.

Employers must accurately characterize the exposure of each employee. In some cases, this will entail monitoring all exposed employees. In other cases, monitoring of ''representative'' employees is sufficient. Under paragraph (d)(1)(iv), representative exposure sampling is permitted when a number of employees perform essentially the same job under the same conditions. For such situations, it may be sufficient to monitor a fraction of these employees in order to obtain data that are representative of the remaining employees. Representative personal sampling for employees engaged in similar work with beryllium exposure of similar frequency and duration can be achieved by monitoring the employee(s) reasonably expected to have the highest exposures. For example, this may involve monitoring the beryllium exposure of the employee closest to an exposure source. This exposure result may then be attributed to the remaining employees in the group.

Representative exposure monitoring must at a minimum include one full-shift sample taken for each job classification, in each beryllium work area, for each shift. These samples must consist of at least one sample characteristic of the entire shift or consecutive representative samples taken over the length of the shift. Where employees are not performing the same job tasks under the same conditions, representative sampling will not adequately characterize actual exposures, and employers must monitor each employee individually.

Under paragraph (d)(1)(v), the employer would be required to use monitoring and analytical methods that can measure airborne levels of beryllium to an accuracy of plus or minus 25 percent (+/−25 percent and can produce accurate measurements at a statistical confidence level of 95 percent for airborne concentrations at or above the action level. OSHA believes the following methods could meet these criteria: NIOSH 7704 (also ASTM D7202), ASTM D7439, OSHA 206, OSHA 125G, and OSHA 125G using ICP–MS. All of these methods are available to commercial laboratories analyzing beryllium samples. It should be noted that most of these analytical methods were validated using soluble beryllium compounds and hence the efficacy of the sample preparation (specifically digestion of particulate beryllium in mineral acids) step must be verified prior to use (Stefaniak et al., 2008). Verification can be aided, in part, through use of an appropriate reference material. However, not all of these methods are appropriate for measuring beryllium oxide, so employers must verify that the analytical methods they use are appropriate for measuring the form(s) of beryllium present in the workplace. A certified reference material consisting of high-fired beryllium oxide is available from the National Institute of Standards and Technology as Standard Reference Material 1877: Beryllium oxide powder. This reference material carries a certified value for beryllium content and was developed to meet the need to demonstrate analytical method efficacy for poorly soluble forms of beryllium (Winchester et al., 2009). OSHA requests comment on whether these methods would satisfy the requirements of proposed paragraph (d)(1)(v), and whether other methods would also meet these criteria.

[46] Although OSHA has used the phrase ''most likely to produce exposures'' in other standards in the past (*e.g.,* Ethylene Oxide (29 CFR 1910.1047)), OSHA's intended meaning for previous standards and for the proposed standard is that employers must characterize exposures for *all* operations likely to produce exposures above the STEL. Accordingly, OSHA is using the phrase ''likely to produce exposures'' rather than ''most likely to produce exposures'' in this proposed standard to clarify this longstanding intent.

Rather than specifying a particular method that must be used, OSHA proposes to take a performance-oriented approach and instead allow the employer to use the method of its choosing as long as that method meets the accuracy specifications in paragraph (d)(1)(v), and the reported results represent the total airborne concentration of beryllium for the operation and worker being characterized. For example, a respirable fraction sample or size selective sample would not be directly comparable to either PEL, and therefore would not be considered valid.

Paragraph (d)(2) contains proposed requirements for initial monitoring. OSHA proposes that employers characterize the 8-hour TWA exposure and 15-minute short-term exposure for each employee who is known to be exposed to airborne beryllium at any level or whose exposure is reasonably expected. Further obligations under the standard would be based on the results of this assessment. These obligations may include periodic monitoring, establishment of regulated areas, and implementation of control measures.

Initial monitoring need not be conducted in two circumstances. First, under paragraph (d)(2)(i), initial monitoring is not required where the employer has previously monitored for beryllium exposure and the data were obtained during work operations and under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations. In addition, the characteristics of the beryllium-containing material being handled when the employer previously monitored must closely resemble the characteristics of the beryllium-containing material used in the employer's current operations. Such historical monitoring must satisfy all other requirements of this section, including the accuracy and confidence requirements in paragraph (d)(1)(v). If these requirements are satisfied, the employer may rely on such earlier monitoring results to satisfy the initial monitoring requirements of this section. This provision is designed to make it clear that OSHA does not intend to require employers who have recently performed appropriate employee monitoring to conduct initial monitoring. For historical data to satisfy the employer's obligation to monitor for 8-hour TWA exposures under paragraph (d)(1)(ii), these data must characterize 8-hour TWA exposures that satisfy the requirements of paragraph (d)(2)(i). For historical monitoring to satisfy an employer's obligation to monitor for 15-minute short-term exposures under paragraph (d)(1)(iii), these data must reflect 15-minute short-term exposures. OSHA anticipates that paragraph (d)(2)(i) will reduce the compliance burden on employers, since redundant monitoring would not be required.

Second, under paragraph (d)(2)(ii), where the employer has objective data demonstrating that a particular product or material containing beryllium or a specific process, operation, or activity involving beryllium cannot release dust, fumes, or mist in concentrations at or above the action level or STEL under any reasonably expected conditions of use, the employer may rely upon such data to satisfy initial monitoring requirements. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Objective data used in place of initial monitoring under paragraph (d)(2) must demonstrate that the work operation or the product cannot reasonably be foreseen to release beryllium in airborne concentrations at or above the action level or above the STEL under the expected conditions of use that will cause the greatest possible release. The data must demonstrate that exposures cannot meet or exceed the action level *and* that exposures cannot exceed the STEL; if the data do not satisfy both of these requirements, they do not meet the criteria of paragraph (d)(2)(ii) and would not exempt the employer from conducting initial monitoring. When using the term ''objective data,'' OSHA is referring to manufacturers' case studies, laboratory studies, and other research that demonstrates, usually by means of exposure data, that exposures above the action level or STEL cannot occur. The objective data may include monitoring data, or mathematical modeling or calculations based on the chemical and physical properties of a material. For example, data collected by a trade association from its members that reflect workplace conditions closely resembling the processes, material, control methods, work practices, and environmental conditions in the employer's current operations may be used. OSHA has allowed employers to use objective data in lieu of initial monitoring in other standards, such as those for formaldehyde (29 CFR 1910.1048) and asbestos (29 CFR 1910.1001).

Paragraph (d)(3) contains requirements for periodic monitoring. The requirement for this continued monitoring depends on the results of initial monitoring. If the initial monitoring indicates that employee exposures are below the action level, no further monitoring would be required unless, under paragraph (d)(4), changes in the workplace could result in new or additional exposures. If the initial determination reveals employee exposures to be at or above the action level and at or below the TWA PEL, the employer must perform periodic monitoring at least annually. In stating ''at least annually,'' OSHA intends that employers must monitor at least once during the 12-month period after initial monitoring is performed, and then at least once in every subsequent 12-month period. Of course, the proposed requirement for annual monitoring does not preclude employers from monitoring more frequently.

OSHA recognizes that exposures in the workplace can vary from day to day, between shifts, and even within the same operation. Beryllium exposures for many operations have been shown to be highly variable, with some exposures exceeding the current TWA PEL. When airborne concentrations fluctuate in this way, the probability of exceeding the PELs increases. Periodic monitoring provides the employer with additional and up-to-date information to use to make informed decisions on whether additional control measures are necessary.

Periodic monitoring provides the employer with exposure information for additional use beyond that of determining compliance with the PELs. Periodic monitoring will provide data to determine whether or not engineering controls are working properly and work practices are effective in preventing exposure. Selection of appropriate respiratory protection also depends on adequate knowledge of employee exposures obtained through periodic monitoring.

This proposal does not require periodic monitoring where exposures are above the TWA PEL, which represents a departure from past OSHA standards such as Chromium (29 CFR 1910.1026) and Cadmium (29 CFR 1910.1027). OSHA has eliminated the requirement for periodic monitoring where exposures are above the PEL in response to a multi-stakeholder proposal to this effect (Materion and Steelworkers, 2012). OSHA anticipates this could be an appropriate way to reduce costs for employers where exposures are above the TWA PEL after the employer has implemented all feasible engineering and work practice controls. However, the employer must continue to assess the status of available feasible engineering and work practice controls to ensure that the employer has reduced exposures to the lowest level feasible. And even where this standard does not explicitly require periodic monitoring, employers may need to conduct periodic monitoring to ensure that controls are working properly, and that employees are adequately protected and are receiving the services and benefits to which they are entitled under this standard such as medical surveillance and medical removal. OSHA requests comment on whether the proposed annual periodic monitoring for exposures at or above the action level but below the TWA PEL is sufficiently protective for employees, or whether annual periodic monitoring should be required when exposures exceed the TWA PEL (see Section I of this preamble, Issues and Alternatives).

Under paragraph (d)(4), employers are to perform additional monitoring when there is a change in production processes, materials, equipment, personnel, work practices, or control methods, that may result in new or additional exposures to beryllium. In addition, there may be other situations that can result in new or additional exposures that are unique to an employer's work situation. In order to cover those special situations, OSHA requires the employer to perform additional monitoring whenever the employer has any reason to believe that a change has occurred that may result in new or additional exposures. For example, an employer would be required to perform additional monitoring when an employee has a confirmed positive result for beryllium sensitization, exhibits signs or symptoms of CBD, or is diagnosed with CBD. These conditions necessitate additional monitoring to ascertain if airborne exposures contributed to the positive results of the medical testing. Another example of a situation requiring additional monitoring would be a process modification that would increase the amount of beryllium-containing material used thereby possibly increasing employee exposure. Once additional monitoring has been performed and exposures characterized, the employer can take appropriate action to protect exposed employees.

Under paragraph (d)(5) employers must notify each employee of his or her monitoring results within 15 working days after receiving the results. Employees who must be notified include both the employees whose exposures were monitored directly and those whose exposures are represented by the monitoring. The employer must either notify each employee individually in writing, or post the monitoring results in an appropriate location accessible to all employees required to be notified. This proposed requirement is consistent with other OSHA standards, such as those for methylenedianiline (29 CFR 1910.1050), 1,3-butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052). In addition, whenever the TWA PEL or STEL has been exceeded, the written notification required by paragraph (d)(5)(i) must contain a description of the suspected or known sources of exposure as well as the corrective action(s) being taken by the employer to reduce the employee's exposure to or below the applicable PEL. This requirement is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required under section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)).

Paragraph (d)(6) requires the employer to provide employees and their designated representatives an opportunity to observe any monitoring of employee exposure to beryllium. Employees who must be allowed to observe monitoring include both the employees whose exposures are being monitored and those whose exposures are represented by the monitoring. When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer must provide the observer with that protective clothing or equipment, at no cost. The employer must also assure that the observer uses such clothing or equipment appropriately and complies with all other applicable safety and health requirements and procedures.

The requirement for employers to provide employees and their representatives the opportunity to observe monitoring is consistent with the OSH Act. Section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)) mandates that regulations requiring employers to keep records of employee exposures to toxic materials or harmful physical agents provide employees or their representatives with the opportunity to observe monitoring or measurements. Also, Section 6(b)(7) of the Act (29 U.S.C. 655(b)(7)) states that, where appropriate, OSHA standards are to prescribe suitable protective equipment to be used in dealing with hazards. The provision for observation of monitoring and protection of the observers is also consistent with OSHA's other substance-specific health standards, such as those for cadmium (29 CFR 1910.1027) and methylene chloride (29 CFR 1910.1052).

After reviewing commenter responses to the SBREFA inquiry and the Agency's RFI on beryllium, OSHA has learned that the amount of employer effort and diligence in assessing exposure levels is proportional to the presumed degree of exposure (OSHA, 2008b). Commenters whose companies make products with high-content beryllium are much more likely to have incorporated considerable sampling into their exposure assessment protocol. (Brush Wellman, 2003, Honeywell, 2003). In other instances, where manufacturers use less beryllium or low-content beryllium alloys, such as in specialty or precision products, sampling occurs less frequently. (OSHA, 2007a).

Representatives of various stamping firms who are currently experiencing low levels of exposure felt that their industry as a whole should be exempt from the initial exposure assessment provision of this standard and any additional requirements related to exposure monitoring. (OSHA, 2007a). However, available information demonstrates that initial exposure assessment needs to be applied to all industries where beryllium is processed or otherwise handled (see this preamble at section V, Health Effects). For example, OSHA's technological feasibility analysis for fabrication of beryllium alloy products summarizes exposures for workers in the stamped and formed metal products sector (see this preamble at Section IX.D, Technological Feasibility). Exposure monitoring data indicate that while for most production tasks, the median baseline exposure is less than the proposed action level of 0.1 $\mu g/m^3$, some tasks have the potential to generate exposures greater than 0.1 $\mu g/m^3$. Initial exposure monitoring will help identify the areas and job tasks needing additional controls, or demonstrate that no additional controls are needed. Initial monitoring also aids the employer in determining whether controls currently in use to prevent or reduce beryllium exposure are effective.

To address many of these comments, OSHA has established performance-oriented language for the exposure assessment provisions of this standard, allowing employers to choose any method of exposure monitoring that meets the accuracy specifications in paragraph (d)(1)(v) of this standard, and that measures the total airborne concentration of beryllium for the operation and worker exposures being characterized. In addition, employers may use historical or objective data in accordance with proposed paragraph (d)(2) of this standard to satisfy their initial monitoring obligations. OSHA believes this flexibility in the proposal accommodates commenters' concerns without jeopardizing beryllium-exposed workers' health.

SERs also commented that exposure monitoring is costly and that OSHA should consider alternatives that allow employers with very low exposures to be exempt from monitoring. As a possible means of alleviating costs, the Panel recommended that OSHA encourage the use of objective data and explain more clearly the requirements for its use. (OSHA, 2008b). OSHA has clarified in this preamble the circumstances under which an employer may use historical and objective data in lieu of initial monitoring. OSHA is also considering whether to create a guidance product on the use of objective data. The Agency requests comments on whether a guidance product on the use of objective data would be helpful to businesses seeking to comply with the beryllium standard, and what questions or areas of information it should address.

In addition, OSHA has reduced to annually the frequency of periodic monitoring where exposures are at or above the action level and at or below the TWA PEL, rather than the six-month frequency proposed during the SBREFA process. OSHA has also removed the requirement for periodic monitoring every three months where exposures exceed the PEL. The new provisions were suggested in the Materion-USW recommended standard submitted to OSHA in 2012 (Materion and USW, 2012). While these changes to the proposed standard reduce the cost burden of exposure monitoring for employers, they also may reduce employees' protection from overexposure to beryllium.

OSHA notes that the frequency and performance of exposure monitoring in the draft proposal presented to the SBREFA Panel are similar to OSHA's typical approach to periodic exposure monitoring. Most OSHA standards require monitoring at least every six months where exposure levels meet or exceed the action level, and every three months where exposures are above the TWA PEL. For example, the standards for vinyl chloride (29 CFR 1910.1017), inorganic arsenic (29 CFR 1910.1018), lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), methylene chloride (29 CFR 1910.1052), acrylonitrile (29 CFR 1910.1045), ethylene oxide (29 CFR 1910.1047), formaldehyde (29 CFR 1910.1048), all specify periodic monitoring at least every six months where exposures are above the action level. Periodic exposure monitoring is also required where exposures exceed the PEL in most health standards issued since OSHA began specifying frequency for periodic monitoring. In many cases monitoring is required every three months where exposures exceed the PEL (methylene chloride (29 CFR 1910.1052), ethylene oxide (29 CFR 1910.1047), acrylonitrile (29 CFR 1910.1045), inorganic arsenic (29 CFR 1910.1018), lead (29 CFR 1910.1025), and vinyl chloride (29 CFR 1910.1017)); in other cases, it is required at least every six months (cadmium (29 CFR 1910.1027), 1,3-Butadiene (29 CFR 1910.1051), formaldehyde (29 CFR 1910.1048), benzene (29 CFR 1910.1028) and asbestos (29 CFR 1910.1001)). Thus, the periodic monitoring requirements outlined in this proposal and in the Materion-USW recommended standard depart significantly from OSHA's usual requirements.

OSHA requests comment on the proposed schedule for periodic monitoring. Are the proposed requirements both practical for employers and protective for employees? OSHA also requests comment on Regulatory Alternatives 9, 10, and 11 below, which would modify the frequency and performance of exposure monitoring to be more similar to previous standards and to the draft proposal presented to the SBREFA Panel.

Regulatory Alternative 9

This alternative would require employers to perform exposure monitoring at least every 180 days where exposures are at or above the action level or above the STEL, and at or below the TWA PEL. If the initial monitoring required by paragraph (d)(2) of this section reveals employee 8-hour TWA exposure at or above the action level, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's TWA exposures. If the initial 15-minute short-term exposure monitoring reveals employee exposure above the STEL, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's 15-minute short-term exposures. Where 8-hour TWA exposures are above the TWA PEL, no monitoring would be required.

Regulatory Alternative 10

This alternative would require employers to perform monitoring at least every 180 days where exposures are at or above the action level or above the STEL. Unlike the periodic monitoring requirement in the current proposal, this alternative would include periodic monitoring where exposures are above the TWA PEL. If the initial 8-hour TWA exposure monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's TWA exposures. If the initial 15-minute short-term exposure monitoring reveals employee exposure above the STEL, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's short-term exposures.

Regulatory Alternative 11

This alternative would require employers to perform monitoring at least every 180 days where exposures are at or above the action level and at or below the TWA PEL. It would require employers to perform monitoring at least every 90 days where exposures are above the TWA PEL or STEL.

If the initial 8-hour TWA exposure monitoring required by paragraph (d)(2) of this section reveals employee TWA exposure at or above the action level and at or below the TWA PEL, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's TWA exposures. If this initial monitoring reveals employee exposure above the TWA PEL or STEL, the employer shall repeat such monitoring for each such employee at least every 90 days to evaluate the employee's 8-hour TWA and 15-minute short-term exposures.

(e) Beryllium Work Areas and Regulated Areas

Proposed paragraph (e) requires employers to establish and maintain beryllium work areas wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure, and regulated areas wherever employees are, or can reasonably be expected to be, exposed to airborne concentrations of beryllium in excess of the TWA PEL or STEL. Paragraph (e) would also require employers to demarcate beryllium work areas and regulated areas, and limit access to regulated areas to authorized persons.

The proposed requirements for these areas serve several important purposes. First, requiring employers to establish and demarcate beryllium work areas and regulated areas ensures that workers and other persons are aware of the potential presence of airborne beryllium. Second, the demarcation of regulated areas must include warning signs describing the dangers of beryllium exposure in accordance with paragraph (m) of this standard, which ensures that persons entering regulated areas will be aware of these dangers. Third, limiting access to regulated areas restricts the number of people potentially exposed to beryllium at levels above the TWA PEL or STEL, and the serious health effects associated with such exposure. Limiting access to regulated areas has the added benefit of reducing the employer's obligation to implement certain provisions of the proposed rule triggered by employee exposure in a regulated area.

Proposed paragraph (e)(1)(i) would require employers to establish beryllium work areas where employees are, or can reasonably be expected to be, exposed to airborne beryllium. OSHA intends this provision to apply to all areas and situations where employees are actually exposed to airborne beryllium and to areas and situations where the employer has reason to anticipate or believe that airborne exposures may occur. The requirements for beryllium work areas under proposed paragraph (e)(1)(i) are not tied to a particular level of exposure, but rather are triggered by the presence of airborne beryllium at any exposure level.

Proposed paragraph (e)(1)(ii) would require employers to establish regulated areas wherever employees are actually exposed to airborne beryllium above either the TWA PEL or STEL, and wherever such exposure can reasonably be expected. This requirement would apply if any exposure monitoring or historical or objective data indicate that airborne exposures are in excess of either the TWA PEL or STEL, or if the employer has reason to anticipate or believe that airborne exposures may be above the TWA PEL or STEL, even if the employer has not yet characterized or monitored those exposures. For example, if newly introduced processes involving beryllium appear to be creating dust and have not yet been monitored, the employer should reasonably anticipate that airborne exposures could exceed the TWA PEL or STEL. In this situation the employer must designate and demarcate the area as a regulated area to protect workers and other persons until monitoring results establish that exposures are at or below the TWA PEL and STEL. The employer may then remove the regulated area designation.

Proposed paragraph (e)(2)(i) requires employers to demarcate each beryllium work area to distinguish it from the rest of the workplace. The proposal specifies that employers must identify beryllium work areas ''through signs or any other methods that adequately establish and inform each employee of the boundaries of each beryllium work area.'' This means that the demarcation must effectively alert workers and other persons that airborne beryllium may be present. Proposed paragraph (e)(2)(ii) requires employers to identify regulated areas and post warning signs at each approach to the regulated area in accordance with proposed paragraph (m)(2) of this standard.

This proposed rule gives employers flexibility in determining the best means to demarcate beryllium work areas and regulated areas (with the exception of paragraph (m), which sets forth specific requirements for warning signs at entry points to regulated areas). OSHA is aware that employers use various methods to demarcate certain areas in the workplace, including barricades, textured flooring, roped-off areas, ''No entry''/''No access'' signs, and painted boundary lines (AIA, 2003, Honeywell, 2003, DOD, 2003). Allowing employers to choose the methods that best demarcate beryllium work areas and regulated areas is consistent with OSHA's belief that employers are in the best position to make such determinations, based on the specific conditions in their workplaces. Whatever demarcation methods the employer selects must be clear and understandable enough to alert workers to the boundaries of the beryllium work area or regulated area. This may mean, for example, including more than one language on a sign, if the inclusion of a second language would make the sign understandable to workers with limited English reading skills.

In determining what demarcation might be necessary and effective, employers should consider factors including:

• The configuration of the beryllium work area or regulated area;

• Whether the beryllium work area or regulated area is permanent or temporary;

• The airborne concentrations of beryllium in the beryllium work area or regulated area;

• The number of employees working in areas adjacent to any beryllium work area or regulated area; and

• The period of time the beryllium work area or regulated area is expected to have hazardous exposures.

OSHA requests comment on the proposed requirement to demarcate beryllium work areas and regulated areas. OSHA also requests comment on whether the standard should allow the performance-based approach indicated in the proposal or whether the rule should specify what types of demarcation employers must use.

Proposed paragraph (e)(3) requires employers to limit access to regulated areas. Because of the potentially serious health effects of exposure to beryllium and the need for persons entering the regulated area to be properly protected, OSHA believes that the number of persons allowed to access regulated areas should be limited to those individuals listed in proposed paragraph (e)(3). Specifically, this provision would require employers to limit access to regulated areas to: (i) persons the employer authorizes or requires to be in a regulated area to perform work duties; (ii) persons entering a regulated area as designated representatives of employees for the purposes of exercising the right to observe exposure monitoring procedures under paragraph (d)(6) of this standard; and (iii) persons authorized by law to be in a regulated area.

The first group, persons the employer authorizes or requires to be in a regulated area to perform work duties, may include workers and other persons whose jobs involve operating machinery, equipment, and processes located in regulated areas; performing maintenance and repair operations on machinery, equipment, and processes in those areas; conducting inspections or quality control tasks; and supervising those who work in regulated areas.

The second group is made up of persons entering a regulated area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring under paragraph (d)(6). As explained in this section of the preamble regarding paragraph (d), providing employees and their representatives with the opportunity to observe monitoring is consistent with the OSH Act and OSHA's other substance-specific health standards, such as those for cadmium (29 CFR 1910.1027) and methylene chloride (29 CFR 1910.1052).

The third consists of persons authorized by law to be in a regulated area. This category includes persons authorized to enter regulated areas by the OSH Act, OSHA regulations, or any other applicable law. OSHA compliance officers would fall into this group.

Proposed paragraph (e)(4) requires employers to provide and ensure that each employee entering a regulated area uses personal protective clothing and equipment, including respirators, in accordance with paragraphs (g) and (h) of this standard.

In general, commenters did not oppose the concept of regulated areas. Stakeholders responding to the RFI supported the need for regulated areas

(ASAS, 2002; AFL–CIO, 2003; Honeywell, 2003). For example, the Department of Defense thought the use of regulated areas was a good way to limit the number of workers potentially exposed to beryllium (DOD, 2003).

Most small entity representatives (SERs) who participated in the SBREFA process were not concerned about the impact of tying the regulated area requirements to one of the PEL options presented in the SBREFA draft proposed standard (OSHA, 2007b). Only one of the SERs indicated that it may have a process where typical or average exposures are above the lowest PEL option of 0.1 μg/m^3 (OSHA, 2007a), which is one half the currently proposed TWA PEL.

SERs were divided on the issue of whether it was possible to isolate or segregate operations to meet the conditions of a regulated area. Most of the SERs did not currently isolate or segregate their beryllium processes, and several expressed concern about the difficulty and costs associated with isolating or segregating their beryllium processes (OSHA, 2008b). Some SERs said they have large, open plant floors making it difficult to isolated specific beryllium operations (OSHA, 2008b). Other SERs said the proposed requirement for a regulated area would be difficult and costly because they move machinery and equipment for production purposes. They said that segregating or restricting processes or machines and equipment to certain areas would affect productivity to some extent (OSHA, 2008b). SERs who use beryllium-containing materials only occasionally, frequently as part of a larger order, said that it would be impractical to isolate specific areas or machines for beryllium work (OSHA, 2008b). SERs in the precision metal products industry indicated their beryllium operations already were well controlled with machine enclosures (*e.g.,* lathes and forming machines) and therefore would not need to segregate these operations (OSHA, 2008b). The Panel recommended that OSHA revisit the cost analysis of regulated areas if the lowest PEL option (0.1 μg/m^3) is proposed (OSHA, 2008b). The Panel also recommended that OSHA consider dropping or limiting the provision for regulated areas (OSHA, 2008b). In response to this recommendation, OSHA analyzed Regulatory Alternative #12, which would not require employers to establish regulated areas.

The proposed rule presented during the SBREFA process did not contain any requirements for beryllium work areas. These requirements were added by OSHA after the SBREFA process in response to a proposal OSHA received from a stakeholder group (Materion and USW, 2012). However, because the proposal presented during the SBREFA process included a range of proposed TWA PELs down to 0.1 μg/m^3, SERs had the opportunity to comment on the requirements for regulated areas at very low exposure levels. OSHA believes that SER comments about regulated areas should reflect SER concerns about beryllium work areas as well. OSHA has also made the establishment and demarcation requirements for beryllium work areas flexible and performance-based to address SER concerns. OSHA invites comment on the proposed requirements for beryllium work areas and regulated areas, and on Regulatory Alternative 12 below. OSHA also requests comments and information on work settings where establishing regulated areas could be problematic or infeasible and what other approaches might be used to warn employees in such work settings of high risk areas.

Regulatory Alternative 12

This alternative would eliminate the requirement to establish and demarcate regulated areas within facilities where there is beryllium exposure. It does not eliminate the proposal's requirement to establish and demarcate beryllium work areas.

OSHA is aware that eliminating the requirement for regulated areas may ease the costs and burdens of compliance for some employers. However, this potential benefit of Alternative #12 must be considered in light of the reasons regulated areas were included in the proposal, and are a feature of most OSHA health regulations. As discussed previously, the proposed requirements for regulated areas serve to ensure that access to areas where beryllium exposures exceed the TWA PEL or STEL is restricted, reducing the number of people exposed to beryllium at levels that create a high risk of adverse health effects. Second, the requirement for warning signs ensures that persons who enter areas where exposures exceed the TWA PEL or STEL will be aware of the hazards present and take appropriate precautions such as the proper use of personal protective equipment.

OSHA believes the proposed requirements for beryllium work areas and regulated areas balance commenters' concerns with the need to reduce the number of employees exposed to beryllium and notify those exposed of the risks involved. The proposed standard does not require employers to establish and demarcate beryllium work areas or regulated areas by permanently segregating and isolating processes generating airborne beryllium. Instead, the standard allows employers to use temporary or flexible methods to demarcate beryllium work areas and regulated areas.

OSHA believes that these flexible, performance-based requirements could accommodate open work spaces, changeable plant layouts, and sporadic or occasional beryllium use without imposing undue costs or burdens. For example, the standard does not prohibit employers from moving machinery or equipment for production purposes as occurs in the beryllium-copper alloy industry (OSHA, 2008b). Where employers need to move machinery and equipment, the proposed rule allows employers to use methods such as temporary designations and flexible demarcations. OSHA also notes that some employers have enclosed machines (*e.g.,* lathes) to prevent the release of airborne beryllium into the workplace, thereby potentially eliminating the need for the machine to be in a regulated area (OSHA, 2008b).

(f) Methods of Compliance

Paragraph (f) of the proposed rule establishes methods for reducing employee exposure to beryllium through the use of a written exposure control plan and engineering and work practice controls.

Under proposed paragraph (f)(1)(i), employers must establish, implement, and maintain a written exposure control plan for beryllium work areas. OSHA believes that adherence to the written exposure control plan will help reduce skin contact with beryllium, which can lead to beryllium sensitization, and airborne exposure, which can lead to beryllium sensitization, CBD, and lung cancer. Because skin contact and airborne exposure can occur in any workplace within the scope of the standard, OSHA has made the preliminary determination to require a written exposure control plan for all employers within the scope of the standard. In addition, requiring employers to establish and maintain a written exposure control plan is consistent with other OSHA health standards, including 1,3 butadiene (29 CFR 1910.1051) and bloodborne pathogens (29 CFR 1910.1030).

OSHA's proposal to require a written exposure control plan is based in part on the recommendation of two stakeholders, Materion Corporation and the Steelworkers Union. Materion and the Steelworkers submitted a joint proposal for a standard to the Agency (Materion and Steelworkers, 2012) that includes a requirement for a written exposure control plan. In the stakeholders' joint proposal, the written exposure control plan included requiring documentation of operations and jobs likely to have exposure to beryllium at various levels; procedures for minimizing the migration of beryllium; procedures for keeping work surfaces clean; and documentation of engineering and work practice controls. OSHA's proposed requirements for maintaining and implementing a written exposure control plan follow the example of the stakeholders' proposal in most respects.

Under proposed paragraphs (f)(1)(i)(A), (B), and (C), the written exposure control plan must contain inventories of operations and job titles reasonably expected to have any exposure to airborne beryllium, exposure at or above the action level, and exposure above the TWA PEL or STEL. And, under proposed paragraph (f)(1)(i)(G), the plan must include an inventory of engineering and work practice controls required by paragraph (f)(2) of this standard.

A record of which operations and job titles are likely to have exposures at certain levels and which engineering and work practice controls the company has selected to control exposures will make it easier for employers to implement monitoring, hygiene practices, housekeeping, engineering and work practice controls, and other measures. These inventories will also help to assure employees' awareness of the exposures associated with their jobs, their eligibility for medical surveillance, and the controls that should be in use throughout the workplace. This will enable employees to work together with employers to ensure that the appropriate engineering controls and work practices are in use and functioning and that provisions such as medical surveillance, housekeeping, and PPE are properly implemented. In addition, these inventories, like all of the items required to be included in the written exposure control plan, will help safety and health personnel, including OSHA Compliance Officers, carry out their duties. A written plan provides detailed information to interested parties including employees, employee representatives, supervisors, and safety consultants of the employer's determination of the jobs and operations that may place employees at risk of exposure and the measures the employer has selected to control exposure.

Under proposed paragraph (f)(1)(D) through (F) and (H), the exposure control plan must contain procedures for: minimizing cross-contamination, including preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas; keeping surfaces in the beryllium work area as free as practicable of beryllium; minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace; and removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators. Each of these procedures serves to minimize the spread of beryllium throughout and outside the workplace. They also work to reduce the likelihood of skin contact and re-entrainment of beryllium particulate into the workplace atmosphere. Additional discussion of some of these requirements may be found in this section of the preamble, Summary and Explanation, at paragraph (h), Personal Protective Clothing and Equipment; paragraph (i), Hygiene Areas and Practices; and paragraph (j), Housekeeping.

The requirement to document these procedures in writing, as part of the exposure control plan, will help to ensure that employees are advised of their responsibilities and can easily review the procedures if they have questions. Because employees play an important part in exposure control through compliance with the rules regarding hygiene practices, housekeeping, and other measures, employees should have easy access to documentation detailing the procedures in place in their workplace. A review of the written exposure control plan should be part of the hazard communication training for employees as required by 1910.1200 and proposed paragraph (m). Additionally, the documentation of the procedures will help OSHA Compliance Officers assess employers' procedures.

Proposed paragraph (f)(1)(ii) requires that employers update their exposure control plans whenever any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in new or additional exposures to beryllium. Paragraph (f)(1)(ii) also requires employers to update their plans when an employee is confirmed positive for beryllium sensitization, is diagnosed with CBD, or shows other signs and symptoms related to beryllium exposure. In addition, the paragraph requires employers to update their plans if the employer has any reason to believe that new or additional exposures are occurring or will occur.

The requirements to update the exposure control plan if changes in the workplace result in or can be expected to result in new or additional exposures, or where the employer has any reason to believe that such exposures are occurring or will occur, ensure that an employer's plan reflects the current conditions in the workplace. If an employee becomes sensitized or develops CBD, the employer should investigate the source(s) of exposure responsible, and must make any necessary changes to address the source(s) of exposure, and update the written exposure control plan as necessary to reflect any new information or corrective action resulting from the employer's investigation. For example, the employer may find that housekeeping procedures in the employee's area need improvement, or that more appropriate PPE could be used. In some cases, the employer may find that additional engineering or work practice controls are appropriate to the processes in use. When the employer discovers new sources of exposure or makes changes in its control strategy, the employer must update its written exposure control plan to reflect current conditions in the workplace. Employers such as Materion and Axsys Technologies, who have worked to identify and document the exposure sources associated with cases of sensitization and CBD in their facilities, have used this information to develop and update beryllium exposure control plans (Bailey *et al.,* 2010; Schuler *et al.,* 2012; Madl *et al.,* 2007). OSHA believes this proposed process, whereby an employer uses employee health outcome data to check and improve the effectiveness of the employer's exposure control plan, is consistent with other performance-oriented aspects of this proposed standard.

Proposed paragraph (f)(1)(iii) requires employers to make a copy of the exposure control plan accessible to each employee who is or can reasonably be expected to be exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records Standard (29 CFR 1910.1020). As mentioned above, access to the exposure control plan will enable employees to partner with their employers in keeping the workplace safe.

Paragraph (f)(2) of the proposed rule contains requirements for the implementation of engineering and work practice controls to minimize beryllium exposures in beryllium work areas. The proposed rule relies on engineering and work practice controls as the primary means to reduce exposures. Where, after the implementation of feasible engineering and work practice controls, exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL, employers are required to supplement these controls with respiratory protection, according to the requirements of paragraph (g) of the proposed rule. OSHA proposes to require primary reliance on engineering and work practice controls because reliance on these methods is consistent with good industrial hygiene practice, with the Agency's experience in ensuring that workers have a healthy workplace, and with OSHA's traditional adherence to a hierarchy of controls.

OSHA requires adherence to this hierarchy of controls in a number of standards, including the Air Contaminants (29 CFR 1910.1000) and Respiratory Protection (29 CFR 1910.134) standards, as well as other substance-specific standards. The Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (see *AFL–CIO* v. *Marshall,* 617 F.2d 636 (D.C. Cir. 1979) (cotton dust standard); *United Steelworkers* v. *Marshall,* 647 F.2d 1189 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981) (lead standard); *ASARCO* v. *OSHA,* 746 F.2d 483 (9th Cir. 1984) (arsenic standard); *Am. Iron & Steel* v. *OSHA,* 182 F.3d 1261 (11th Cir. 1999) (respiratory protection standard); *Pub. Citizen* v. *U.S. Dep't of Labor,* 557 F.3d 165 (3rd Cir. 2009) (hexavalent chromium standard)).

The Agency understands that engineering controls are reliable, provide consistent levels of protection to a large number of workers, can be monitored continually and inexpensively, allow for predictable performance levels, and can efficiently remove toxic substances from the workplace. Once removed, the toxic substances no longer pose a threat to employees. The effectiveness of engineering controls does not generally depend to any substantial degree on human behavior, and the operation of control equipment is not as vulnerable to human error as is personal protective equipment. For these reasons, engineering controls are preferred by OSHA and the safety and health professional community in general.

The provisions related to engineering and work practice controls begin in paragraph (f)(2)(i)(A). For each operation in a beryllium work area, employers must ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure:

(1) Material and/or process substitution;

(2) Ventilated partial or full enclosures;

(3) Local exhaust ventilation at the points of operation, material handling, and transfer; or

(4) Process control, such as wet methods and automation. OSHA has included a non-mandatory appendix presenting a non-exhaustive list of engineering controls employers may use to comply with paragraph (f)(2)(i) (Appendix B).

Proposed paragraph (f)(2)(i)(B) offers two exemptions from the engineering and work practice controls requirements. First, under paragraph (f)(2)(i)(B)(1), an employer is exempt from using engineering and work practice controls where the employer can establish that the controls are not feasible.

Second, under paragraph (f)(2)(i)(B)(2), an employer is exempt from using the controls where the employer can demonstrate that exposures are below the action level, using no fewer than two representative personal breathing zone samples taken 7 days apart, for each affected operation.

The engineering work practice control requirement in paragraph (f)(2)(i)(A), like the written exposure control plan requirement, was proposed by the United Steelworkers and Materion as part of their joint submission to OSHA (Materion and United Steelworkers, 2012). The inclusion of the engineering work practice control provision in paragraph (f)(2)(i)(A) addresses a concern regarding the proposed PEL. OSHA expects that day-to-day changes in workplace conditions may cause frequent excursions above the PEL in workplaces where periodic sampling indicates exposures are between the action level and the PEL. Normal variability in the workplace and work processes, such as workers' positioning or patterns of airflow, can lead to excursions above the PEL. OSHA believes that substitution or engineering controls such as those outlined in paragraph (f)(2)(i)(A) provide the most reliable means to control variability in exposure levels. OSHA therefore included this requirement in the proposal. The Agency included the exemption in paragraph (f)(2)(i)(B)(2) to reduce the cost burden to employers with operations where measured exposures are below the action level, and therefore less likely to exceed the PEL in the course of typical exposure fluctuations. This exemption is similar to a provision in 1,3 Butadiene (29 CFR 1910.1051), which requires an exposure goal program where exposures exceed the action level.

OSHA recognizes that the requirements of paragraph (f)(2)(i) are not typical of OSHA standards, which usually require engineering controls only where exposures exceed the PEL(s). The Agency is therefore considering Regulatory Alternative #6, which would drop the provisions of paragraph (f)(2)(i) from the proposed standard. OSHA requests comments on the potential benefits of including such a provision in the beryllium standard, the potential costs and burdens associated with it, and whether OSHA should include or exclude this provision in the final standard.

Proposed paragraph (f)(2)(ii) applies when exposures exceed the TWA PEL or STEL after employers have implemented the control(s) required by paragraph (f)(2)(i). It requires employers to implement additional or enhanced engineering and work practice controls to reduce exposures to or below the PELs. For example, an enhanced engineering control may entail a redesigned hood on a local ventilation system to more effectively capture airborne beryllium at the source.

However, under proposed paragraph (f)(2)(iii), wherever the employer demonstrates that it is not feasible to reduce exposures to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(ii), the employer shall implement and maintain engineering and work practice controls to reduce exposures to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard.

Paragraph (f)(3) of the proposed rule would prohibit the employer from rotating workers to different jobs to achieve compliance with the PELs. Worker rotation can potentially reduce exposures to individual employees, but increases the number of employees exposed. Because OSHA has made a preliminary determination that exposure to beryllium can result in sensitization, CBD, and cancer, the Agency considers it inappropriate to place more workers at risk. Since no absolute threshold has been established for sensitization or resulting CBD or the carcinogenic effects of beryllium, it is prudent to limit the number of workers exposed at any concentration.

This provision is not a general prohibition of worker rotation wherever workers are exposed to beryllium. It is only intended to restrict its use as a compliance method for the proposed PEL; worker rotation may be used as deemed appropriate by the employer in activities such as to provide cross-training or to allow workers to alternate physically demanding tasks with less strenuous activities. This same provision was used for the asbestos (29 CFR 1910.1001 and 29 CFR 1926.1101), chromium (VI) (29 CFR 1910.1026), 1,3 butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), cadmium (29 CFR 1910.1027 and 29 CFR 1926.1127), and methylenedianiline (29 CFR 1926.60) OSHA standards.

The SERs who participated in the SBREFA process did not voice opposition to a requirement for a written exposure control program or challenge the utility of a written program in helping to control exposures (OSHA, 2008b). Several indicated that they already had a beryllium exposure control program in place. Some SERs suggested that OSHA should tie the written exposure control program requirement to exposures exceeding a revised PEL (OSHA, 2008b). The SERs' request to tie the written exposure control program requirement to the PEL appears to emerge from their belief that employees exposed below the proposed PEL are not at risk from beryllium exposure (OSHA, 2008b).

As stated earlier, OSHA's proposed standard would require a written exposure control plan for all beryllium work areas; *i.e.,* wherever airborne beryllium is found in the workplace. OSHA believes a written exposure control plan is needed to reduce employees' risks in low-exposure areas, where the proposed standard does not require employers to install engineering controls, as well as in high-risk areas. The Agency's preliminary risk assessment shows that adverse health effects from beryllium exposure occur at levels below the proposed PEL, and even below the proposed action level (see this preamble at Section VIII, Significance of Risk). In addition, dermal contact with beryllium can occur in jobs where exposures are below the PEL or the action level. Dermal exposure to beryllium can cause beryllium sensitization, a necessary first step in the development of CBD (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk). However, in response to the SERs' comments on the written exposure control plan and other requirements that may affect workplaces with exposure levels below the proposed PEL, OSHA is considering Regulatory Alternative #8 (see chapter VIII of the PEA). Where the proposed standard requires written exposure control plans to be maintained in any facility covered by the standard, Regulatory Alternative #8 would require only facilities with exposures above the TWA PEL or STEL to maintain a plan. OSHA requests comment on the proposed written exposure control plan requirement and on Regulatory Alternative #8.

Several SERs expressed doubt that material substitution could be an effective means of reducing beryllium exposures in their facilities. One SER stated that substitutes for beryllium alloys are not presently viable for industrial uses that require certain high-performance electrical characteristics, or wear resistance (OSHA, 2007a). Another SER commented that substitutes for beryllium alloys in the dental appliance industry have also been associated with occupational disease (OSHA, 2007a).

OSHA recognizes that the use of substitutes for beryllium may not be feasible or appropriate for some employers. The Agency's intent is to offer material substitution as one possible means of compliance with the proposed standard. Employers must determine whether material substitution is an effective and appropriate means of exposure control for their facilities. In addition, it is employers' responsibility to check the toxicity of any material they may use in their facilities, including potential substitutes for beryllium.

OSHA anticipates that most small businesses will be able to comply with the proposed standard regardless of whether they choose to substitute other materials for beryllium in their facilities.

(g) Respiratory Protection

Paragraph (g) of the proposed standard lays out the situations in which employers are required to protect employees' health through the use of respiratory protection. Specifically, this paragraph would require that employers provide respiratory protection at no cost and ensure that employees utilize the protection during the situations listed in paragraph (g)(1). As detailed in proposed paragraph (g)(2), the required respiratory protection must comply with the Respiratory Protection standard (29 CFR 1910.134).

Proposed paragraph (g)(1) requires employers to ensure that each employee required to use a respirator does so. Accordingly, simply providing respirators to employees will not satisfy an employer's obligations under proposed paragraph (g)(1) unless the employer also ensures that its employees wear the respirators when required. Proposed paragraph (g)(1) would also require employers to provide required respirators at no cost to employees. This requirement is consistent with OSHA's Respiratory Protection standard, which also requires employers to provide required respiratory protection to employees at no cost (29 CFR 1910.134(c)(4)).

Paragraph (g)(1) requires appropriate respiratory protection during certain enumerated situations. Proposed paragraph (g)(1)(i) requires respiratory protection during the installation and implementation of engineering and/or work practice controls where exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL. The Agency realizes that changing workplace conditions may require employers to install new engineering controls, modify existing controls, or make other workplace changes to reduce employee exposure to beryllium to at or below the TWA PEL and STEL. In these cases, the proposed standard recognizes that installing appropriate engineering controls and implementing proper work practices may take time. During this time, employers must demonstrate that they are making prompt, good faith efforts to purchase and install appropriate engineering controls and implement effective work practices, and to evaluate their effectiveness for reducing exposure to beryllium to at or below the TWA PEL and STEL.

Proposed paragraph (g)(1)(ii) requires the provision of respiratory protection during any operations, including maintenance and repair operations and other non-routine tasks, when engineering and work practice controls are not feasible and exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL. OSHA included this provision because the Agency realizes that certain operations may take place when engineering and work practice controls are not operational or capable of controlling exposures to at or below the TWA PEL and STEL. For example, during maintenance and repair operations, engineering controls may lose their full effectiveness or require partial or total breach, bypass, or shutdown. Under these circumstances, if exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL, the employer must provide and ensure the use of respiratory protection.

Proposed paragraph (g)(1)(iii) requires the provision of respiratory protection where beryllium exposures exceed the TWA PEL or STEL even after the employer has installed and implemented all feasible engineering and work practice controls. OSHA anticipates that there will be very few situations where feasible engineering and work practice controls are incapable of lowering employee exposure to beryllium to at or below the TWA PEL or STEL (see this preamble at section IX.D, Technological Feasibility). In such cases, the proposed standard requires that employers install and implement all feasible engineering and work practice controls and supplement those controls by providing respiratory protection (proposed paragraph (f)(2)(iii)). OSHA reiterates that paragraph (f)(2)(iii) would also require employers to demonstrate that engineering and work practice controls are not feasible or sufficient to reduce exposure to levels at or below the TWA PEL and STEL. OSHA requests comment about the proposed situations during which employers should be required to provide and ensure the use of respiratory protection.

Proposed paragraph (g)(1)(iv) requires the provision of respiratory protection in emergencies. At such times, engineering controls may not be functioning fully or may be overwhelmed or rendered inoperable. Also, emergencies may occur in areas where there are no engineering controls. The proposed standard recognizes that the provision of respiratory protection is critical in emergencies, as beryllium exposures may be very high and engineering controls may not be adequate to control an unexpected release of beryllium.

The situations in which respiratory protection is required are generally consistent with the requirements in other OSHA health standards, such as those for chromium (VI)(29 CFR 1910.1026), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052). Those standards and this proposed standard also reflect the Agency's traditional adherence to a hierarchy of controls in which engineering and work practice controls are preferred to respiratory protection (see the discussion of proposed paragraph (f) earlier in this section of the preamble).

Whenever respirators are used to comply with the requirements of this proposed standard, paragraph (g)(2) requires that the employer implement a comprehensive written respiratory protection program in accordance with OSHA's Respiratory Protection standard (29 CFR 1910.134). The Respiratory Protection standard is designed to ensure that employers properly select and use respiratory protection in a manner that effectively protects exposed workers. Under 29 CFR 1910.134(c)(1), the employer's respiratory protection program must include:

- Procedures for selecting appropriate respirators for use in the workplace;
- Medical evaluations of employees required to use respirators;
- Respirator fit testing procedures;
- Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;
- Procedures and schedules for maintaining respirators;
- Procedures to ensure adequate quality, quantity, and flow of breathing air for atmosphere-supplying respirators;
- Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations, and in the proper use of respirators; and
- Procedures for evaluating the effectiveness of the program.

In accordance with the Agency's policy to avoid duplication and to establish regulatory consistency, proposed paragraph (g)(2) incorporates by reference the requirements of 29 CFR 1910.134 rather than reprinting those requirements in this proposed standard. OSHA notes that the respirator selection provisions in 1910.134 include requirements for Assigned Protection Factors (APFs) and Maximum Use Concentrations (MUCs) that OSHA adopted in 2006 (71 FR 50122–50192, August 24, 2006). The APFs and MUCs provide employers with critical information for the selection of respirators to protect workers from exposure to atmospheric workplace contaminants.

OSHA believes that the proposed respiratory protection requirements are feasible even for small employers. Although none of the SERs who participated in the SBREFA process made specific recommendations about respiratory protection, some said that they currently have existing respiratory protection programs in place as supplemental support to engineering and work practice controls (OSHA, 2008b).

OSHA requests comment on the proposed requirement to establish and maintain a respiratory protection program that complies with 29 CFR 1910.134. OSHA would like to hear from companies of all sizes regarding whether they have respiratory protection programs to protect employees from beryllium exposures. If so, please explain the parameters of your program including types of respirators used, when and where respirators are required, program evaluation, and annual costs.

(h) Personal Protective Clothing and Equipment

Paragraph (h) of the proposed standard requires employers to provide employees with personal protective clothing and equipment (PPE) where employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL; where work clothing or skin may become visibly contaminated with beryllium, including during maintenance and repair activities or during non-routine tasks; and where employees are exposed to soluble beryllium compounds. These PPE requirements are intended to prevent adverse health effects associated with dermal exposure to beryllium, and accumulation of beryllium on clothing, shoes, and equipment that can result in additional inhalation exposure. The requirements also protect employees in other work areas from exposures that could occur if contaminated clothing carried beryllium to those areas, as well as employees and other individuals outside the workplace. The proposed standard requires the employer to provide PPE at no cost to employees, and to ensure that employees use the provided PPE in accordance with the written exposure control plan as described in paragraph (f)(1) of this proposed standard and OSHA'S Personal Protective Equipment standards (29 CFR part 1910 subpart I).

Proposed paragraph (h)(1)(i) requires the provision and use of PPE for employees exposed to airborne beryllium in any form exceeding the TWA PEL or STEL because such exposure would likely result in skin contact by means of deposits on employees' skin or clothes or on surfaces touched by employees. And, OSHA believes that regardless of the level of exposure, the use of PPE further reduces exposure where employees' clothing or skin could become visibly contaminated with beryllium (paragraph (h)(1)(ii)).

The term ''visibly contaminated with beryllium'' means visibly contaminated with any material that contains beryllium. The proposed standard does not specify criteria for determining whether work clothing or skin may become visibly contaminated with beryllium. When evaluating whether this definition is satisfied, OSHA expects that the employer will assess the workplace in a manner consistent with the Agency's general requirements for the use of personal protective equipment in general industry (29 CFR part 1910 subpart I). These standards require the employer to assess the workplace to determine if hazards associated with dermal or inhalation exposure to a substance such as beryllium are, or are likely to be, present.

The proposed standard also requires the provision and use of PPE where employees are exposed to soluble beryllium compounds, regardless of the level of airborne exposure (paragraph (h)(1)(iii)). Solubility is a concern because dermal absorption may occur at a greater rate for soluble beryllium than for insoluble beryllium. Once absorbed through the skin, beryllium can induce a sensitization response that is a necessary first step toward CBD (See the Health Effects section of this preamble, section V.A.2). However, there is also evidence that beryllium in other forms can be absorbed through the skin and cause sensitization (see this preamble at section V.B.2, Health Effects). OSHA requests comment on this provision, and whether employers should also be required to provide PPE to limit dermal contact with insoluble forms of beryllium as specified in Regulatory Alternative #13 below.

Requiring PPE is consistent with section 6(b)(7) of the OSH Act which states that, where appropriate, standards shall prescribe suitable protective equipment to be used in connection with hazards. The proposed requirements for PPE are based upon widely accepted principles and conventional practices of industrial hygiene, and in some respects are similar to other OSHA health standards such as those for chromium (VI) (29 CFR 1910.1026), lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), and methylenedianiline (MDA; 29 CFR 1910.1050). However, the requirement to use PPE where work clothing or skin may become ''visibly contaminated'' with beryllium differs from prior health standards, which do not require contamination to be visible in order for PPE to be required. For example, the standard for chromium (VI) requires the employer to provide appropriate PPE where a hazard is present or is likely to be present from skin or eye contact with chromium (VI) (29 CFR 1910.1026). The lead (29 CFR 1910.1025) and cadmium (29 CFR 1910.127) standards require PPE where employees are exposed above the PEL or where there is potential for skin or eye irritation, regardless of airborne exposure level. In the case of MDA, PPE must be provided where employees are subject to dermal exposure to MDA, where liquids containing MDA can be splashed into the eyes, or where airborne concentrations of MDA are in excess of the PEL (29 CFR 1910.1050). While OSHA's language regarding PPE requirements varies somewhat from standard to standard, previous standards tend to emphasize potential for contact with a substance that can trigger health effects via dermal exposure, rather than ''visible contamination'' with the substance.

The employer must exercise reasonable judgment in selecting appropriate PPE. This requirement is consistent with OSHA's current standards for provision of personal protective equipment for general industry (29 CFR part 1910 subpart I). As described in the non-mandatory appendix providing guidance on conducting a hazard assessment for OSHA general industry standards (29 CFR 1910 subpart I appendix B), the employer should ''exercise common sense and appropriate expertise'' in assessing hazards. By ''appropriate expertise,'' OSHA expects individuals conducting hazard assessments to be familiar the employer's work processes, materials, and work environment. A thorough hazard assessment should include a walk-through survey to identify sources of hazards to employees, wipe sampling to detect beryllium contamination on surfaces, review of injury and illness data, and employee input on the hazards to which they are exposed. Information obtained in this manner provides a basis for the identification and evaluation of potential hazards. OSHA believes that the implementation of a comprehensive and thorough program to determine areas of potential exposure, consistent with the employer's written exposure control plan, is a sound safety and health practice and a necessary element of ensuring overall worker protection.

Based on the hazard assessment results, the employer must determine what PPE is necessary to protect employees. The proposed requirement is performance-oriented, and is designed to allow the employer flexibility in selecting the PPE most suitable for each particular workplace. The type of PPE needed will depend on the potential for exposure, the physical properties of the beryllium-containing material used, and the conditions of use in the workplace. For example, shipping and receiving activities may necessitate only work uniforms and gloves. In other situations such as when a worker is performing facility maintenance, gloves, work uniforms, coveralls, and respiratory protection may be appropriate. Beryllium compounds can exist in acidic or alkaline form, and these characteristics may influence the choice of PPE. Face shields may be appropriate in situations where there is a danger of being splashed in the face with soluble beryllium or a liquid containing beryllium. Coveralls with a head covering may be appropriate when a sudden release of airborne beryllium could result in beryllium contamination of clothing, hair, or skin. Respirators are addressed separately in the explanation of proposed paragraph (g) earlier in this section of the preamble.

Note that paragraph (i)(2) of this proposed standard requires change rooms only where employees are required to remove their personal clothing. Although some personal protective clothing may be worn over street clothing, it is not appropriate for workers to wear protective clothing over street clothing if doing so could reasonably result in contamination of the workers' street clothes. In situations in which it is not appropriate for workers to wear protective clothing over their street clothes, the employer must select and ensure the use of protective clothing that is worn in lieu of (rather than over) street clothing.

Paragraph (h)(2) contains proposed requirements for removal and storage of PPE. This provision is intended to reduce beryllium contamination in the workplace and limit beryllium exposure outside the workplace. Wearing contaminated clothing outside the beryllium work area could lengthen the duration of exposure and carry beryllium from beryllium work areas to other areas of the workplace. In addition, contamination of personal clothing could result in beryllium being carried to employees' cars and homes, increasing employees' exposure as well as exposing others to beryllium hazards. A National Jewish Medical and Research Center collaborative study with NIOSH documented inadvertent transfer of beryllium from the workplace to workers' automobiles, and stressed the need for separating clean and contaminated (''dirty'') PPE (Sanderson, 1999). Toxic metals brought by workers into the home via contaminated clothing and vehicles continue to result in exposure to children and other household members. A recent study of battery recycling workers found that lead surface contamination above the Environmental Protection Agency level of concern (> 40 μg/ft^2) was common in the workers' homes and vehicles (Centers for Disease Control and Prevention, 2012).

Under proposed paragraph (h)(2)(i)(A), beryllium-contaminated PPE must be removed at the end of the work shift or at the completion of tasks involving beryllium exposure, whichever comes first. This language is intended to convey that PPE contaminated with beryllium should not be worn when tasks involving beryllium exposure have been completed for the day. For example, if employees perform work tasks involving beryllium exposure for the first two hours of a work shift, and then perform tasks that do not involve exposure, they should remove their PPE after the exposure period to avoid the possibility of increasing the duration of exposure and contamination of the work area from beryllium residues on the PPE (*i.e.,* re-entrainment of beryllium particulate). If, however, employees are performing tasks involving exposure intermittently throughout the day, or if employees are exposed to other contaminants where PPE is needed, this provision is not intended to prevent them from wearing the PPE until the completion of their shift, unless it has become visibly contaminated with beryllium (paragraph (h)(2)(i)(B)).

Paragraph (h)(2)(i)(B) would require employers to ensure that employees remove PPE that has become visibly contaminated with beryllium. This language is intended to convey that PPE that is visibly contaminated with beryllium should be changed at the earliest reasonable opportunity, for example, at the end of the task during which it became visibly contaminated. This language is intended to protect employees working with beryllium and their co-workers from exposure due to accumulation of beryllium on PPE, and reduces the likelihood of cross-contamination from beryllium-contaminated PPE.

Proposed paragraph (h)(2)(ii) requires employees to remove PPE consistent with the written exposure control plan required by proposed paragraph (f)(1). Paragraph (f)(1) specifies that the employer's written exposure control plan must contain procedures for minimizing cross-contamination, and procedures for the storage of beryllium-contaminated PPE, among other provisions (see (f)(1)(i)(D) & (H)). Paragraph (h)(2)(iii) would require employers to ensure that protective clothing is stored separately from employees' street clothing. OSHA believes these provisions are necessary to prevent the spread of beryllium throughout and outside the workplace.

To further limit exposures outside the workplace, OSHA proposes in paragraph (h)(2)(iv) that the employer ensure that beryllium-contaminated PPE is only removed by employees who are authorized to do so for the purpose of laundering, cleaning, maintaining, or disposing of such PPE. These items must be brought to an appropriate location away from the workplace. To be an appropriate location for purposes of paragraph (h)(2)(iv), the facility must be equipped to handle beryllium-contaminated items in accordance with this proposed standard. The standard would further require in paragraph (h)(2)(v) that PPE removed from the workplace for laundering, cleaning, maintenance, or discarding be placed in closed, impermeable bags or containers. These requirements are intended to minimize cross-contamination and migration of beryllium, and to protect employees or other individuals who later handle beryllium-contaminated items. Required warning labels would alert those handling the contaminated PPE of the potential hazards of exposure to beryllium. Such labels must conform with the HCS (29 CFR 1910.1200) and paragraph (m)(3) of this proposed standard. These warning requirements are meant to reduce confusion and ambiguity regarding critical information communicated in the workplace by requiring that this information be presented in a clear and uniform manner.

Proposed paragraph (h)(3)(i) would require the employer to ensure that reusable PPE is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness. These requirements must be completed at a frequency, and in a manner, necessary to ensure that PPE continues to serve its intended purpose of protecting workers from beryllium exposure.

In keeping with the performance-orientation of the proposed standard, OSHA does not specify how often PPE should be cleaned, repaired or replaced. The Agency believes that appropriate time intervals may vary widely based on the types of PPE used, the nature of the beryllium exposures, and other circumstances in the workplace. However, even in the absence of a mandated schedule, the employer is still obligated to keep the PPE in the condition necessary to perform its protective function. A number of Small Entity Representatives (SERS) from OSHA's SBREFA panel noted they now use low maintenance Tyvek disposable protective suits for some high exposure areas to address potential contamination situations (OSHA, 2007a).

Under paragraph (h)(3)(ii), removal of beryllium from PPE by blowing, shaking, or any other means which disperses beryllium in the air would be prohibited as this practice could result in unnecessary exposure to airborne beryllium.

Paragraph (h)(3)(iii) would require the employer to inform in writing any person or business entity who launders, cleans, or repairs PPE required by this standard of the potentially harmful effects of exposure to airborne beryllium and dermal contact with soluble beryllium compounds, and of the need to handle the PPE in accordance with this standard. This provision is intended to limit dermal or inhalation exposure to beryllium, and to emphasize the need for hazard awareness and protective measures consistent with the proposed standard among persons who clean, launder, or repair beryllium-contaminated items.

Comments from SERs indicate that a number of beryllium-related businesses already have comprehensive protocols in place for the use and maintenance of PPE (OSHA, 2007a). One commenter indicated that it has effectively reduced sensitization and CBD through the use of respirators, other PPE, and engineering controls (OSHA, 2007a). Another commenter stated that it utilizes PPE to reduce skin exposure (OSHA, 2007a). These existing PPE programs achieve many of the Agency's goals and incorporate many of the requirements of this proposed standard.

The primary objections from SERs came from companies that raised concerns regarding the ''trigger'' (*e.g.,* exposure level or surface contamination) for PPE in the draft standard, and particularly the use of such terms as ''anticipated,'' ''routine,'' and ''contaminated surface area'' in connection with the requirements to protect against dermal exposure to beryllium (OSHA, 2007a). They also contend that for certain processes such as stamping, change rooms, PPE, and other hygiene practices are not necessary (OSHA, 2007a). Much of this criticism was based on early pre-proposal drafts in circulation to the SBREFA Panel (OSHA, 2007b). Since that time, OSHA has endeavored to refine the regulatory text to reflect the concerns and comments submitted on this topic. ''Contaminated surface area'' is no longer a trigger for PPE; however, employers must provide PPE if a contaminated surface presents the potential for workers' skin or clothing to become visibly contaminated with beryllium (paragraph (h)(1)(ii)). The term ''routine'' has been removed as a trigger, and paragraph (h)(1)(ii) makes clear that protections are required where skin or clothing may become visibly contaminated whether during routine or non-routine tasks. OSHA clarified that dermal protections are required only where the skin may become visibly contaminated with beryllium. OSHA believes that this proposed standard addresses commenters' objections with textual changes and this explanation of the text, which together provide further guidance to those who would be covered by the standard.

However, OSHA is concerned that the requirement to use PPE where work clothing or skin may become ''visibly contaminated'' with beryllium or where soluble forms of beryllium are used may not be sufficiently protective of beryllium-exposed workers. OSHA has preliminarily concluded that sensitization can occur through dermal exposure. And although solubility may play a role in the level of sensitization risk, the available evidence suggests that contact with insoluble as well as soluble beryllium can cause sensitization via dermal contact (see this preamble at section V, Health Effects). Furthermore, at exposure levels below the current or proposed PEL, beryllium surface contamination is unlikely to be visible yet may still cause sensitization. The specification of ''visible contamination'' is a departure from most OSHA standards, which do not specify that contamination must be visible in order for PPE to be required. OSHA is therefore considering Regulatory Alternative #13, which would require appropriate PPE wherever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. Please provide comments on this alternative, including the benefits and drawbacks of a comprehensive PPE requirement, and any relevant data or studies the Agency should consider.

(i) Hygiene Areas and Practices

Paragraph (i) of the proposed standard requires that, when certain conditions are met, employers must provide employees with readily accessible washing facilities, change rooms, and showers. Proposed paragraph (i) also requires employers to take certain steps to minimize exposure in eating and drinking areas, and prohibits certain practices that may contribute to beryllium exposure. OSHA believes that strict compliance with these provisions would substantially reduce employee exposure to beryllium.

The proposed standard requires certain hygiene facilities and procedures in beryllium work areas, and additional hygiene facilities and procedures when airborne exposures exceed the TWA PEL or STEL. OSHA believes that skin contact with beryllium can occur even at low airborne exposures. Skin wipe sample analysis of dental laboratory technicians performing grinding operations demonstrated that beryllium was present on the hands of workers even when airborne exposures were well below the PEL (ERG, 2006).

As discussed in the Health Effects section of this preamble, section V, respiratory tract, skin, eye, or mucosal contact with beryllium can result in sensitization, which is a necessary first step toward the development of CBD. Also, beryllium can contaminate employees' clothing, shoes, skin, and hair, prolonging workers' beryllium exposure and exposing others such as family members if proper hygiene practices are not observed. A study by the National Jewish Medical and Research Center of Denver, Colorado, measured the levels of beryllium on workers' skin and vehicle surfaces at a machining plant where many workers did not change out of their clothes and shoes at the end of their shifts. The study showed elevated surface levels of beryllium were present on workers' skin and in their vehicles, demonstrating that workers carried residual beryllium on their hands and shoes when leaving work (Sanderson *et al.,* 1999). Paragraph (i) of the proposed standard would reduce employees' skin contact with beryllium, the possibility of accidental ingestion and inhalation of beryllium, and the spread of beryllium within and outside the workplace.

Paragraph (i)(1) would require the employer to provide readily accessible washing facilities capable of removing beryllium from the hands, face, and neck, and to ensure that employees working in beryllium work areas use these facilities when necessary. This requirement is performance-oriented, and does not specify any particular frequency. At a minimum, employees working in a beryllium work area must wash their hands, faces, and necks at the end of the shift to remove any residual beryllium. Likewise, washing prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet would also protect employees against beryllium ingestion and inhalation.

Typically, washing facilities would consist of one or more sinks, soap or another cleaning agent, and a means for employees to dry themselves after washing. OSHA does not intend to require the use of any particular soap or cleaning agent. Employers can provide whatever washing materials and equipment they choose, as long as those materials and equipment are effective in removing beryllium from the skin and do not themselves cause skin or eye problems.

Washing reduces exposure by limiting the period of time that beryllium is in contact with the skin, and helps prevent accidental ingestion. Although engineering and work practice controls and protective clothing and equipment are designed to prevent hazardous skin and eye contact, OSHA realizes that in some circumstances exposure will nevertheless occur. For example, an employee who wears gloves to protect against hand contact with beryllium may inadvertently touch his or her face with the contaminated glove during the course of the day. The purpose of requiring washing facilities is to mitigate adverse health effects when skin or eye contact with beryllium occurs.

Under proposed paragraph (i)(2), where employees are required to remove their personal clothing in order to use personal protective clothing, the employer must provide designated change rooms with separate storage facilities for street and work clothing to prevent cross contamination. Change rooms must be in accordance with the Sanitation standard (29 CFR 1910.141). OSHA intends the change rooms requirement to apply to all covered workplaces where employees must change their clothing (*i.e.,* take off their street clothes) to use protective clothing. In situations where removal of street clothes is not necessary (*e.g.,* in a workplace where only gloves are used as protective clothing), change rooms are not required. Note that paragraph (h) of this proposed standard requires employers to provide ''appropriate'' personal protective clothing. It is not appropriate for employees to wear protective clothing over street clothing if doing so results in contamination of the employee's street clothes. In such situations, the employer must ensure that employees wear protective clothing in lieu of (rather than over) street clothing, and provide change rooms.

Change rooms must be designed in accordance with the written exposure control plan required by paragraph (f)(1) of this proposed standard, and with the Sanitation standard (29 CFR 1910.141). These provisions require change rooms to be equipped with storage facilities (*e.g.,* lockers) for protective clothing, and separate storage facilities for street clothes, to prevent cross-contamination. Minimizing contamination of employees' personal clothes will also reduce the likelihood that beryllium will contaminate employees' cars and homes, and other areas outside the workplace.

Because of the risk of beryllium sensitization via the skin as described in section V of this preamble, Health Effects, OSHA has determined that employers must provide showers if their employees could reasonably be expected to be exposed above the TWA PEL or STEL (paragraph (i)(3)(i)(A)), and if employees' hair or body parts other than hands, face, and neck could reasonably be expected to be contaminated with beryllium (paragraph (i)(3)(i)(B)). Employers are only required to provide showers if paragraphs (i)(3)(i)(A) and (B) both apply. Other OSHA health standards, such as the standards for cadmium (29 CFR

1910.1027) and lead (29 CFR 1910.1025), also require showers when exposures exceed the PEL. OSHA's standard for coke oven emissions (29 CFR 1910.1029) requires employers to provide showers and ensure that employees working in a regulated area shower at the end of the work shift. The standard for methylenedianiline (MDA) (29 CFR 1910.1050) requires employers to ensure that employees who may potentially be exposed to MDA above the action level shower at the end of the work shift.

Paragraph (i)(3)(ii) requires employers to ensure that employees use the showers at the end of the work activity or shift involving beryllium if the employees reasonably could have been exposed above the TWA PEL or STEL, and if beryllium could reasonably have contaminated the employees' body parts other than hands, face, and neck. This language is intended to convey that showers are required for employees who satisfy both paragraphs (i)(3)(ii)(A) and (B) when work activities involving beryllium exposure have been completed for the day. For example, if employees perform work activities involving beryllium exposure for the first two hours of a work shift, and then perform activities that do not involve exposure, they should shower after the exposure period to avoid increasing the duration of exposure, potential of accidental ingestion, and contamination of the work area from beryllium residue on their hair and body parts other than hands, face, and neck. If, however, employees are performing tasks involving exposure intermittently throughout the day, this provision is not intended to require them to shower before the completion of the last task involving exposure.

To minimize the possibility of food contamination and the likelihood of additional exposure to beryllium through inhalation or ingestion, paragraph (i)(4) would require that employers provide employees with a place to eat and drink where beryllium exposure is below the action level, and where the surfaces are maintained as free as practicable of beryllium. Eating and drinking areas must further comply with the Sanitation standard (29 CFR 1910.141(g)), which prohibits consuming food or beverages in a toilet area or in any area with exposures above an OSHA PEL.

The requirement to maintain surfaces as free as practicable of beryllium is included in other OSHA health standards such as those for lead in general industry (29 CFR 1910.1025), lead in construction (29 CFR 1926.62), chromium (IV) (29 CFR 1910.1026), and asbestos (29 CFR 1910.1001). As OSHA explained in a January 13, 2003, letter of interpretation concerning the meaning of ''as free as practicable'' in OSHA's Lead in Construction standard (29 CFR 1926.62), OSHA evaluates whether a surface is ''as free as practicable'' of a contaminant by the rigor of the employer's program to keep surfaces clean (OSHA, 2003). A sufficient housekeeping program may be indicated by a routine cleaning schedule and the use of effective cleaning methods to minimize the possibility of exposure from accumulation of beryllium on surfaces. OSHA's compliance directive on Inspection Procedures for Chromium (IV) Standards provides additional detail on how OSHA interprets ''as free as practicable'' for enforcement purposes (OSHA, 2008a). As explained in the directive, if a wipe sample reveals a toxic substance on a surface, and the employer has not taken practicable measures to keep the surface clean, the employer has not kept the surface as free as practicable of the toxic substance.

The proposed standard does not require the employer to provide separate eating and drinking areas to employees at the worksite. Employees may consume food or beverages offsite. However, where the employer chooses to allow employees to consume food or beverages at a worksite where beryllium is present, the employer would be required to maintain the area in accordance with paragraph (i)(4) of this proposed standard.

Paragraph (i)(5)(i) would prohibit eating, drinking, smoking, chewing tobacco or gum, or applying cosmetics in regulated areas. Where exposures can reasonably be expected at levels above the proposed TWA PEL or STEL, there is a greater risk of beryllium contaminating the food, drink, tobacco, gum, or cosmetics. Prohibiting these activities would reduce the potential for this manner of exposure.

Under paragraph (i)(5)(ii), employers would also be required to ensure that employees do not enter eating or drinking areas wearing contaminated protective clothing or equipment. This is to further minimize the likelihood that employees will be exposed to beryllium in eating and drinking areas through inhalation, dermal contact, and ingestion.

The draft regulatory text presented during the SBREFA process would have required handwashing facilities and certain other hygiene provisions when exposures exceeded the TWA PEL, or when there was ''anticipated skin exposure.'' Small Entity Representatives (SERs) from OSHA's SBREFA panel expressed concern that the phrase ''anticipated skin exposure'' was vague and lacked definition (OSHA, 2007a). Commenters suggested that this could require employers at workplaces with low exposures to make significant modifications to the workplace, such as installing showers and change rooms. OSHA has evaluated the hygiene triggers and clarified that change rooms are only required when employees must remove their street clothes in order to wear protective clothing. Showers are only required when exposures exceed the TWA PEL or STEL, and beryllium could reasonably contaminate employees' hair or body parts other than hands, face, and neck. OSHA has removed the phrase ''anticipated skin exposure'' from the proposed standard. OSHA believes these changes address the commenters' concerns.

(j) Housekeeping

Paragraph (j) of the proposed standard requires employers to maintain surfaces in beryllium work areas as free as practicable of accumulations of beryllium; promptly clean spills and emergency releases; use appropriate cleaning methods; and properly dispose of beryllium-contaminated waste, debris, and materials. These provisions are especially important because they minimize additional sources of exposure that engineering controls are not designed to address. Good housekeeping measures are a cost-effective way to control employee exposures by removing settled beryllium that could otherwise become re-entrained into the surrounding atmosphere by physical disturbances or air currents and could enter an employee's breathing zone. Contact with contaminated surfaces may also result in dermal exposure to beryllium. As discussed in this preamble at section V, Health Effects, researchers have identified skin exposure to beryllium as a pathway to sensitization. The proposed provisions in this paragraph are consistent with housekeeping requirements in other OSHA standards for toxic metals including cadmium (29 CFR 1910.1027), chromium (VI)(29 CFR 1910.1026), and lead (29 CFR 1910.1025).

Paragraph (j)(1) requires the employer to ensure that all surfaces in beryllium work areas are maintained as free as practicable of accumulations of beryllium, and that spills and emergency releases are cleaned up promptly. Employers must follow the procedures that they have listed under their exposure control plan required by paragraph (f)(1) to clean beryllium-contaminated surfaces, and use the cleaning methods required by paragraph (j)(2). Good housekeeping practices are essential in controlling beryllium exposure. Beryllium-containing material deposited on ledges, equipment, floors, and other surfaces must be promptly removed to prevent these deposits from becoming airborne and to minimize the likelihood of skin contact with beryllium.

Paragraph (j)(1) directs the employer to maintain surfaces where beryllium may accumulate ''as free as practicable'' of beryllium. In this context, the phrase ''as free as practicable'' sets forth the baseline goal in the development of an employer's housekeeping program to keep work areas free from surface contamination. For a detailed discussion of the meaning of the phrase ''as free as practicable,'' see the discussion of proposed paragraph (i) earlier in this section of the preamble.

Employers must regularly clean surfaces in beryllium work areas to minimize re-entrainment of dust into the work environment, and to ensure that accumulations of beryllium do not become sources of exposure. Although OSHA does not define ''surface'' in the proposed standard, the term would include surfaces workers come into contact with such as working surfaces, floors, and storage facilities, as well as surfaces workers do not directly contact such as rafters. Because all surfaces in beryllium work areas could potentially accumulate beryllium that workers could later inhale, touch, or ingest, all surfaces in beryllium works areas must be kept as free as practicable of beryllium.

OSHA has preliminarily decided not to require employers to measure beryllium contamination on surfaces, because the Agency does not have the necessary data to understand the relationship between surface level of beryllium and risk of absorption through the skin. The use of wipe samples, however, remains a useful qualitative tool to detect the presence of beryllium on surfaces.

As mentioned above, when beryllium is released into the workplace as a result of a spill or emergency release, paragraph (j)(1)(ii) would require the employer to ensure prompt and proper cleanup in accordance with the written exposure control plan required by paragraph (f)(1) and to use the cleaning methods required by paragraph (j)(2) of this proposed standard. Spills or emergency releases not attended to promptly are likely to result in additional employee exposure or skin contact.

Paragraph (j)(2) provides that clean-up procedures for beryllium-containing material must minimize employee exposure. OSHA recognizes that each work environment is unique, so OSHA has established performance-oriented requirements for housekeeping to allow employers to determine how best to clean beryllium work areas while minimizing employee exposure. Paragraph (j)(2)(i) of the proposed standard would require that surfaces contaminated with beryllium be cleaned by high efficiency particulate air filter (HEPA) vacuuming or other methods that minimize the likelihood of beryllium exposure. OSHA believes HEPA vacuuming is a highly effective method of cleaning beryllium-contaminated surfaces. However, other cleaning methods equally effective at minimizing the likelihood of beryllium exposure may be used.

Paragraph (j)(2)(ii) would permit dry sweeping or brushing in certain cases only. The employer must demonstrate that it has tried cleaning with a HEPA-filter vacuum or another method that minimizes the likelihood of exposure, and that those methods were not effective under the particular circumstances found in the workplace. OSHA has included this provision in an attempt to provide employers flexibility when exposure-minimizing cleaning methods would not be effective, but OSHA is not aware of any circumstances in which dry sweeping or brushing would be necessary. OSHA requests comment on whether dry sweeping or brushing would ever be necessary, and if so, under what circumstances (see section I of this preamble, Issues and Alternatives).

Paragraph (j)(2)(iii) would prohibit the use of compressed air in cleaning beryllium-contaminated surfaces unless it is used in conjunction with a ventilation system designed to capture any resulting airborne beryllium. This provision is also intended to prevent the dispersal of beryllium into the air.

Proposed paragraph (j)(2)(iv) details further protections for those employees who are using certain cleaning methods. Under this provision, where employees use dry sweeping, brushing, or compressed air to clean beryllium-contaminated surfaces, the employer must provide respiratory protection and protective clothing and equipment and ensure that each employee uses this protection in accordance with paragraphs (g) and (h) of this standard. The failure to provide proper and adequate protection to those employees performing cleanup activities would defeat the purpose of the housekeeping practices required to control beryllium exposure.

Paragraph (j)(2)(v) would require employers to ensure that equipment used to clean beryllium from surfaces is handled in a manner that minimizes employee exposure and the re-entrainment of beryllium into the workplace environment. For example, cleaning and maintenance of HEPA-filtered vacuum equipment must be done carefully to avoid exposure to beryllium. Similarly, filter changes and bag and waste disposal must be performed in a manner that minimizes the risk of employee exposure to airborne beryllium. This provision is consistent with the requirement in proposed paragraph (f)(1)(i)(F) for the written exposure control plan, under which employers must establish and implement procedures for minimizing the migration of beryllium. And of course, employees handling and maintaining cleaning equipment must be protected in accordance with the other paragraphs of this proposed standard as well, including the requirements for respiratory protection and PPE in paragraphs (g) and (h).

Proposed paragraph (j)(3)(i) would require that items visibly contaminated with beryllium and consigned for disposal be disposed of in sealed, impermeable bags or other closed impermeable containers. Proposed paragraph (j)(3)(ii) requires these containers to be marked with warning labels to inform individuals who handle these items of the potential hazards associated with beryllium exposure, and the labels must contain specific language in accordance with paragraph (m)(3) of the proposed standard. Alerting employers and employees who are involved in disposal to the potential hazards of beryllium exposure will better enable them to implement protective measures.

Proposed paragraph (j)(3)(iii) gives employers two options for materials designated for recycling that are visibly contaminated with beryllium: Sealing them in impermeable enclosures and labeling them in accordance with proposed paragraph (m)(3), or cleaning them to remove visible particulate. Proposed paragraph (j)(3)(iii) allows employers this flexibility to facilitate the recycling process, and ensures that employees handling these items for recycling purposes will not be exposed to visible particulate if the items are not sealed in impermeable enclosures and labeled with warnings about the dangers of beryllium exposure.

OSHA believes that the concept and importance of housekeeping programs in protecting workers from beryllium exposure are generally well understood and acknowledged by the affected employer community. Small Entity Representatives (SERs) on the SBREFA Advisory Panel indicated that most of the responding small business entities engaged in regular and routine housekeeping activities in areas where beryllium-containing material has been used or processed (OSHA, 2008b). Housekeeping activities included wet mopping, vacuuming, and sweeping in and around machinery and other surfaces. In performing these tasks, respirator and PPE usage varied. In some cases, employers provided the protection, but did not require its usage. In other instances, no protection was available to workers performing housekeeping duties. (OSHA, 2007a).

Those companies that did have comprehensive housekeeping policies provided the Agency with a number of useful practices and examples in response to the RFI as well as during the SBREFA process. One company offered its 8-step housekeeping and control strategy into the record as a comprehensive model (Brush Wellman, 2003). Another company presented its facility housekeeping program specifying a number of containment measures such as tack mats, absorbent carpet, and damp disposable towels to collect any contamination from beryllium operations. Certain practices were expressly prohibited such as dry sweeping, brushing, wiping, and the use of compressed air systems to clean machinery (Honeywell, 2003). Researchers with the National Jewish Hospital and Research Center found that most of the beryllium facilities that they visited prohibited the use of compressed air in beryllium areas (NJMRC, 2003).

Several commenters also questioned the vagueness of the term ''contaminated surfaces'' (OSHA, 2008b). The proposed standard no longer uses this term. Rather, proposed paragraph (j) would require employers to maintain surfaces in beryllium work areas ''as free as practicable of accumulations of beryllium,'' which is explained earlier in this section.

(k) Medical Surveillance

Under paragraph (k)(1) of the proposed standard, OSHA would require employers to make medical surveillance available at no cost, and at a reasonable time and place, for all employees who have worked in a regulated area for more than 30 days in the past 12 months; show signs and symptoms of CBD; are exposed to beryllium during an emergency; or were exposed to beryllium in concentrations above 0.2 $\mu g/m^3$ for more than 30 days in a 12-month period for 5 years or more.

Under paragraph (k)(1)(ii), the required medical surveillance must be performed by or under the direction of a licensed physician. OSHA chose to require licensed physicians, as opposed to PLHCPs, to oversee medical surveillance in this standard, and to provide certain services required by this standard (see, *e.g.,* paragraphs (k)(1)(ii) and (k)(5)). OSHA has in the past allowed a PLHCP to perform all aspects of medical surveillance, regardless of whether the PLHCP is a licensed physician (see OSHA's standards regulating chromium (VI) (29 CFR 1910.1026) and methylene chloride (29 CFR 1910.1052)). OSHA has proposed that a licensed physician perform some of the requirements of paragraph (k) in response to a multi-stakeholder coalition proposal to this effect. OSHA believes this requirement strikes an appropriate balance between ensuring that a licensed physician supervises the overall care of the employee, while giving the employer the flexibility to retain the services of a variety of qualified licensed health care professionals to perform certain other services required by paragraph (k). However, OSHA also believes it may be appropriate to allow a PLHCP who is not a licensed physician to perform all of the services required by proposed paragraph (k) (see also section I of this preamble, Issues and Alternatives). OSHA requests comment on this proposed requirement.

The purpose of medical surveillance for beryllium is, where reasonably possible, to identify beryllium-related adverse health effects so that appropriate intervention measures can be taken, and to determine the employee's fitness to use personal protective equipment such as respirators. The proposed standard is consistent with Section 6(b)(7) of the OSH Act (29 U.S.C. 655(b)(7)), which requires that, where appropriate, medical surveillance programs be included in OSHA health standards to aid in determining whether the health of employees is adversely affected by exposure to toxic substances. Other OSHA health standards, such as Chromium (VI) (29 CFR 1910.1026), Methylene Chloride (29 CFR 1910.1052), and Cadmium (29 CFR 1910.1027), also include medical surveillance requirements.

The proposed standard is intended to encourage participation in medical surveillance by requiring at paragraph (k)(1)(i) that the employer provide medical examinations without cost to employees (also required by section 6(b)(7) of the Act (29 U.S.C. 655(b)(7)), and at a reasonable time and place. If participation requires travel away from the worksite, the employer would be required to bear all travel costs. Employees must be paid for time away from work spent attending medical examinations, including travel time.

Paragraph (k)(1)(i)(A) proposes to require employers to make medical surveillance available to all employees who worked in a regulated area for more than 30 days in the past 12 months. This requirement attempts to ensure that those employees who are at most risk for developing beryllium-related adverse health effects have access to medical services so that such adverse health effects can be detected early.

In addition, paragraph (k)(1)(i)(B) would require that employers provide medical surveillance to any employee who shows signs or symptoms of CBD. It is expected that employees experiencing signs and symptoms of exposure will report them to their employers. If an employer becomes aware that an employee shows signs and symptoms of CBD either through employee self-reporting or from observation of the employee, the employer is required to provide medical surveillance to the employee. However, this provision is not intended to force employers to survey their workforce, make diagnoses, or determine causality.

Proposed paragraph (k)(1)(i)(B) recognizes that some employees may exhibit signs and symptoms of the adverse health effects associated with beryllium exposure even when not exposed above the TWA PEL or the STEL for more than 30 days per year. OSHA's preliminary risk assessment concludes that there is significant risk of adverse health effects from beryllium exposure below the proposed PEL (see this preamble at section VI, Preliminary Risk Assessment). In addition, beryllium sensitization and CBD could develop in employees who are especially sensitive to beryllium, may have been unknowingly exposed, or may have been exposed to greater amounts than the exposure assessment suggests.

Self-reporting by employees will be supported by the training required under proposed paragraph (m)(4)(ii) on the health hazards of beryllium exposure and the signs and symptoms of CBD, and the medical surveillance and medical removal requirements of the proposed standard in paragraphs (k) and (l). Employees have a right under section 11(c) of the OSH Act to report suspected work-related health effects to their employers without retaliation. Any employer program or practice that discourages employees from reporting or penalizes workers who report work-related health effects would violate section 11(c). See Memorandum from Richard E. Fairfax to Regional Administrators (March 12, 2012), available at *http://www.osha.gov/as/opa/whistleblowermemo.html*.

As discussed in this preamble at section V, Health Effects, CBD causes fatigue, weakness, difficulty breathing, and a persistent dry cough, among other symptoms. In more advanced cases, CBD may also result in anorexia and weight loss, as well as right side heart enlargement (cor pulmonale) and heart disease. By requiring covered employers to make a medical exam available when an employee exhibits these types of symptoms, the proposed standard would protect all employees who may have developed CBD, whether or not these employees have been exposed to beryllium in an emergency or for more than 30 days in a regulated area.

Paragraph (k)(1)(i)(C) would require that appropriate surveillance also be made available for employees exposed to beryllium during an emergency, regardless of the airborne concentrations of beryllium to which these employees are routinely exposed in the workplace. Emergency situations involve uncontrolled releases of airborne beryllium, and the significant exposures that can occur in these situations justify a requirement for medical surveillance. The proposed requirement for medical examinations after exposure in an emergency is consistent with several other OSHA health standards, including the standards for chromium (VI) (29 CFR 1910.1026), methylenedianiline (29 CFR 1910.1050), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

Paragraph (k)(1)(i)(D) would require medical surveillance to be provided to employees who have been exposed to beryllium above 0.2 μg/m³ for more than 30 days in a 12-month period for 5 years or more. The five-years of exposure would not need to be consecutive to satisfy this provision. OSHA included this provision to ensure that these employees receive the low-dose helical tomography (CT scan, low-dose computed tomography (LDCT), or CT screening) required by paragraph (k)(3)(ii)(F) of the proposed standard, even if these employees have not been exposed above 0.2 μg/m³ in the previous 12-month period, are not exhibiting signs and symptoms of CBD, and have not been exposed in an emergency. The CT scan is a method of detecting tumors, and is commonly used to diagnose lung cancer.

Paragraph (k)(2) of the proposed standard specifies how frequently medical examinations are to be offered to those employees covered by the medical surveillance program. Under paragraph (k)(2)(i)(A), employers would be required to provide each employee with a medical examination within 30 days after the employee has worked in a regulated area for more than 30 days in the past 12 months, unless the employee has received a medical examination provided in accordance with this standard within the previous 12 months. Paragraph (k)(2)(i)(B) requires employers to provide medical examinations to employees exposed to beryllium during an emergency, and to those who are showing signs or symptoms of CBD, within 30 days of the employer becoming aware that these employees meet the criteria of paragraph (k)(1)(i)(B) or (C). Paragraph (k)(2)(i)(B) requires an examination without regard to whether these employees received an exam in the previous 12 months.

Paragraph (k)(2)(ii) of the proposed standard requires that employers provide an examination annually (after the first examination is made available) to employees who continue to meet the criteria of paragraph (k)(1)(i)(A) or (B). This includes employees who have worked in a regulated area for more than 30 days in the past 12 months and employees who continue to exhibit signs and symptoms of CBD. The requirement for annual examinations in paragraph (k)(2)(ii) means that an examination must be made available at least once every 12 months.

Employees exposed in an emergency, who are covered by paragraph (k)(1)(i)(C), are not included in the annual examination requirement unless they also meet the criteria of paragraph (k)(1)(i)(A) or (B), because OSHA expects that most effects of exposure will be detected during the medical examination provided within 30 days of the emergency, pursuant to paragraph (k)(2)(i)(A). An exception to this is beryllium sensitization, which OSHA believes may result from exposure in an emergency, but may not be detected within 30 days of the emergency. Thus, proposed paragraph (k)(3)(ii)(E) requires biennial testing for beryllium sensitization for employees exposed in emergencies. This paragraph is discussed in more detail later in this section of the preamble. Employees covered by paragraph (k)(1)(i)(D) are also not required to receive exams annually unless they also meet the criteria of paragraph (k)(1)(i)(A) or (B).

OSHA believes that the annual provision of medical surveillance, and the biennial provision of beryllium sensitization testing and CT scans for certain employees, are appropriate frequencies for screening employees for beryllium-related diseases. The main goals of medical surveillance for employees are to detect beryllium sensitization before employees develop CBD, and to detect CBD, lung cancer, and other adverse health effects at an early stage. The proposed requirement for annual examinations is consistent with other OSHA health standards, including those for chromium (VI) (29 CFR 1910.1026) and formaldehyde (29 CFR 1910.1048). Based on the Agency's experience, OSHA believes that annual surveillance and biennial tests for beryllium sensitization and CT scans would strike a reasonable balance between the need to diagnose health effects at an early stage, while being sufficiently affordable for employers.

Finally, proposed paragraph (k)(2)(iii) would require the employer to offer a medical examination at the termination of employment, if the departing employee meets the criteria of paragraph (k)(1)(i)(A), (B), or (C) at the time the employee's employment is terminated. This would apply to employees who worked in a regulated area for more than 30 days during the previous 12 months, employees showing signs or symptoms of CBD, and employees who were exposed to beryllium in an emergency at any time during their employment. This proposed requirement is waived if the employer provided the departing employee with an exam during the six months prior to the date of termination. The provision of an exam at termination is intended to ensure that no employee terminates employment while carrying a detectable, but undiagnosed, health condition related to beryllium exposure.

Proposed paragraph (k)(3) details the contents of the examination. Paragraph (k)(3)(i) would require the employer to ensure that the PLHCP advises the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination. Benefits of participating in medical surveillance may include early detection of adverse health effects, and aiding intervention efforts to prevent or treat disease. However, there may also be risks associated with medical testing for some conditions, which the PLHCP should communicate to the employee.

Paragraph (k)(3)(ii) then specifies that the medical examination must consist of a medical and work history; a physical examination with emphasis on the respiratory tract, skin breaks, and wounds; and pulmonary function tests.

Special emphasis is placed on the portions of the medical and work history focusing on beryllium exposure, health effects associated with beryllium exposure, and smoking.

The physical exam focuses on organs and systems known to be susceptible to beryllium toxicity. For example, proposed paragraph (k)(3)(ii)(C) focuses on the skin, and paragraph (k)(3)(ii)(D) focuses on the lungs. The information obtained will allow the PLHCP and supervising physician to assess the employee's health status, identify adverse health effects related to beryllium exposure, and determine if limitations should be placed on the employee's exposure to beryllium. The proposed standard does not include a comprehensive list of specific tests that must be part of the medical examination. OSHA does not believe that any particular test—beyond those listed in paragraph (k)(3)(ii)(D)–(F)—is necessarily applicable to all employees covered by the medical surveillance requirements. The Agency proposes to give the PLCHP the flexibility to determine any other appropriate tests to be selected for a given employee, as provided in paragraph (k)(3)(ii)(G).

Under paragraph (k)(3)(ii)(E), an employee must be offered a BeLPT (or a more reliable and accurate test for identifying beryllium sensitization) at the employee's first examination, and then every two years after the first examination unless the employee is confirmed positive. The requirement to test for beryllium sensitization applies whether or not an employee is otherwise entitled to a medical examination in a given year. For example, for an employee exposed during an emergency who would normally be entitled to 1 exam within 30 days of the emergency but not annual exams thereafter, the employer must still provide this employee with a test for beryllium sensitization every 2 years. This biennial requirement applies until the employee is confirmed positive. OSHA believes that the biennial testing required under paragraph (k)(3)(ii)(E) is adequate to monitor employees that have the potential to develop sensitization while being sufficiently affordable for employers.

OSHA considers the BeLPT to be a reliable medical surveillance tool for the purposes of a medical surveillance program. However, OSHA considers two abnormal test results necessary to confirm a finding of beryllium sensitization when using the BeLPT (''confirmed positive''). Therefore, a BeLPT must also be offered within one month of an employee receiving a single abnormal result. However, this requirement is waived if a more reliable and accurate test becomes available that could confirm beryllium sensitization based on one test result. OSHA requests comment on how to determine whether a test is more reliable and accurate than the BeLPT for identifying beryllium sensitization. OSHA has included a non-mandatory appendix that describes the BeLPT, discusses several studies of the BeLPT's validity and reliability, and states criteria OSHA believes are important to judge a new test's validity and reliability (Appendix A).

Under paragraph (k)(3)(ii)(F), a CT scan must be offered to employees who have been exposed to beryllium at concentrations above 0.2 μg/m^3 for more than 30 days in a 12-month period for 5 years or more. The five years of exposure do not need to be consecutive. As with the requirement for sensitization testing explained above, the CT scan must be offered to an employee who meets the criteria of paragraph (k)(1)(i)(D) without regard to whether the employee is otherwise required to receive a medical exam in a given year. The CT scan must be offered to employees who meet the criteria of paragraph (k)(1)(i)(D) for the first time beginning on the start-up date of this standard, or 15 years after the employee's first exposure to beryllium above 0.2 μg/m^3 for more than 30 days in a 12-month period, whichever is later. OSHA proposed the requirement for CT screening based in part on the Agency's consideration of the draft recommended standard submitted by industry and union stakeholders (Materion and USW, 2012).

The CT scan requirement may be triggered by exposures that occurred before or after the effective date of this standard, or a combination of exposures before and after the effective date. This requirement may also be triggered by exposures that occurred when the employee was working for a different employer. An employer is required to offer a CT scan to employees who meet the criteria of paragraph (k)(1)(i)(D) if the employer has exposure records demonstrating that the employee meets the criteria, regardless of whether the exposure records were generated by the employer or given to the employer by the employee or a third party.

In a recent systematic review of CT screening trials for lung cancer, Bach *et al.* found a significant (20 percent) mortality reduction in the population studied (26,309 men and women between ages 55 and 74, with at least 30 pack-years of smoking history) (National Lung Screening Trial, 2011). The benefits of screening for other populations are less clear at this time. CT screening was not shown to offer significant reduction in mortality in two other, smaller trial populations with at least 20 pack-years of smoking history (DANTE, 2009; DLCST, 2012). In addition, there is yet to be agreement on how to properly compute and set the radiation dose for LDCT. Clarification on such procedural issues will help inform analyses of LDCT-associated radiation exposure and its risks as part of a screening protocol for employees exposed to occupational carcinogens (Christensen, 2014).

OSHA seeks comment on the proposed requirement and whether it is likely to benefit the beryllium-exposed employee population. As appropriate, please submit information, studies and data to support your comments.

OSHA notes that another form of CT scanning, High Resolution Computed Tomography (HRCT), is available and may be useful in screening for CBD. In patients with CBD, HRCT scanning of the chest is more sensitive than plain chest radiography in identifying abnormalities (NAS, 2008). However, HRCT scans showing no signs consistent with CBD have been reported in 25 percent of patients with biopsy-proven noncaseating granulomas (Newman *et al.,* 1994). OSHA seeks comment on whether HRCT should be included in the list of diagnostic procedures a CBD Diagnostic Center should be able to provide (see this Preamble at Section XVIII, paragraph (b), Definitions).

Other types of tests and examinations not mentioned in this standard, including X-ray, arterial blood gas, diffusing capacity, and oxygen desaturation during exercise, may also be useful in evaluating the effects of beryllium exposure. In addition, medical examinations that include more invasive testing, such as bronchoscopy, alveolar lavage, and transbronchial biopsy, have been demonstrated to provide additional valuable medical information. OSHA believes that the PLHCP is in the best position to decide which medical tests are necessary for each individual examined. Where specific tests are deemed appropriate by the PLHCP, the proposed standard, at paragraph (k)(3)(ii)(G), would require that they be provided.

Proposed paragraph (k)(4) details which information must be provided to the PHLCP. Specifically, the proposed standard would require the employer to ensure the examining PLHCP has a copy of the standard and all the appendices, and to provide to the examining PLHCP the following information, if known or reasonably available to the employer: a description of the employee's former and current duties as they relate to beryllium exposure ((k)(4)(i)); the employee's former and current exposure levels ((k)(4)(ii)); a description of any personal protective clothing and equipment, including respirators, used or to be used by the employee, including when and for how long the employee has used that clothing and equipment ((k)(4)(iii)); and information the employer has obtained from previous medical examinations provided to the employee, that is currently within the employer's control ((k)(4)(iv)). OSHA believes making this information available to the PLHCP will aid in the PLHCP's evaluation of the employee's health as it relates to the employee's assigned duties and fitness to use personal protective equipment, including respirators, when necessary. In order to protect the employee's privacy, employee medical information may only be provided to the PLHCP by the employer after the employee has signed a medical release.

Providing the PLHCP with exposure monitoring results, as required under paragraph (k)(4)(ii), will assist the physician completing the written medical opinion in determining if an employee is likely to be at risk of adverse effects from beryllium exposure at work. A well-documented exposure history would also assist the PLCHP in determining if a condition (*e.g.,* dermatitis, decrease in diffusing capacity, or gradual changes in arterial blood gases) may be related to beryllium exposure. See this preamble at section V, Health Effects, for a more detailed discussion of the health effects associated with beryllium exposure.

Proposed paragraph (k)(5) would require employers to obtain a written medical opinion from the licensed physician who performed or directed the exam within 30 days of the examination. The purpose of requiring the physician to supply a written opinion to the employer is to provide the employer with a documented medical basis for the employee's eligibility for medical removal, and to assess the employee's ability to use protective clothing and equipment, including respirators. In addition, provision of the written opinion to the employer may alert the employer to sources of beryllium exposure or problems with exposure controls at its worksite. OSHA believes the 30-day period will allow the licensed physician sufficient time to receive and consider the results of any tests included in the examination, and allow the employer to take any necessary protective measures in a timely manner. The proposed requirement that the opinion be in written form is intended to ensure that employers and employees have the benefit of the same information and that no information gets lost in oral communications. OSHA requests comment on the relative merits of the proposed standard's requirement that employers obtain the PLHCP's written opinion or an alternative that would provide employees with greater discretion over the information that goes to employers (see this preamble at Section 1, Issues and Alternatives, Issue #26).

Paragraphs (k)(5)(i)(A)–(C) of the proposed standard specify what must be included in the licensed physician's written opinion. The first item for inclusion is the licensed physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of CBD from further exposure. The standard also proposes that the medical opinion include any recommended limitations on the employee's exposure, including recommended use of, and limitations on the use of, personal protective clothing or equipment such as respirators.

The licensed physician would also need to state in the written opinion that the PLHCP has explained the results of the medical examination to the employee, including the results of any tests conducted, any medical conditions related to exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment, including respirators. Under proposed paragraph (k)(5)(i)(C), OSHA anticipates that the employee will be informed directly by the PLCHP of all results of his or her medical examination, including conditions of non-occupational origin. Direct consultation between the PLHCP and employee ensures that the employee will receive all information about the employee's health status, including non-occupationally related conditions that are not communicated to the employer.

Proposed paragraph (k)(5)(ii) would require the employer to ensure that neither the licensed physician nor any other PLHCP reveals to the employer findings or diagnoses which are unrelated to beryllium exposure. OSHA has proposed this provision to reassure employees participating in medical surveillance that they will not be penalized or embarrassed as a result of the employer obtaining information about them not directly pertinent to beryllium exposure. Paragraph (k)(5)(iii) would also require the employer to provide a copy of the licensed physician's written opinion to the employee within two weeks after receiving it to ensure that the employee has been informed of the results of the examination in a timely manner.

Proposed paragraph (k)(6)(i) provides for the referral to a CBD diagnostic center of any employee who is confirmed positive for beryllium sensitization. Within 30 days after the employer learns of the confirmed positive result, the employer must ensure that a licensed physician designated by the employer consults with the employee about referral to a CBD diagnostic center for further testing, to determine whether a sensitized employee has CBD. If the employee chooses to obtain a clinical evaluation at a CBD diagnostic center, the diagnostic center must be agreed upon by the employer and the employee. The employer and employee must make a good faith effort to agree on a CBD diagnostic center that is acceptable to them both. Under paragraph (k)(6)(ii), the employer is responsible for all costs associated with testing performed at the center. The term CBD diagnostic center is defined in proposed paragraph (b), and discussed in this section of the preamble regarding proposed paragraph (b).

Finally, under paragraph (k)(7), the employer would be required to convey the results of the medical tests to OSHA for evaluation and analysis at the request of the Assistant Secretary. The results of the tests may be used to evaluate the nature, variability, reliability, and relevance of the beryllium sensitization test results, to evaluate the effectiveness of the beryllium standard in reducing beryllium-related occupational disease, or for other scientific purposes. Results conveyed to OSHA must first be stripped of employees' names, social security numbers, and other identifying information.

Employees of beryllium vendors who qualify for benefits under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) (42 U.S.C. 7384–7385s–15) and its implementing regulations (20 CFR part 30) may also qualify for medical surveillance benefits under this proposed standard. Covered medical surveillance provided to eligible persons under the EEOICPA program is paid for by the federal government.

Employees covered by both the EEOICPA program and this proposed standard would not be required to attend separate medical examinations for the separate programs. Rather, these dual-coverage employees could attend consolidated medical examinations at which they would receive the services required under both programs. These examinations would be paid for by the federal government under the EEOICPA program to the extent that the services provided are covered under the EEOICPA program. If this proposed standard requires services that are not covered by the EEOICPA program, the employer would be required to pay for these additional services.

As stated in the SBREFA Report, the medical surveillance section ''was the most controversial part of the draft standard for most SERs and received the most comment'' (OSHA, 2008b). SERs generally were concerned about the cost of medical surveillance, commenting that surveillance is unnecessary for employees with low beryllium exposures (OSHA, 2008b). The requirement of dermal triggers for medical surveillance was confusing for SERs and led to a number of comments (OSHA, 2008b). One SER suggested that the medical surveillance requirements should be performance-based, which would allow employers to determine which tests were appropriate for their employees (OSHA, 2008b). Use of the BeLPT was also controversial, given SERs' concerns about its accuracy and costs (OSHA, 2008b). OSHA requests comment on the proposed requirements for beryllium sensitization testing, including issues raised in this preamble at section I, Issues and Alternatives, and on the regulatory alternatives presented later in this section.

In response to these concerns, OSHA notes several changes made to the regulatory text since the SBREFA panel was convened. In the proposed standard, medical surveillance is limited to those employees who have worked in a regulated area for more than 30 days per year in the previous 12-month period, employees showing signs and symptoms of CBD, employees exposed during emergencies, and employees who have been exposed above 0.2 $\mu g/m^3$ for more than 30 days in a 12-month period for five years or more. Requiring medical surveillance for employees with exposures in a regulated area (*i.e.,* with exposures above the TWA PEL or STEL for more than 30 days in a year) should alleviate some SERs' concerns that surveillance is not necessary for employees with low exposures. Employees with exposures at or above the action level but below the PEL are no longer included in medical surveillance, unless they show signs or symptoms of CBD or were exposed during an emergency. Since the SBREFA panel was held, OSHA has also removed the requirement for medical surveillance based only on dermal exposure to beryllium, eliminating the confusion caused by the dermal exposure provision.

These changes will result in fewer employees being eligible for medical surveillance than were covered in the draft standard presented to the SBREFA panel. The changes will thereby reduce costs to employers. However, OSHA has preliminarily determined that a significant risk of beryllium sensitization, CBD, and lung cancer exist at exposure levels below the proposed PEL, and there is evidence that beryllium sensitization can occur from short-term exposures (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk). The Agency therefore anticipates that some employees will develop adverse health effects and may not receive the benefits of early intervention in the disease process because they are not eligible for medical surveillance (see this preamble at Section V, Health Effects). Thus, OSHA is considering three regulatory alternatives that would expand eligibility for medical surveillance to a broader group of employees than those eligible in the proposed standard. Under Regulatory Alternative #14, medical surveillance would be available to employees who are exposed to beryllium above the proposed PEL, including employees exposed for fewer than 30 days per year. Regulatory Alternative #15 would expand eligibility for medical surveillance to employees who are exposed to beryllium above the proposed action level, including employees exposed for fewer than 30 days per year. Regulatory Alternative #21 would extend eligibility for medical surveillance as set forth in proposed paragraph (k) to all employees in shipyards, construction, and general industry who meet the criteria of proposed paragraph (k)(1). However, all other provisions of the standard would be in effect only for employers and employees that fall within the scope of the proposed rule. Most of these alternatives would provide surveillance to fewer employees (and cost less to employers) than the draft regulation presented to the SBREFA Panel, but would provide more surveillance (and cost more to employers) than the medical surveillance requirements in the current proposal.

The SER who suggested allowing performance-based surveillance stated that this would permit employers ''to design and determine what tests were appropriate'' (OSHA, 2008b). OSHA is considering two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. Regulatory Alternative #18 would eliminate the CT scan requirement from the proposed rule.

OSHA is evaluating these alternatives and has also included some performance-based elements in its medical surveillance requirements (*e.g.,* (k)(3)(G)). However, the Agency has preliminarily determined that the testing required by the proposed standard is necessary and appropriate for the employees who must be offered medical surveillance. OSHA believes it is important to detect cases of sensitization, CBD and other beryllium-related health effects early so that employees can quickly be removed from exposure, be provided appropriate protective clothing and equipment, benefit from medical removal, and receive treatment, as applicable. As discussed in this preamble at section VIII, Significance of Risk, early intervention in the disease process may slow or prevent progression to more advanced disease. Further, this surveillance is particularly necessary in a standard such as this one, where OSHA has preliminarily found a significant risk of material impairment of health at the proposed PEL. OSHA requests comments on the proposed requirements for sensitization testing, CT scans, and medical examinations, and on Regulatory Alternatives #14 and #15 discussed above.

Finally, at least one SER commented that providing annual BeLPTs would result in high costs with no added benefit to employees (OSHA, 2008b). As discussed previously, OSHA would also allow substitution of a more accurate and reliable test for the BeLPT should such a test become available. When this occurs, employers can choose to use whichever test is less expensive. OSHA has also, in its proposed standard, reduced the frequency of required BeLPTs (or other test substituted for the BeLPT) to every two years, with follow-up tests for employees who receive abnormal test results. This change would significantly reduce the cost of testing, but would also delay early detection of beryllium-related health effects and intervention to prevent disease progression among employees in medical surveillance. In addition, the longer the time interval between when an employee becomes sensitized and when the employee's case is identified in the surveillance program, the more difficult it will be to identify and address the exposure conditions that led to the employee's sensitization. Therefore, lengthening the time between sensitization tests will diminish the usefulness of the surveillance information in identifying and correcting problem areas and reducing risks to other employees.

The benefits of regular medical surveillance for beryllium-related health effects and the costs of surveillance to employers are important and complex factors in the proposed standard, and OSHA requests feedback from the regulated and medical communities to help determine the most appropriate schedule for periodic testing. In particular, the Agency requests comments on several alternatives to the proposed frequency of sensitization testing, CT scans, and general medical examinations. Regulatory alternative #17 would require employers to offer annual testing for beryllium sensitization to eligible employees, as in the draft proposal presented to the SBREFA panel. Regulatory Alternative #19 would similarly increase the frequency of periodic CT scans from biennial to annual scans. Finally, under Regulatory Alternative #20, all periodic components of the medical surveillance exams would be available biennially to eligible employees. Instead of requiring employers to offer eligible employees a medical examination every year, employers would be required to offer eligible employees a medical examination every other year. The frequency of testing for beryllium sensitization and CT scans would also be biennial for eligible employees, as in the proposed standard. For all comments on the medical surveillance provisions of the proposed standard, please provide an explanation of your position, and supporting data or studies as appropriate.

(l) Medical Removal Protection

Paragraph (l) of the proposed rule contains the provisions related to medical removal protection (MRP). Proposed paragraph (l)(1) explains that employees in jobs with exposure at or above the action level become eligible for medical removal when they are diagnosed with CBD or confirmed positive for beryllium sensitization. These medical findings may be made pursuant to the surveillance requirements of proposed paragraph (k). The terms ''CBD'' and ''confirmed positive'' are defined in proposed paragraph (b).

Proposed paragraph (l)(1) is in keeping with OSHA's provisions for MRP in past standards, where the Agency has specified objective removal criteria. For example, the Lead standard (29 CFR 1910.1025) requires that an employee be removed from exposure at or above the action level when an employee's blood lead concentration exceeds a certain value. Similarly, the Cadmium standard (29 CFR 1910.1027) includes objective biological monitoring criteria that trigger removal.

Paragraph (l)(2) lays out the options for employees who are eligible for MRP. Specifically, paragraph (l)(2)(i) would permit eligible employees to choose removal as described under proposed paragraph (l)(3), and proposed paragraph (l)(2)(ii) would permit them to remain in a job with exposure at or above the action level and wear a respirator in accordance with the Respiratory Protection standard (29 CFR 1910.134). Eligible employees must choose one of these two options. OSHA requests comment on whether the standard should establish a timeframe in which eligible employees must choose one of the options in paragraph (l)(3) (such as within 7 days, 14 days, or 30 days), and whether the standard should require the employee to wear a respirator if the employee fails to choose one of the options within the specified timeframe.

Proposed paragraph (l)(3) describes eligible employees' removal options. When an employee chooses removal, the employer is required to remove the employee to comparable work if such work is available. Comparable work is a position for which the employee is already qualified or can be trained within one month, in an environment where beryllium exposure is below the action level. Comparable work would not require the employee to use a respirator, although the employee may choose to use a respirator to minimize beryllium exposure. An employer is not required to place an employee on paid leave if the employee refuses comparable work offered under paragraph (l)(3)(i). An employee must be transferred to comparable work, trained for comparable work, or placed on paid leave immediately after choosing removal.

If comparable work is not immediately available, paragraph (l)(3)(ii) would require the employer to place the employee on paid leave for six months or until comparable work becomes available, whichever occurs first. If comparable work becomes available before the end of the six month paid leave period, the employer is obligated to offer the open position to the employee. Should the employee decline, the employer has no further obligation to continue the paid leave.

Proposed paragraph (l)(3)(iii) would continue a removed employee's rights and benefits for six months, regardless of whether the employee is removed to comparable work or placed on paid leave. The six month period would begin when the employee is removed, which means either the day the employer transfers the employee to comparable work, or the day the employer places the employee on paid leave. For this period, the provision would require the employer to maintain the employee's base earnings, seniority, and other rights and benefits of employment as they existed at the time of removal. This provision is typical of medical removal provisions in other OSHA standards, such as Cadmium (29 CFR 1910.1027) and Benzene (29 CFR 1910.1028).

Paragraph (l)(4) would reduce an employer's obligation to provide MRP benefits to a removed employee if, and to the extent that, the employee receives compensation from a publicly or employer-funded compensation program for earnings lost during the removal period, or receives income from another employer made possible by virtue of the employee's removal. Benefits received under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) do not constitute wage replacement, and therefore would not offset the employee's medical removal benefits under this proposed standard.

By protecting an employee's rights and benefits during the first six months of removal, and by reducing in certain circumstances an employer's obligation to compensate employees for earnings lost, OSHA emphasizes that MRP is not intended to serve as a workers' compensation system. The primary reason MRP has been included in this standard is to provide eligible employees a six-month period to adjust to the comparable work arrangement or seek alternative employment, without any further exposure at or above the action level.

The prospect of a medical removal provision concerned some SERS. Some stated that there is no evidence that removing sensitized employees will change their health outcomes (OSHA 2008b). Others commented that they did not believe medical removal was appropriate because neither sensitization nor CBD is reversible (OSHA 2008b).

OSHA believes that medical removal is an important means of protecting employees who have become sensitized or developed CBD, and is an appropriate means to enable them to avoid further exposure. The scientific information on effects of exposure cessation is limited at this time, but the available evidence suggests that removal from exposure can be beneficial for individuals who are sensitized or have early-stage CBD (see this preamble at section VIII, Significance of Risk). As discussed in the Health Effects section of this preamble, section V, only those who are sensitized can develop CBD. As CBD progresses, symptoms become serious and debilitating. Steroid treatment is less effective at later stages, once fibrosis has developed (see this preamble at section VIII, Significance of Risk). Given the progressive nature of the disease, OSHA believes it is reasonable to conclude that removal from exposure to beryllium will benefit sensitized employees and those with CBD.

There is widespread support for removal of individuals with sensitization or CBD from further beryllium exposure in the medical community and among other experts in beryllium disease prevention and treatment. Physicians at National Jewish, one of the main CBD research and treatment sites in the US, ''consider it important and prudent for individuals with beryllium sensitization and CBD to minimize their exposure to airborne beryllium,'' and ''recommend individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry to have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour time-weighted average'' (National Jewish site on Chronic Beryllium Disease: Work Environment Management, accessed May 2013). The Department of Energy included MRP in its Chronic Beryllium Disease Prevention Program (10 CFR part 850), stating that without MRP, employers would be ''free to maintain high-risk workers in their current jobs, which would not be sufficiently protective of their health'' (64 FR 68894, December 8, 1999). MRP is included in the recommended beryllium standard that beryllium industry and union stakeholders submitted to OSHA in 2012 (Materion and United Steelworkers, 2012).

OSHA believes that MRP also improves the medical surveillance program described in proposed paragraph (k). Paragraph (k)(1)(i)(B) requires medical examinations for employees showing signs or symptoms of CBD. The success of that program will depend in part on employees' willingness to report their symptoms, submit to examinations, respond to questions, and comply with instructions. Guaranteeing paid leave or comparable work can help allay an employee's fear that a CBD diagnosis will negatively affect earnings or career prospects. MRP encourages employees to report their symptoms and seek treatment, as OSHA has previously recognized when including medical removal in regulations governing the exposure to lead (43 FR 52973, November 14, 1978), benzene (52 FR 34557, September 11, 1987), and cadmium (57 FR 42367–68, September 14, 1992). This reasoning was also cited by the Department of Energy in support of the medical removal provisions of its Chronic Beryllium Disease Prevention Program, stating that the availability of medical removal benefits encourages worker participation and cooperation in medical surveillance (64 FR 68893, December 8, 1999).

MRP also provides an incentive for employers to keep employee exposures low. The risk of developing CBD or beryllium sensitization decreases at lower exposures (see this preamble at section VI, Preliminary Risk Assessment), meaning that employers can improve their chances of avoiding MRP costs by lowering employee exposure levels. OSHA previously noted this incentive when describing MRP provisions in the Lead standard (43 FR 52973, November 14, 1978) and the Cadmium standard (57 FR 42368, September 14, 1992).

Finally, OSHA's preliminary risk assessment indicates that significant risk remains at the proposed TWA PEL (see this preamble at section VI, Preliminary Risk Assessment). MRP offers additional protection for situations in which workers develop CBD or beryllium sensitization despite exposures at or below the PEL. As discussed above regarding the definition of ''action level'' in paragraph (b), if OSHA finds a continuing exposure risk at the PEL, it has the authority to impose additional feasible requirements on employers to further reduce risk when those requirements will result in a greater than minimal incremental benefit to workers' health (*Asbestos II,* 838 F.2d at 1274).

During the SBREFA process, SERs commented that small entities may lack the flexibility and resources to provide comparable positions for MRP-eligible employees (OSHA 2008b). The SBREFA Panel recommended that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (OSHA, 2008b). In response to this recommendation, the Agency has provided flexibility in how employers may comply with MRP requirements. Where employers have no comparable positions in environments with exposures below the action level, the proposed standard permits an employer to place eligible employees on paid leave for six months, or until comparable work becomes available. Under proposed paragraph (l)(4), if an employee is placed on paid leave and receives government or employer-provided compensation, or such paid leave allows the employee to secure other work, the original employer's compensation obligations would be offset. Also in response to the Panel's recommendations, OSHA analyzed Regulatory Alternative #22, which would eliminate the proposed requirement to offer MRP to employees with beryllium sensitization or CBD.

Finally, OSHA notes that there is considerable scientific uncertainty about the effects of exposure cessation on the development of CBD among sensitized individuals and the progression from early-stage to late-stage CBD. Members of the medical community support removal from beryllium exposure as a prudent step in the management of beryllium sensitization and disease. For example, physicians at National Jewish Medical Center, a leading organization in CBD research and treatment, recommend individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry to have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour TWA (*http://www.nationaljewish.org/healthinfo/conditions/beryllium-disease/environment-management/*). However, the scientific literature on the effects of exposure cessation is limited. It suggests that removal from exposure can have beneficial effects for some individuals, but provides no conclusive evidence on whether exposure cessation will prevent CBD or CBD progression for most people (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk).

OSHA proposes to include MRP in the beryllium standard, providing workers with sensitization or CBD the opportunity and means to minimize their further exposure to beryllium via MRP in keeping with the recommendation of beryllium specialists in the medical community and with the draft recommended standard provided by union and industry stakeholders (Materion and Steelworkers, 2012).

OSHA solicits comments on the health effects of MRP and the proposed provisions for MRP. Is MRP an appropriate means of intervention in the disease process for workers with beryllium sensitization or CBD? Do the proposed MRP provisions appropriately balance SBREFA commenters' concerns with the need to reduce beryllium exposure for employees with sensitization or CBD? Please comment on whether MRP should be included in the standard (Regulatory Alternative #22). Please explain your positions on these issues and provide any relevant data or studies.

(m) Communication of Hazards to Employees

Paragraph (m) of this proposal sets forth the employer's obligations to comply with OSHA's Hazard Communication standard (HCS)(29 CFR 1910.1200), and to take additional steps to warn and train employees about the hazards of beryllium.

Paragraph (m)(1)(i) of this proposal requires chemical manufacturers, importers, distributors, and employers to comply with all applicable requirements of the HCS for beryllium. As described in this preamble at section V, Health Effects, and section VI, Preliminary Beryllium Risk Assessment, OSHA considers beryllium a hazardous chemical.

In classifying the hazards of beryllium, the employer must address at least the following: Cancer; lung effects (chronic beryllium disease and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation (paragraph (m)(1)(ii)). According to the HCS, employers must classify hazards if they do not rely on the classifications of chemical manufacturers, importers, and distributors (see 29 CFR 1910.1200(d)(1)).

Paragraph (m)(1)(iii) requires that employers include beryllium in the hazard communication program established to comply with the HCS, and ensure that each employee has access to labels on containers and safety data sheets for beryllium and is trained in accordance with the HCS and paragraph (m)(4) of this proposal.

According to paragraph (e)(1)(ii) of this proposal, employers must establish and maintain regulated areas wherever employees are or can reasonably be expected to be exposed to beryllium at levels above the TWA PEL or STEL, and each employee entering a regulated area must wear a respirator and protective clothing and equipment in accordance with paragraphs (g) and (h) of this standard. Under paragraph (m)(2) of this proposal, employers must provide and display warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area. Employers must ensure that warning signs required by paragraph (m)(2) are legible and readily visible, and that they bear the following legend:

Danger; Beryllium; May Cause Cancer; Causes Damage to Lungs; Authorized Personnel Only; Wear respiratory protection and protective clothing and equipment in this area.

Some SERs objected to having cancer warnings displayed on the legends for warning signs and labels. They expressed the opinion that cancer warnings would unnecessarily scare customers and employees. Further, they alleged evidence for beryllium causation of cancer was not sufficient (OSHA, 2008b). OSHA disagrees with these comments. OSHA has thoroughly reviewed the literature for beryllium carcinogenicity, and has preliminarily concluded that beryllium is carcinogenic. OSHA's finding that inhaled beryllium causes lung cancer is based on the best available epidemiological data, reflects evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations (see this preamble at section V, Health Effects). For example, the International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), and American Conference of Governmental Industrial Hygienists (ACGIH) have all classified beryllium as a known human carcinogen (IARC, 2009). OSHA believes that the weight of evidence is sufficient to support the requirement for cancer warnings on signs and labels.

The signs required by paragraph (m)(2) of this proposal are intended to serve as a warning to employees and others who may not be aware that they are entering a regulated area, and to remind them of the hazards of beryllium so that they take necessary protective steps before entering the area. These signs are also intended to supplement the training that employees must receive regarding the hazards of beryllium, since even trained employees need to be reminded of the locations of regulated areas and of the precautions necessary before entering these dangerous areas (see paragraph (m)(4) of this proposal and 29 CFR 1910.1200(h) for training requirements).

The use of warning signs is important to make employees who are regularly scheduled to work at these sites aware of beryllium hazards, to alert employees who have limited access to these sites of beryllium hazards, and to warn those who do not have access to regulated areas to avoid the area. Access must be limited to authorized personnel to ensure that those entering the area are adequately trained and equipped, and to limit exposure to those whose presence is absolutely necessary. By limiting access to authorized persons, employers can minimize employee exposure to beryllium in regulated areas and thereby minimize the number of employees that may require medical surveillance or be subject to the other requirements in this proposal associated with working in a regulated area.

Paragraph (m)(2) specifies the wording of the warning signs for regulated areas in order to ensure that the proper warning is consistently given to employees, and to notify employees that respirators and personal protective clothing and equipment are required in the regulated area. OSHA believes that the use of the word ''Danger'' is appropriate, based on the evidence of the toxicity of beryllium. ''Danger'' is used to attract the attention of employees to alert them to the fact that they are entering an area where the TWA PEL or STEL may be exceeded, and to emphasize the importance of the message that follows. The use of the word ''Danger'' is also consistent with other OSHA health standards dealing with toxins such as cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), asbestos (29 CFR 1910.1001), and benzene (29 CFR 1910.1028). In addition, use of the word ''Danger'' for this chemical is consistent with the Globally Harmonized System of Classification and Labeling of Chemical guidelines (GHS) (77 FR 17740–48, March 26, 2012). In the **Federal Register** notice for the revised HCS, which incorporates the GHS, OSHA explains that for substance-specific standards, warning signs must be as consistent as possible with label information for that substance (*Id.*).

Paragraph (m)(3) requires that labels be affixed to all bags and containers of clothing, equipment, and materials visibly contaminated with beryllium. The term ''materials'' includes waste, scrap, debris, and any other items visibly contaminated with beryllium that are consigned for disposal or recycling (see paragraphs (h)(2)(iv) and (v) and (j)(3)(i) through (iii)). The labels must state:

Danger; Contains Beryllium; May Cause Cancer; Causes Damage to Lungs; Avoid Creating Dust; Do Not Get on Skin.

The purpose of this labeling requirement is to ensure that all affected employees, not only the employees of a particular employer, are apprised of the presence of beryllium-containing materials and the hazardous nature of beryllium exposure. With this knowledge, employees can take steps to protect themselves through proper work practices established by their employers. Employees are also better able to alert their employers if they believe exposures or skin contamination can occur.

As discussed previously, these labeling requirements are consistent with the HCS, which requires classification of hazardous chemicals and labeling appropriate for the classification (see 77 FR 17740–48, March 26, 2012). In addition, these requirements for labeling are consistent with the mandate of section (6)(b)(7) of the OSH Act, which requires that OSHA health standards prescribe the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed.

Paragraph (m)(4) contains requirements for employee information and training, and applies to all employees who are or can reasonably be expected to be exposed to airborne beryllium. Employers must ensure that employees receive information and training in accordance with the requirements of the HCS (29 CFR 1910.1200(h)), including specific information on beryllium as well as any other hazards addressed in the workplace hazard communication program. Under the HCS, employers must provide their employees with information such as the location and availability of the written hazard communication program, including lists of hazardous chemicals and safety data sheets, and the location of operations in their work areas where hazardous chemicals are present. The HCS also requires employers to train their employees on ways to detect the presence or release of hazardous chemicals in the work area such as any monitoring conducted, the physical and health hazards of the chemicals in the work area, measures employees can take to protect themselves, and the details of the employer's hazard communication program (29 CFR 1910.1200(h)(3)).

Under paragraph (m)(4)(i)(B), training must be provided to each employee by the time of initial assignment, which means before the employee's first day of work in a job that could reasonably be expected to involve exposure to airborne beryllium. This training must be repeated at least annually thereafter ((m)(4)(i)(C)). OSHA believes that annual retraining is necessary due to the hazards of beryllium exposure, and for reinforcement of employees' knowledge of those hazards. The annual training requirement is consistent with other OSHA standards such as those for lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), benzene (29 CFR 1910.1028), coke oven emissions (29 CFR 1910.1029), cotton dust (29 CFR 1910.1043), and butadiene (29 CFR 1910.1051).

Paragraph (m)(4)(ii) requires the employer to ensure that each employee who is or can reasonably be expected to be exposed to airborne beryllium can demonstrate knowledge of nine enumerated categories of information (see paragraph (m)(4)(ii)(A)—(I)). Providing information and training on these topics is essential to informing employees of current hazards and explaining how to minimize potential health hazards associated with beryllium exposure. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and safety data sheets. These written forms of communication will be most effective when employees understand the information presented and are aware of how to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects. Training should lead to better work practices and hazard avoidance.

The training requirements in paragraph (m)(4)(ii) are performance-oriented. This paragraph lists the topics that training must address, but does not prescribe specific training methods. OSHA believes that the employer is in the best position to determine how to conduct training that imparts knowledge and promotes retention. Appropriate training may include video, DVD or slide presentations; classroom instruction; hands-on training; informal discussions during safety meetings; written materials; or a combination of these methods. This performance-oriented approach is intended to encourage employers to tailor training to the needs of their workplaces, thereby resulting in the most effective training program in each individual workplace.

For training to be effective, the employer must ensure that it is provided in a manner that each employee is able to understand. OSHA recognizes that employees have varying education levels, literacy levels, and language skills, and is requiring that they receive training in a language and at a level of complexity that accounts for these differences. This may require, for example, providing materials, instruction, or assistance in Spanish rather than English if the employees being trained are Spanish-speaking and do not understand English well. The employer would not be required to provide training in the employee's preferred language if the employee understands both languages; as long as the employee is able to understand the language used, the intent of the proposed standard would be met.

To ensure that employees comprehend the material presented during training, it is critical that trainees have the opportunity to ask questions and receive answers if they do not fully understand the material that is presented to them. When video presentations or computer-based programs are used, employers may meet this requirement by having a qualified trainer available to address questions after the presentation, or providing a telephone hotline so that trainees will have direct access to a qualified trainer.

In addition to being performance-oriented, these training requirements are also results-oriented. Paragraph (m)(4)(ii) requires employers to ensure that affected employees can demonstrate knowledge of the nine topics enumerated in paragraph (m)(4)(ii)(A) through (I). Accordingly, employers must ensure that employees participate in and comprehend the training, and are able to demonstrate knowledge of the specified topics. Some examples of methods to ensure knowledge are discussions of the required training subjects, written tests, or oral quizzes. Although the standard only requires annual retraining, employers must ensure that employees can demonstrate up-to-date knowledge of the listed topics at all times.

Paragraph (m)(4)(iii) requires employers to provide additional training, even if a year has not passed since the previous training, when workplace changes (such as modification of equipment, tasks, or procedures) result in new or increased employee exposure that exceeds or can reasonably be expected to exceed either the TWA PEL or the STEL. Some examples of changes in work conditions triggering the requirement for additional training include changes in work production operations or personnel that affect the way employees operate equipment. Additional training would also be required if employers introduce new production or personal protective equipment where employees do not yet know how to properly use the new equipment. Misuse of either the new production equipment or PPE could result in new exposures above the TWA PEL or STEL. As another example, employers must provide additional training before employees repair or upgrade engineering controls if exposures during these activities will exceed or can reasonably be expected to exceed either the TWA PEL or the STEL. OSHA believes the additional training requirement in this proposal is essential because it ensures that employees are able to actively participate in protecting themselves under the conditions found in the workplace, even if those conditions change.

Paragraph (m)(5) requires that employers make copies of the standard and its appendices readily available at no cost to each employee and designated employee representative. This requirement ensures that employees and their representatives have direct access to regulations affecting them, and knowledge of the protective measures employers must take on employees' behalf.

Commenters to both the RFI and SBREFA recognized the importance of educating and training their employees about the hazards of beryllium exposure. In commenting on an earlier OSHA draft standard for beryllium during the SBREFA process, several companies (*e.g.,* Morgan Bronze Products, Precision Stamping, and Mid Atlantic Coatings) supported training that was understandable to the employee. They agreed that employees should be able to demonstrate knowledge of health hazards associated with beryllium exposure, and the medical surveillance program as described in paragraph (k) of this section. They also supported additional training when exposures exceed the PEL (OSHA 2008b). Most SERs reported already training their employees about beryllium risks and how employees can protect themselves (OSHA, 2008b). OSHA agrees with comments supporting the necessity of training, and in order to assist in the development of training programs, intends to develop outreach materials and other guidance materials.

(n) Recordkeeping

Paragraph (n) of the proposed standard requires employers to maintain records of exposure measurements, historical monitoring data, objective data, medical surveillance, and training. The recordkeeping requirements are proposed in accordance with section 8(c) of the OSH Act (29 U.S.C. 657(c)), which authorizes OSHA to require employers to keep and make available records as necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries and illnesses. The proposed recordkeeping provisions are also consistent with OSHA's standard addressing access to employee exposure and medical records (29 CFR 1910.1020).

Proposed paragraph (n)(1)(i) requires employers to keep records of all measurements taken to monitor employee exposure to beryllium as required by paragraph (d) of this standard. Paragraph (n)(1)(ii) would require that such records include the following information: The date of measurement for each sample taken; the operation involving exposure to beryllium that was monitored; the sampling and analytical methods used and evidence of their accuracy; the number, duration, and results of samples taken; the types of respiratory protection and other personal protective equipment used; and the name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

These requirements are consistent with those found in other OSHA standards, such as those for methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). These standards, like most of OSHA's substance-specific standards, require that exposure monitoring and medical surveillance records include the employee's social security number. OSHA has included this requirement in the past because social security numbers are particularly useful in identifying employees, since each number is unique to an individual for a lifetime and does not change when an employee changes employers. When employees have identical or similar names, identifying employees solely by name makes it difficult to determine to which employee a particular record pertains. However, based on privacy concerns, OSHA examined alternatives to requiring social security numbers for employee identification as part of its Standards Improvement Project-Phase II (''SIPs'') Final Rule. The Agency analyzed public comment on the necessity, usefulness, and effectiveness of social security numbers as a means of identifying employee records. OSHA also analyzed comments regarding privacy concerns raised by this requirement, as well as the availability of other effective methods of identifying employees for OSHA recordkeeping purposes. Comments were divided regarding whether social security information should be retained for exposure and medical records. The Agency examined the comments and decided not to take any action in the SIPs final rule regarding the use of social security numbers because the conflicting comments all raised significant concerns, and OSHA wished to study the issue further. (See 70 FR 1112, 1126–27, March 7, 2005).

In this rulemaking, OSHA proposes to continue to require the use of social security numbers. OSHA emphatically recommends against distributing or posting employees' social security numbers with monitoring results. OSHA welcomes comment on this issue.

Proposed paragraph (n)(2) addresses historical monitoring data. Paragraph (n)(2)(i) would require employers to establish and maintain an accurate record of any historical monitoring data used to satisfy the initial monitoring requirements in paragraph (d)(2) of this standard. As explained earlier in this preamble, paragraph (d)(2) permits employers to substitute beryllium monitoring results obtained at an earlier time for the initial monitoring requirements, as long as employers abide by the criteria specified. Paragraph (n)(2)(ii) requires the employer to establish and maintain records or documents showing that the criteria discussed in paragraph (d)(2) are met. This would mean documenting the workplace conditions present when the historical data were collected, for purposes of showing that those conditions closely resemble the conditions present in the employer's current operations. Employers should also document the dates of reliance on the historical data as well as the dates on which the historical data were collected.

Proposed paragraph (n)(3) addresses objective data. Proposed paragraph (n)(3)(i) requires employers to establish and maintain accurate records of the objective data relied upon to satisfy the requirement for initial monitoring in proposed paragraph (d)(2). Under proposed paragraph (n)(3)(ii), the record must contain the following information: The data relied upon; the beryllium-containing material in question; the source of the data; a description of the operation exempted from initial monitoring and how the data support the exemption; and other information demonstrating that the data meet the requirements for objective data in accordance with paragraph (d)(2). Such other information may include reports of engineering controls, work area layout and dimensions, and natural air movements pertaining to the data and current conditions.

Since historical and objective data may be used to exempt the employer from certain types of monitoring, as specified in paragraph (d), it is critical that the use of these types of data be carefully documented. Historical and objective data are intended to provide the same degree of assurance that employee exposures have been correctly characterized as would exposure monitoring. The records must demonstrate a reasonable basis for conclusions drawn from the data.

Under proposed paragraph (n)(4)(i) employers must establish and maintain accurate medical surveillance records for each employee covered by the medical surveillance requirements of the standard in paragraph (k). Paragraph (n)(4)(ii) lists the categories of information that an employer would be required to record: the employee's name, social security number, and job classification; a copy of all physicians' written opinions; and a copy of the information provided to the PLHCP as required by paragraph (k)(4) of this standard.

OSHA believes that medical records, like exposure records, are necessary and appropriate. Medical records document the results of medical surveillance and the screening of employees. Employers can use the information contained in the records to identify and adjust hazardous workplace conditions and mitigate exposures. Employees can use these records to make informed decisions regarding medical surveillance and medical removal. PLHCPs would have the records to use in any further employee consultations or in making recommendations at a later time. In sum, medical records play an important part in properly evaluating the effects of beryllium exposure on employees' health.

Paragraph (n)(5)(i) would require that employers prepare and maintain records of any training required by this standard. At the completion of training, the employer would be required to prepare a record that indicates the name, social security number, and job classification of each employee trained; the date the training was completed; and the topic of the training. This record maintenance requirement would also apply to records of annual retraining or additional training as described in paragraph (m)(4).

Proposed paragraphs (n)(1) through (4) require employers to maintain exposure measurements, historical monitoring data, and medical surveillance records, respectively, in accordance with OSHA's Records Access standard (29 CFR 1910.1020). That standard, specifically 29 CFR 1910.1020(d), requires employers to ensure the preservation and retention of exposure and medical records. Exposure measurements and historical monitoring data are considered employee exposure records that must be maintained for at least 30 years in accordance with 29 CFR 1910.1020(d)(1)(ii). Medical surveillance records must be maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020(d)(1)(i).

Proposed paragraph (n)(5)(ii) requires employers to retain training records, including records of annual retraining or additional training required under this standard, for a period of three years after the completion of the training. OSHA believes that the retention period for training records is reasonable for documentation purposes. The three year period for the maintenance of training records is consistent with the Bloodborne Pathogens standard (29 CFR 1910.1030). Other OSHA standards require training records to be kept for one year beyond the last date of employment (*e.g.,* Asbestos (29 CFR 1910.1001), Methylenedianiline in construction (29 CFR 1926.60), and Asbestos in construction (29 CFR 1926.1101)).

These maintenance provisions, as well as the access requirements discussed below, ensure that records are available to employees so that they may examine the employer's exposure measurements, historical monitoring data, and objective data, as well as medical surveillance and training records, and evaluate whether employees are being adequately protected. Moreover, compliance with the requirement to maintain records of exposure data will enable the employer to show, at least for the duration of the retention-of-records period, that the requirements of this standard were carried out appropriately. For example, maintenance of these types of data could protect employers from allegations of violating paragraph (d)(2). The lengthy record retention period is necessitated by the long latency period commonly associated with diseases such as chronic beryllium disease and cancer (see this preamble at section V, Health Effects).

Paragraph (n)(6) requires that all records mandated by this standard must be made available for examination and copying to the Assistant Secretary, the Director of NIOSH, each employee, and each employee's designated representative as stipulated by OSHA's Records Access standard (29 CFR 1910.1020).

Paragraph (n)(7) requires that employers comply with the Records Access standard regarding the transfer of records. Specifically, the requirements for the transfer of records are explained in 29 CFR 1910.1020(h), which instructs employers either to transfer records to successor employers or, if there is no successor employer, to inform employees of their access rights at least three months before the cessation of the employer's business.

Commenters to the RFI fully endorsed the need for the collection and maintenance of health-related records dealing with beryllium exposure, as well as those for employee hazard training (Brush Wellman, 2003). No comments were received in opposition to the need for such recordkeeping. However, one commenter suggested that most dental labs will not have any incentive to comply with the recordkeeping requirements because they have fewer than ten employees and therefore would not be subject to OSHA audits of their records. The commenter noted that OSHA will have difficulty measuring the effectiveness of the standard if small businesses do not keep accurate records (OSHA, 2007a). OSHA does not intend to exempt small businesses from the recordkeeping requirements in this proposal because the Agency believes the severity of disease resulting from beryllium exposure is great enough to justify requiring small businesses to maintain employee health records in accordance with this proposal. Also, recordkeeping for fewer employees should be less resource-intensive than for a larger organization. OSHA requests comment on the appropriateness of the proposed recordkeeping requirements.

(o) Dates

According to paragraph (o), this standard will become effective 60 days after the publication of the final rule in the **Federal Register**. OSHA intends for this period to allow affected employers the opportunity to familiarize themselves with the standard and to make preparations in order to be in compliance by the start-up dates. Under paragraph (o)(2), employer obligations to comply with most requirements of the final rule would begin 90 days after the effective date (150 days after publication of the final rule). This additional time period is designed to allow employers to complete initial exposure assessments or otherwise make exposure determinations by use of historical or objective data, to establish regulated areas, to obtain appropriate work clothing and equipment, and to comply with other provisions of the rule.

There are two exceptions to the normal start-up intervals—establishing change rooms and implementing engineering controls—that provide additional time for employers to comply. Change rooms are required no later than one year after the effective date of the standard, and engineering controls need to be in place within two years after the effective date. The delayed start-up dates allow affected employers sufficient time to design and construct change rooms where necessary, and to design, obtain, and install any required control equipment. In addition, the longer intervals for change rooms and engineering controls are consistent with other OSHA substance-specific standards such as those for chromium (VI) (29 CFR 1910.1026) and cadmium (29 CFR 1910.1027). OSHA solicits comment on the appropriateness of these proposed start-up dates.

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List of Subjects in 29 CFR Part 1910

Cancer, Chemicals, Hazardous substances, Health, Occupational safety and health, Reporting and recordkeeping requirements.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, directed the preparation of this notice. OSHA is issuing this notice under Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 41 of the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); section 107 of the Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 3704); Secretary of Labor's Order 1–2012 (77 FR 3912, January 25, 2012); and 29 CFR part 1911.

Signed at Washington, DC, on July 14, 2015.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Proposed Standard

Chapter XVII of Title 29 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart Z—Toxic and Hazardous Substances

■ 1. The authority citation for subpart Z of part 1910 is revised to read as follows:

Authority: Sections 4, 6, 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act of 1970, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653. Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

§ 1910.1000 [Amended]

■ 2. In § 1910.1000:

■ a. Table Z–1 is amended by revising the entry for ''Beryllium and beryllium compounds (as Be)''; and by adding footnote ''W''; and

■ b. Table Z–2 is amended by adding footnote ''Y''.

The revisions and additions read as follows:

TABLE Z–1—LIMITS FOR AIR CONTAMINANTS

Substance	CAS No. (c)	ppm (a) [1]	mg/m³ (b) [1]	Skin designation
* * * * * * *				
Beryllium and beryllium compounds (as Be); see 1910.1024 [W].				
* * * * * * *				

[1] The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

a. Parts of vapor or gas per million parts of contaminated air by volume at 25 °C and 760 torr.

b. Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

c. The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

d. The final benzene standard in § 1910.1028 applies to all occupational exposures to benzene except in some circumstances the distribution and sale of fuels, sealed containers and pipelines, coke production, oil and gas drilling and production, natural gas processing, and the percentage exclusion for liquid mixtures; for the excepted subsegments, the benzene limits in Table Z–2 apply. See § 1910.1028 for specific circumstances.

e. This 8-hour TWA applies to respirable dust as measured by a vertical elutriator cotton dust sampler or equivalent instrument. The time-weighted average applies to the cottom waste processing operations of waste recycling (sorting, blending, cleaning and willowing) and garnetting. See also § 1910.1043 for cotton dust limits applicable to other sectors.

f. All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by the Particulates Not Otherwise Regulated (PNOR) limit which is the same as the inert or nuisance dust limit of Table Z–3.

* * * * * * *

[W] See Table Z–2 for the exposure limits for any operations or sectors for which the exposure limits in § 1910.1024 are not in effect.

TABLE Z–2

Substance	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling average concentration for an 8-hr shift	
			Concentration	Maximum duration
* * * * * * *				
Beryllium and beryllium compounds (as Be) [Y]	2 µg/m³	5 µg/m³	25µg/m³	30 minutes
* * * * * * *				

* * * * * *

[Y] This standard applies to any operations or sectors for which the Beryllium standard, 1910.1024, is not in effect.

■ 3. Section 1910.1024 is added to subpart Z to read as follows:

§ 1910.1024 Beryllium

(a) *Scope and application.* (1) This section applies to occupational exposures to beryllium in all forms, compounds, and mixtures in general industry, except those articles and materials exempted by paragraphs (a)(2) and (3) of this section.

(2) This section does not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process.

(3) This section does not apply to materials containing less than 0.1% beryllium by weight.

(b) *Definitions.*

Action level means a concentration of airborne beryllium of 0.1 micrograms per cubic meter of air (µg/m³) calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee.

Beryllium lymphocyte proliferation test (BeLPT) means the measurement of blood lymphocyte proliferation in a laboratory test when lymphocytes are challenged with a soluble beryllium salt. A confirmed positive test result indicates the person has beryllium sensitization.

Beryllium work area means any work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure.

CBD Diagnostic Center means a medical diagnostic center that has on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD) that includes bronchoalveolar lavage, transbronchial biopsy and interpretation of the biopsy pathology, and the beryllium bronchoalveolar lavage lymphocyte proliferation test (BeBALLPT).

Chronic beryllium disease (CBD) means a chronic lung disease associated with exposure to airborne beryllium.

Confirmed Positive means two abnormal test results from either consecutive BeLPTs or a second abnormal BeLPT result within a 2-year period of the first abnormal test result. It also means the result of a more reliable and accurate test indicating a person has been identified as having beryllium sensitization.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any uncontrolled release of airborne beryllium.

Exposure and *exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

High-efficiency particulate air (HEPA) filter means a filter that is at least 99.97 percent efficient in removing particles 0.3 micrometers in diameter.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (k) of this standard.

Regulated area means an area that the employer must demarcate, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's exposure exceeds, or can reasonably be expected to exceed, either of the permissible exposure limits (PELs).

This standard means this beryllium standard, 29 CFR 1910.1024.

(c) *Permissible Exposure Limits (PELs).* (1) *Time-weighted average (TWA) PEL.* The employer shall ensure that each employee's exposure does not exceed 0.2 μg/m^3 calculated as an 8-hour TWA.

(2) *Short-term exposure limit (STEL).* The employer shall ensure that each employee's exposure does not exceed 2.0 μg/m^3 as determined over a sampling period of 15 minutes.

(d) *Exposure monitoring*—(1) *General.* (i) These exposure monitoring requirements apply when employees are, or may reasonably be expected to be, exposed to airborne beryllium.

(ii) Except as provided in paragraphs (d)(2)(i) and (ii) of this section, the employer shall determine the 8-hour TWA exposure for each employee based on one or more breathing zone samples that reflect the exposure of employees on each work shift, for each job classification, in each beryllium work area.

(iii) Except as provided in paragraph (d)(2)(i) and (ii) of this section, the employer shall determine short-term exposure from 15-minute breathing zone samples measured in operations that are likely to produce exposures above the STEL for each work shift, for each job classification, and in each beryllium work area.

(iv) The employer may perform representative sampling to characterize exposure, provided that the employer:

(A) Performs representative sampling where several employees perform the same job tasks, in the same job classification, on the same work shift, and in the same work area, and have similar duration and frequency of exposure;

(B) Takes sufficient personal breathing zone air samples to accurately characterize exposure on each work shift, for each job classification, in each work area; and

(C) Samples those employee(s) who are expected to have the highest exposure.

(v) *Accuracy of measurement.* The employer shall use a method of exposure monitoring and analysis that can measure beryllium to an accuracy of plus or minus 25 percent within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(2) *Initial exposure monitoring.* The employer shall conduct initial exposure monitoring to determine the 8-hour TWA exposure and 15-minute short-term exposure for each employee. The employer does not have to conduct initial exposure monitoring in the following situations:

(i) Where the employer has conducted exposure monitoring for beryllium and relies on these historical data, provided that:

(A) The work operations and workplace conditions that were in place when the historical monitoring data were obtained reflect workplace conditions closely resembling the processes, material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations;

(B) The characteristics of the beryllium-containing material being handled when the historical monitoring data were obtained closely resemble the characteristics of the beryllium-containing material used during the job for which initial monitoring will not be performed; and

(C) The exposure monitoring satisfied all other requirements of this section, including Accuracy of Measurement in paragraph (d)(1)(v).

(ii) Where the employer relies on objective data to satisfy initial monitoring requirements, provided that such data:

(A) Demonstrate that any material containing beryllium or any specific process, operation, or activity involving beryllium cannot release beryllium dust, fumes, or mist in concentrations at or above the action level or above the STEL under any expected conditions of use; and

(B) Reflect workplace conditions closely resembling the processes, material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations.

(3) *Periodic exposure monitoring.* If initial exposure monitoring indicates that exposures are at or above the action level and at or below the TWA PEL, the employer shall conduct periodic exposure monitoring at least annually in accordance with paragraph (d)(1) of this section.

(4) *Additional monitoring.* The employer also shall conduct exposure monitoring within 30 days after any of the following situations occur:

(i) Any change in production processes, equipment, materials, personnel, work practices, or control methods that can reasonably be expected to result in new or additional exposure; or

(ii) The employer has any other reason to believe that new or additional exposure is occurring.

(5) *Employee notification of monitoring results.* (i) Within 15 working days after receiving the results of any exposure monitoring completed under this standard, the employer shall notify each employee whose exposure is measured or represented by the monitoring individually in writing of the monitoring results or shall post the monitoring results in an appropriate location that is accessible to each of these employees.

(ii) Where exposures exceed the TWA PEL or STEL, the written notification required by paragraph (d)(5)(i) of this section shall include suspected or known sources of exposure and the corrective action(s) the employer has taken or will take to reduce exposure to or below the PELs, where feasible corrective action exists but had not been implemented when the monitoring was conducted.

(6) *Observation of monitoring.* (i) The employer shall provide an opportunity to observe any exposure monitoring required by this standard to each employee whose exposures are measured or represented by the monitoring and each employee's representative(s).

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment (which may include respirators) is required, the employer shall provide each observer with appropriate protective clothing and equipment at no cost to the observer and shall ensure that each observer uses such clothing and equipment.

(iii) The employer shall ensure that each observer complies with all applicable OSHA requirements and the employer's workplace safety and health procedures.

(e) *Beryllium work areas and regulated areas*—(1) *Establishment.* (i) The employer shall establish and maintain a beryllium work area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure.

(ii) The employer shall establish and maintain a regulated area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL.

(2) *Demarcation.* (i) The employer shall identify each beryllium work area through signs or any other methods that adequately establish and inform each employee of the boundaries of each beryllium work area.

(ii) The employer shall identify each regulated area in accordance with paragraph (m)(2) of this section.

(3) *Access.*The employer shall limit access to regulated areas to:

(i) Persons the employer authorizes or requires to be in a regulated area to perform work duties;

(ii) Persons entering a regulated area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring procedures under paragraph (d)(6) of this section; and

(iii) Persons authorized by law to be in a regulated area.

(4) *Provision of personal protective clothing and equipment, including respirators.* The employer shall provide and ensure that each employee entering a regulated area uses:

(i) Respiratory protection in accordance with paragraph (g) of this section; and

(ii) Personal protective clothing and equipment in accordance with paragraph (h) of this section.

(f) *Methods of compliance*—(1) *Written exposure control plan.*

(i) The employer shall establish, implement, and maintain a written exposure control plan for beryllium work areas, which shall contain:

(A) An inventory of operations and job titles reasonably expected to have exposure;

(B) An inventory of operations and job titles reasonably expected to have exposure at or above the action level;

(C) An inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL;

(D) Procedures for minimizing cross-contamination, including but not limited to preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas;

(E) Procedures for keeping surfaces in the beryllium work area as free as practicable of beryllium;

(F) Procedures for minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace;

(G) An inventory of engineering and work practice controls required by paragraph (f)(2) of this standard; and

(H) Procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators.

(ii) The employer shall update the exposure control plan when:

(A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in new or additional exposures to beryllium;

(B) An employee is confirmed positive, is diagnosed with CBD, or shows signs or symptoms associated with exposure; or

(C) The employer has any reason to believe that new or additional exposures are occurring or will occur.

(iii) The employer shall make a copy of the exposure control plan accessible to each employee who is or can reasonably be expected to be exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)).

(2) *Engineering and work practice controls.* (i) (A) For each operation in a beryllium work area, the employer shall ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure:

(*1*) Material and/or process substitution;

(*2*) Ventilated partial or full enclosures;

(*3*) Local exhaust ventilation at the points of operation, material handling, and transfer; or

(*4*) Process control, such as wet methods and automation.

(B) An employer is exempt from using the above controls to the extent that:

(*1*) The employer can establish that such controls are not feasible; or

(*2*) The employer can demonstrate that exposures are below the action level, using no fewer than two representative personal breathing zone samples taken 7 days apart, for each affected operation.

(ii) If after implementing the control(s) required by (f)(2)(i)(A) exposures exceed the TWA PEL or STEL, the employer shall implement additional or enhanced engineering and work practice controls to reduce exposures to or below the PELs.

(iii) Wherever the employer demonstrates that it is not feasible to reduce exposures to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (ii) of this section, the employer shall implement and maintain engineering and work practice controls to reduce exposures to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this section.

(3) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PELs.

(g) *Respiratory protection*—(1) *General.* The employer shall provide at no cost and ensure that each employee uses respiratory protection during:

(i) Periods necessary to install or implement feasible engineering and work practice controls where exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL;

(ii) Operations, including maintenance and repair activities and non-routine tasks, when engineering and work practice controls are not feasible and exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls when such controls are not sufficient to reduce exposure to or below the TWA PEL or STEL;

(iv) Emergencies.

(2) *Respiratory protection program.* Where this standard requires an employee to use respiratory protection, such use shall be in accordance with the Respiratory Protection Standard (29 CFR 1910.134).

(h) *Personal protective clothing and equipment*—(1) *Provision and use.* The employer shall provide at no cost and ensure that each employee uses appropriate personal protective clothing and equipment in accordance with the written exposure control plan required under paragraph (f)(1) of this section and OSHA's Personal Protective Equipment standards (29 CFR part 1910 subpart I):

(i) Where employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL;

(ii) Where employees' clothing or skin may become visibly contaminated with beryllium including during maintenance and repair activities or during non-routine tasks; or

(iii) Where employees' skin can reasonably be expected to be exposed to soluble beryllium compounds.

(2) *Removal and storage.* (i) The employer shall ensure that each employee removes all beryllium-contaminated protective clothing and equipment:

(A) At the end of the work shift or at the completion of tasks involving beryllium, whichever comes first, or

(B) When protective clothing or equipment becomes visibly contaminated with beryllium.

(ii) The employer shall ensure that each employee removes protective clothing visibly contaminated with beryllium as specified in the exposure control plan required by paragraph (f)(1) of this section.

(iii) The employer shall ensure that each employee stores and keeps required protective clothing separate from street clothing.

(iv) The employer shall ensure that no employee removes beryllium-contaminated protective clothing or equipment from the workplace, except for employees authorized to do so for the purposes of laundering, cleaning, maintaining or disposing of beryllium-contaminated protective clothing and equipment at an appropriate location or facility away from the workplace.

(v) When protective clothing or equipment required by this standard is removed from the workplace for laundering, cleaning, maintenance or disposal, the employer shall ensure that protective clothing and equipment are stored and transported in sealed bags or other closed containers that are impermeable and are labeled in accordance with paragraph (m)(3) of this section and the HCS (29 CFR 1910.1200).

(3) *Cleaning and replacement.* (i) The employer shall ensure that all reusable protective clothing and equipment required by this standard is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness.

(ii) The employer shall ensure that beryllium is not removed from protective clothing and equipment by blowing, shaking or any other means that disperses beryllium into the air.

(iii) The employer shall inform in writing the persons or the business entities who launder, clean or repair the protective clothing or equipment required by this standard of the potentially harmful effects of exposure to airborne beryllium and contact with soluble beryllium compounds and that the protective clothing and equipment must be handled in accordance with this standard.

(i) *Hygiene areas and practices*—(1) *General.* For each employee working in a beryllium work area, the employer shall:

(i) Provide readily accessible washing facilities to remove beryllium from the hands, face, and neck; and

(ii) Ensure each employee exposed to beryllium to use these facilities when necessary.

(2) *Change rooms.* In addition to the requirements of paragraph (i)(1)(i) of this section, the employer shall provide affected employees with a designated change room and washing facilities in accordance with this standard and the Sanitation Standard (29 CFR 1910.141) where employees are required to remove their personal clothing.

(3) *Showers.* (i) The employer shall provide showers in accordance with the Sanitation standard (29 CFR 1910.141) where:

(A) Exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL; and

(B) Beryllium can reasonably be expected to contaminate employees' hair or body parts other than hands, face, and neck.

(ii) Employers required to provide showers under paragraph (i)(3)(i) of this section shall ensure that each employee showers at the end of the work shift or work activity if:

(A) The employee reasonably could have been exposed above the TWA PEL or STEL; and

(B) Beryllium could reasonably have contaminated the employee's hair or body parts other than hands, face, and neck.

(4) *Eating and drinking areas.* Whenever the employer allows employees to consume food or beverages in a beryllium work area, the employer shall ensure that:

(i) Surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employee in eating and drinking areas is exposed to airborne beryllium at or above the action level; and

(iii) Eating and drinking facilities provided by the employer are in accordance with the Sanitation standard (29 CFR 1910.141).

(5) *Prohibited activities.* (i) The employer shall ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

(ii) The employer shall ensure that no employees enter any eating or drinking area with protective work clothing or equipment unless surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body.

(j) *Housekeeping*—(1) *General.* (i) The employer shall maintain all surfaces in beryllium work areas as free as practicable of accumulations of beryllium and in accordance with the exposure control plan required under paragraph (f)(1) of this section and the cleaning methods required under paragraph (j)(2) of this section; and

(ii) The employer shall ensure that all spills and emergency releases of beryllium are cleaned up promptly and in accordance with the exposure control plan required under paragraph (f)(1) of this section and the cleaning methods required under paragraph (j)(2) of this section.

(2) *Cleaning methods.* (i) The employer shall ensure that surfaces in beryllium work areas are cleaned by HEPA-filter vacuuming or other methods that minimize the likelihood and level of exposure.

(ii) The employer shall not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of exposure have been tried and were not effective.

(iii) The employer shall not allow the use of compressed air for cleaning beryllium-contaminated surfaces unless the compressed air is used in conjunction with a ventilation system designed to capture the particulates made airborne by the use of compressed air.

(iv) Where employees use dry sweeping, brushing, or compressed air to clean beryllium-contaminated surfaces, the employer shall provide and ensure that each employee uses respiratory protection and protective clothing and equipment in accordance with paragraphs (g) and (h) of this section.

(v) The employer shall ensure that cleaning equipment is handled and maintained in a manner that minimizes the likelihood and level of employee exposure and the re-entrainment of airborne beryllium in the workplace.

(3) *Disposal.* The employer shall ensure that:

(i) Waste, debris, and materials visibly contaminated with beryllium and consigned for disposal are disposed of in sealed, impermeable enclosures, such as bags or containers;

(ii) Bags or containers of waste, debris, and materials required by (j)(3)(i) of this section are labeled in accordance with paragraph (m)(3) of this section; and

(iii) Materials designated for recycling that are visibly contaminated with beryllium shall be cleaned to remove visible particulate, or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this section.

(k) *Medical surveillance*—(1) *General.* (i) The employer shall make medical surveillance as required by this paragraph available at no cost to the employee, and at a reasonable time and place, as follows:

(A) For each employee who has worked in a regulated area for more than 30 days in the last 12 months;

(B) For each employee showing signs or symptoms of CBD, such as shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue;

(C) For each employee exposed to beryllium during an emergency; and

(D) For each employee who was exposed to airborne beryllium above .2 $\mu g/m^3$ for more than 30 days in a 12-month period for 5 years or more, limited to the procedures described in paragraph (k)(3)(ii)(F) of this section unless the employee also qualifies for an examination under paragraph (k)(1)(i)(A), (B), or (C) of this section.

(ii) The employer shall ensure that all medical examinations and procedures required by this standard are performed by or under the direction of a licensed physician.

(2) *Frequency.* The employer shall provide a medical examination:

(i) Within 30 days after determining that:

(A) An employee meets the criteria of paragraph (k)(1)(i)(A) of this section, unless the employee has received a medical examination, provided in accordance with this standard, within the last 12 months; or

(B) An employee meets the criteria of paragraph (k)(1)(i)(B) or (C) of this section.

(ii) Annually thereafter for each employee who continues to meet the criteria of paragraph (k)(1)(i)(A) or (B) of this section; and

(iii) At the termination of employment for each employee who meets the criteria of paragraph (k)(1)(i)(A), (B), or (C) of this section at the time the employee's employment is terminated, unless an examination has been provided in accordance with this standard during the 6 months prior to the date of termination.

(3) *Contents of examination.* (i) The employer shall ensure that the PLHCP advises the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination.

(ii) The employer shall ensure that the employee is offered a medical examination that includes:

(A) A medical and work history, with emphasis on past and present exposure, smoking history, and any history of respiratory system dysfunction;

(B) A physical examination with emphasis on the respiratory tract;

(C) A physical examination for skin breaks and wounds;

(D) Pulmonary function tests, performed in accordance with the guidelines established by the American Thoracic Society including forced vital capacity and forced expiratory volume at one (1) second (FEV1);

(E) (*1*) A standardized BeLPT upon the first examination and within every 2 years from the date of the first examination until the employee is confirmed positive. If a more reliable and accurate diagnostic test is developed after [EFFECTIVE DATE OF FINAL RULE] of this standard such that beryllium sensitization can be confirmed after one test, a second confirmation test need not be performed.

(*2*) If an employee who has not been confirmed positive receives an abnormal BeLPT result, a second BeLPT is to be performed within 1 month. This requirement for a second test is waived if a more reliable and accurate test for beryllium sensitization does not need to be repeated due to variability, repeatability and accuracy of the test methodology.

(F) Each employee who meets the criteria of paragraph (k)(1)(i)(D) shall be offered a low dose helical tomography (CT Scan). The CT Scan shall be offered every 2 years for the duration of the employee's employment. This obligation begins on the [EFFECTIVE DATE OF FINAL RULE], or on the 15th year after the employee's first exposure above .2 $\mu g/m^3$ for more than 30 days in a 12-month period, whichever is later; and

(G) Any other test deemed appropriate by the PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard and all appendices and shall provide the following information, if known:

(i) A description of the employee's former and current duties that relate to the employee's occupational exposure;

(ii) The employee's former and current levels of occupational exposure;

(iii) A description of any protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that protective clothing and equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the employee, currently within the control of the employer, after obtaining a medical release from the employee.

(5) *Licensed physician's written medical opinion.* (i) The employer shall obtain a written medical opinion from the licensed physician within 30 days of the examination, which contains:

(A) The licensed physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of CBD from further exposure;

(B) Any recommended limitations on the employee's exposure, including the use and limitations of protective clothing or equipment, including respirators; and

(C) A statement that the PLHCP has explained the results of the medical examination to the employee, including any tests conducted, any medical conditions related to exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The employer shall ensure that neither the licensed physician nor any other PLHCP reveals to the employer specific findings or diagnoses unrelated to exposure to airborne beryllium or contact with soluble beryllium compounds.

(iii) The employer shall provide a copy of the licensed physician's written medical opinion to the employee within 2 weeks after receiving it.

(6) *Referral to a CBD diagnostic center.* (i) Within 30 days after an employer learns that an employee has been confirmed positive, the employer's designated licensed physician shall consult with the employee to discuss referral to a CBD diagnostic center that is mutually agreed upon by the employer and the employee.

(ii) If, after this consultation, the employee wishes to obtain a clinical evaluation at a CBD diagnostic center, the employer shall provide the evaluation at no cost to the employee.

(7) *Beryllium sensitization test results research.* Upon request by OSHA, employers must convey employees' beryllium sensitization test results to OSHA for evaluation and analysis. Employers must remove employees' names, social security numbers, and other personally identifying information from the test results before conveying them to OSHA.

(l) *Medical removal.* (1) If an employee works in a job with exposure at or above the action level and is diagnosed with CBD or confirmed positive, the employee is eligible for medical removal.

(2) If an employee is eligible for medical removal, the employee must choose:

(i) Removal as described in paragraph (l)(3) of this section; or

(ii) To remain in a job with exposure at or above the action level, provided that the employee wears a respirator in accordance with the Respiratory Protection standard (29 CFR 1910.134).

(3) If the employee chooses removal:

(i) The employer shall remove the employee to comparable work for which the employee is qualified or can be trained within 1 month. In this standard, comparable work must be in a work environment where the exposure is below the action level. The employee must accept comparable work if such work is available;

(ii) If comparable work is not available, the employer shall place the employee on paid leave for 6 months or until such time as comparable work becomes available, whichever comes first; and

(iii) Whether the employee is removed to comparable work or placed on paid leave, the employer shall maintain for 6 months the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

(4) The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal from a publicly or employer-funded compensation program, or receives income from another employer made possible by virtue of the employee's removal.

(m) *Communication of hazards*— (1) *General.* (i) Chemical manufacturers, importers, distributors, and employers shall comply with all requirements of the HCS (29 CFR 1910.1200) for beryllium.

(ii) In classifying the hazards of beryllium, the employer shall address at least the following hazards: Cancer; lung effects (CBD and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation.

(iii) Employers shall include beryllium in the hazard communication program established to comply with the HCS. Employers shall ensure that each employee has access to labels on containers of beryllium and to safety data sheets, and is trained in accordance with the requirements of the HCS (29 CFR 1910.1200) and paragraph (m)(4) of this section.

(2) *Warning signs*—(i) *Posting.* The employer shall provide and display warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area.

(ii) *Sign specification.* (A) The employer shall ensure that the warning signs required by paragraph (m)(2)(i) of this section are legible and readily visible.

(B) The employer shall ensure each warning sign required by paragraph (m)(2)(i) of this section bears the following legend:

DANGER
BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY
WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING AND EQUIPMENT IN THIS AREA

(3) *Warning labels.* The employer shall label each bag and container of clothing, equipment, and materials visibly contaminated with beryllium consistent with the HCS (29 CFR 1910.1200), and shall, at a minimum, include the following on the label:

DANGER
CONTAINS BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AVOID CREATING DUST
DO NOT GET ON SKIN

(4) *Employee information and training.* (i) For each employee who is or can reasonably be expected to be exposed to airborne beryllium:

(A) The employer shall provide information and training in accordance with the HCS (29 CFR 1910.1200(h));

(B) The employer shall provide initial training to each employee by the time of initial assignment; and

(C) The employer shall repeat the training required under this section annually for each employee.

(ii) The employer shall ensure that each employee who is or can reasonably be expected to be exposed to airborne beryllium can demonstrate knowledge of the following:

(A) The health hazards associated with exposure to beryllium and contact with soluble beryllium compounds, including the signs and symptoms of CBD;

(B) The written exposure control plan, with emphasis on the location(s) of beryllium work areas, including any regulated areas, and the specific nature of operations that could result in employee exposure, especially employee exposure above the TWA PEL or STEL;

(C) The purpose, proper selection, fitting, proper use, and limitations of personal protective clothing and equipment, including respirators;

(D) Applicable emergency procedures;

(E) Measures employees can take to protect themselves from exposure to beryllium and contact with soluble beryllium compounds, including personal hygiene practices;

(F) The purpose and a description of the medical surveillance program required by paragraph (k) of this section including risks and benefits of each test to be offered;

(G) The purpose and a description of the medical removal protection provided under paragraph (l) of this section;

(H) The contents of the standard; and

(I) The employee's right of access to records under the Records Access standard (29 CFR 1910.1020).

(iii) When a workplace change (such as modification of equipment, tasks, or procedures) results in new or increased employee exposure that exceeds, or can reasonably be expected to exceed, either the TWA PEL or the STEL, the employer shall provide additional training to those employees affected by the change in exposure.

(iv) *Employee information.* The employer shall make a copy of this standard and its appendices readily available at no cost to each employee and designated employee representative(s).

(n) Recordkeeping—(1) *Exposure measurements.* (i) The employer shall maintain a record of all measurements taken to monitor employee exposure as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation that is being monitored;

(C) The sampling and analytical methods used and evidence of their accuracy;

(D) The number, duration, and results of samples taken;

(E) The type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and

(F) The name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall maintain this record as required by the Records

Access standard (29 CFR 1910.1020(d)(1)(ii)).

(2) *Historical monitoring data.* (i) The employer shall establish and maintain an accurate record of any historical data used to satisfy the initial monitoring requirements of paragraph (d)(2) of this standard.

(ii) The record shall demonstrate that the data comply with the requirements of paragraph (d)(2) of this section.

(iii) The employer shall maintain this record as required by the Records Access standard (29 CFR 1910.1020).

(3) *Objective data.* (i) Where an employer uses objective data to satisfy the monitoring requirements under paragraph (d)(2) of this section, the employer shall establish and maintain a record of the objective data relied upon.

(ii) This record shall include at least the following information:

(A) The data relied upon;

(B) The beryllium-containing material in question;

(C) The source of the objective data;

(D) A description of the operation exempted from initial monitoring and how the data support the exemption; and

(E) Other information demonstrating that the data meet the requirements for objective data contained in paragraph (d)(2)(ii) of this section.

(iii) The employer shall maintain this record as required by the Records Access standard (29 CFR 1910.1020).

(4) *Medical surveillance.* (i) The employer shall establish and maintain a record for each employee covered by medical surveillance under paragraph (k) of this section.

(ii) The record shall include the following information about the employee:

(A) Name, social security number, and job classification;

(B) A copy of all licensed physicians' written opinions; and

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this section.

(iii) The employer shall ensure that medical records are maintained in accordance with the Records Access standard (29 CFR 1910.1020).

(5) *Training.* (i) At the completion of any training required by this standard, the employer shall prepare a record that indicates the name, social security number, and job classification of each employee trained, the date the training was completed, and the topic of the training.

(ii) This record shall be maintained for 3 years after the completion of training.

(6) *Access to records.* Upon request, the employer shall make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary, the Director, each employee, and each employee's designated representative(s) in accordance the Records Access standard (29 CFR 1910.1020).

(7) *Transfer of records.* The employer shall comply with the requirements involving transfer of records set forth in the Records Access standard (29 CFR 1910.1020).

(o) *Dates.* (1) *Effective date.*This standard shall become effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **Federal Register**].

(2) *Start-up dates.* All obligations of this standard commence and become enforceable [DATE 90 DAYS AFTER EFFECTIVE DATE OF FINAL RULE] except:

(i) Change rooms required by paragraph (i) of this section shall be provided no later than 1 year after [EFFECTIVE DATE OF FINAL RULE]; and

(ii) Engineering controls required by paragraph (f) of this standard shall be implemented no later than 2 years after [EFFECTIVE DATE OF FINAL RULE].

(p) *Appendices.* Appendices A and B of this section are non-mandatory.

Appendix A to § 1910.1024—Immunological Testing for the Determination of Beryllium Sensitization (Non-Mandatory)

I. Background

Exposure to beryllium via inhalation or dermal contact has been determined to cause an immunological reaction (sensitization) in some individuals. Beryllium sensitization can progress to chronic beryllium disease (CBD). Identifying sensitized workers through an immunological screening program is an essential element in any monitoring and surveillance program designed to reduce the risk of developing CBD in the workplace (Kreiss, 1993b, Newman, 2005). Immunological testing for sensitization to beryllium serves to identify workers at risk for progression to CBD. The medical surveillance and medical removal provisions of the proposed standard provide for clinical evaluation of sensitized workers for early-stage CBD and intervention before progression to more debilitating health effects occurs.

2. This appendix provides an overview of the test currently used to detect beryllium sensitization, the peripheral blood Beryllium Lymphocyte Proliferation Test (BeLPT) as well as a description of the test procedure, the best available information on the accuracy of the test, and several repeat-testing algorithms designed to improve the predictive value of the test. It is important that this information be made available to employers, employees, physicians and other medical personnel to ensure their understanding of the test and the meaning of test results, and to provide a basis to compare the reliability and validity (utility) of any other sensitization tests that may be developed with the utility of the BeLPT.

II. The Peripheral Blood Beryllium Lymphocyte Proliferation Test (BeLPT)

1. The BeLPT is an in-vitro blood test that measures the beryllium antigen-specific T-cell mediated immune response. Currently, the BeLPT is the most commonly available diagnostic tool for identifying beryllium sensitization.

2. To perform the BeLPT, venous blood is collected in heparinized tubes. Lymphocytes are isolated from the blood using centrifugation and washed in salt solution. The lymphocytes are counted and evaluated for cell viability. These cells are then cultured in quadruplicate in the presence or absence of beryllium sulfate at 1, 10, and 100 μM concentrations for 3–7 days. During the last 4 hours of the culture, cells are pulsed with a radiolabeled DNA precursor (tritiated thymidine deoxyriboside), harvested onto filters and counted in a liquid scintillation counter. The counts per minute (cpm) from each set of quadruplicates are averaged and expressed as a ratio of the cpm of the beryllium stimulated cells to the unstimulated cells. This ratio is called the stimulation index (SI) (Maier, 2003).

3. The BeLPT is interpreted based on the proportion of SIs that exceeds a cut-off value, the expected SI for non-sensitized individuals. Each laboratory sets its own cut-off for the test (Newman 1996). Traditionally, this cut-off value is determined by testing cells from control/non-exposed individuals, and must be determined with each new serum lot that will be used for culturing the peripheral blood lymphocytes. The cut-off is based on the mean value of the peak stimulation index among controls plus 2 or 3 standard deviations. This methodology was modeled into a statistical method known as the ''least absolute values'' (an adaptation of the ''statistical-biological positive'' method) and relies on natural log modeling of the median stimulation index values (DOE 2001, Frome 2003). This methodology is recommended by the Department of Energy in guidance (DOE–SPEC–1142–2001) developed by DOE to optimize and standardize beryllium sensitivity testing. It is recommended, but not mandated, to be used in all DOE contracts with laboratories for the purchase of BeLPT services. Other labs have used a standard ratio of 3.0 (stimulated to unstimulated) as the cut-off for an abnormal result (Stange 2004, Deubner 2001).

4. BeLPT results are reported as ''normal,'' ''abnormal,'' or ''borderline abnormal.'' According to the DOE a BeLPT result is considered ''abnormal'' if at least two of the six stimulation indices are elevated (DOE 2001). If only one of the six stimulation indices is elevated, the test is considered ''borderline abnormal'' (DOE 2001). If no stimulation index is elevated, the test is normal. A BeLPT may be considered uninterpretable if there are problems with the viability of the cells or lack of response to mitogen, or other problems with the test procedure. (DOE 2001).

5. Due to the nature of the test, issues with variability and reproducibility of a test can

arise between and within labs. Potential sources of variability include: technical problems such as bacterial contamination, cell death, omission of tritiated thymidine pulse, technician skill, degree of automation, use of flat- or round-bottom culture plates, serum concentration, use of beryllium sulfate versus beryllium fluoride, concentration of the culture serum, and the handling of outlier SIs (Mroz 1991).

6. *Test characteristics and testing algorithms.* The utility of any diagnostic, screening or surveillance test relies on the capacity of the test to predict whether or not an individual indeed has the condition intended to be reflected by the test. In the discussion below, sensitivity refers to the proportion of sensitized persons who test positive for sensitization using the BeLPT. Specificity refers to the proportion of non-sensitized persons who test negative. Positive predictive value (PPV) refers to the proportion of persons who test positive, who are actually sensitized. The PPV is related not only to the utility of the test, but also to the prevalence of the condition in the tested population. In the remainder of this discussion, we will refer to the results of a single BeLPT as ''abnormal,'' ''normal,'' and ''borderline,'' and will refer to the outcome of a testing algorithm as ''positive'' for sensitization or ''negative.''

7. Stange et al. (2004) investigated the utility of BeLPT testing in a population of employees of 18 United States Department of Energy (DOE) sites. At these sites, 12,194 current and former employees were tested for beryllium sensitization at four laboratories with BeLPT expertise. Stange *et al.* reported that 68.3 percent of beryllium-sensitized workers tested positive based on a single abnormal BeLPT result (sensitivity). Thus, the rate of false negatives (undetected cases of beryllium sensitization) based on one normal result was 31.7 percent. Stange *et al.* reported a false positive rate of 1.09 percent for one abnormal BeLPT result and a PPV of 0.253, which they found comparable to other widely accepted medical tests. Middleton *et al.* (2006) adjusted Stange's parameters to consider borderline test results and estimated that 59.7 percent of sensitized persons would test abnormal, 27.7 percent would test normal, and 12.6 percent would have borderline results. They estimated that among non-sensitized persons, 97.37 percent would test normal, 1.09 percent would test abnormal, and 1.58 percent would have borderline results. Stange *et al.* recommended repeat testing to confirm an abnormal BeLPT result to assure appropriate referral for CBD medical evaluation (Stange *et al.,* 2004).

8. Middleton *et al.* (2006) studied the characteristics of two testing algorithms. The more basic algorithm used a single initial test plus subsequent split specimen confirmation tests. In the second, enhanced algorithm, an initial test was split and sent to different laboratories for analysis. The sensitivity, specificity, and PPV reported by Middleton were 65.7 percent, 99.9 percent, and 93 percent respectively for the basic algorithm, and 86 percent, 99.8 percent, and 90 percent respectively for the enhanced algorithm. The authors concluded that an algorithm for BeLPT testing and interpretation is best selected or designed after considering the (1) likelihood and level of exposure; (2) purpose of testing (*i.e.,* screening versus medical testing of patients; (3) opportunity for one-time testing versus serial testing; (4) importance of getting the right answer the first time; and (5) number of persons to be tested and the funds available.

9. In April 2006, the Agency for Toxic Substances and Disease Registry (ATSDR) convened an expert panel of seven physicians and scientists to discuss the BeLPT and to consider what algorithm should be used to interpret BeLPT results to establish beryllium sensitization (Middleton *et al.,* 2008). The three criteria proposed by panel members were Criteria A (one abnormal BeLPT result establishes sensitization); Criteria B (one abnormal and one borderline result establish sensitization); and Criteria C (two abnormal results establish sensitization).

10. Using the single-test outcome probabilities developed by Stange *et al.,* the panel convened by ATSDR calculated and compared the sensitivity, specificity, and positive predictive values (PPVs) for each algorithm. The characteristics for each algorithm were as follows:

TABLE A.1—CHARACTERISTICS OF BeLPT ALGORITHMS

[Adapted from Middleton *et al.,* 2008]

	Criteria A (1 abnormal)	Criteria B (1 abnormal + 1 borderline)	Criteria C (2 abnormal)
Sensitivity	68.2%	65.7%	61.2%
Specificity	98.89%	99.92%	99.98%
PPV at 1% prevalence	38.3%	89.3%	96.8%
PPV at 10% prevalence	87.2%	98.9%	99.7%
False positives per 10,000	111	8	2

11. The study demonstrated that confirmation of BeLPT results, whether as one abnormal and one borderline abnormal or as two abnormals, enhances the test's PPV and protects the persons tested from unnecessary and invasive medical procedures. In populations with a high prevalence of beryllium sensitization (*i.e.,* 10 percent or more), however, a single test may be adequate to predict sensitization (Middleton *et al.,* 2008).

12. In a later analysis, Middleton *et al.* (2011) conducted an evaluation using borderline results from BeLPT testing. Utilizing the common clinical algorithm with a criterion that accepted 1 abnormal and 1 borderline as establishing beryllium sensitization resulted in a PPV of 94.4 percent. This study also found that 3 borderline results resulted in a PPV of 91 percent. Both of these PPVs were based on a population prevalence of 2 percent. This study further demonstrates borderline results' value in predicting beryllium sensitization using the BeLPT.

III. New Beryllium-Specific Immunological Test Protocols

1. In the medical surveillance provisions of this standard, OSHA requires the use of a standardized BeLPT, but states that a ''more reliable and accurate diagnostic test'' for beryllium sensitization may be used in lieu of the BeLPT if such a test is developed. The Agency considers the following criteria to be important in judging a new test's validity and reliability:

a. A test report prepared by an independent [1] research laboratory stating that the laboratory has tested the protocol and has found it to be valid and reliable; and

b. An article that has been published in a peer-reviewed journal describing the protocol and explaining how test data support the protocol's validity and reliability.

c. Sensitivity and specificity that meet or exceed those reported for the BeLPT in peer-reviewed publications.

Appendix B to § 1910.1024: Control Strategies To Minimize Beryllium Exposure (Non-Mandatory)

Paragraph (f)(2)(i) of § 1910.1024 requires employers to use one or more of the control methods listed in paragraph (f)(2)(i)(A) of § 1910.1024 to minimize worker exposure in each operation in a beryllium work area, unless the operation is exempt under paragraph (f)(2)(i)(B) of § 1910.1024. This appendix sets forth a non-exhaustive list of control options that employers could use to comply with paragraph (f)(2)(i)(A) of § 1910.1024 for a number of specific beryllium operations.

[1] An example of an ''independent'' research laboratory would be a laboratory with no financial interest in the protocol, and no affiliation with the manufacture or supply of beryllium.

TABLE B.1—EXPOSURE CONTROL RECOMMENDATIONS

Operation	Minimal control strategy *	Application group
Beryllium Oxide Forming (*e.g.,* pressing, extruding).	For pressing operations: (1) Install local exhaust ventilation (LEV) on oxide press tables, oxide feed drum breaks, press tumblers, powder rollers, and die set disassembly stations; (2) Enclose the oxide presses; and (3) Install mechanical ventilation (make-up air) in processing areas. For extruding operations: (1) Install LEV on extruder powder loading hoods, oxide supply bottles, rod breaking operations, centerless grinders, rod laydown tables, dicing operations, surface grinders, discharge end of extrusion presses; (2) Enclose the centerless grinders; and (3) Install mechanical ventilation (make-up air) in processing areas.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites.
Chemical Processing Operations (*e.g.,* leaching, pickling, degreasing, etching, plating).	For medium and high gassing operations (1) Perform operation with a hood having a maximum of one open side; and (2) Design process so as to minimize spills; if accidental spills occur, perform immediate cleanup.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Copper Rolling, Drawing and Extruding.
Finishing (*e.g.,* grinding, sanding, polishing, deburring).	(1) Perform portable finishing operations in a ventilated hood. The hood should include both downdraft and backdraft ventilation, and have at least two sides and a top. (2) Perform stationary finishing operations using a ventilated and enclosed hood at the point of operation. The grinding wheel of the stationary unit should be enclosed and ventilated.	Secondary Smelting; Fabrication of Beryllium Alloy Products; Dental Labs.
Furnace Operations (*e.g.,* Melting and Casting).	(1) Use LEV on furnaces, pelletizer; arc furnace ingot machine discharge; pellet sampling; arc furnace bins and conveyors; beryllium hydroxide drum dumper and dryer; furnace rebuilding; furnace tool holders; arc furnace tundish and tundish skimming, tundish preheat hood, and tundish cleaning hoods; dross handling equipment and drums; dross recycling; and tool repair station, charge make-up station, oxide screener, product sampling locations, drum changing stations, and drum cleaning stations. (2) Use mechanical ventilation (make-up air) in furnace building.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Nonferrous Foundries; Secondary Smelting.
Machining	Use (1) LEV consistent with ACGIH® ventilation guidelines on deburring hoods, wet surface grinder enclosures, belt sanding hoods, and electrical discharge machines (for operations such as polishing, lapping, and buffing); (2) high velocity low volume hoods or ventilated enclosures on lathes, vertical mills, CNC mills, and tool grinding operations; (3) for beryllium oxide ceramics, LEV on lapping, dicing, and laser cutting; and (4) wet methods (e.g., coolants).	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Copper Rolling, Drawing, and Extruding; Precision Turned Products.
Mechanical Processing (*e.g.,* material handling (including scrap), sorting, crushing, screening, pulverizing, shredding, pouring, mixing, blending).	(1) Enclose and ventilate sources of emission; (2) Prohibit open handling of materials; and (3) Use mechanical ventilation (make-up air) in processing areas.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Aluminum and Copper Foundries; Secondary Smelting.
Metal Forming (*e.g.,* rolling, drawing, straightening, annealing, extruding).	(1) For rolling operations, install LEV on mill stands and reels such that a hood extends the length of the mill; (2) For point and chamfer operations, install LEV hoods at both ends of the rod; (3) For annealing operations, provide an inert atmosphere for annealing furnaces, and LEV hoods at entry and exit points; (4) For swaging operations, install LEV on the cutting head; (5) For drawing, straightening, and extruding operations, install LEV at entry and exit points; and (6) For all metal forming operations, install mechanical ventilation (make-up air) for processing areas.	Primary Beryllium Production; Copper Rolling, Drawing, and Extruding; Fabrication of Beryllium Alloy Products.
Welding	For fixed welding operations: (1) Enclose work locations around the source of fume generation and use local exhaust ventilation; and (2) Install close capture hood enclosure designed so as to minimize fume emission from the enclosure welding operation. For manual operations: (1) Use portable local exhaust and general ventilation.	Primary Beryllium Production; Fabrication of Beryllium Alloy Products; Welding.

* All LEV specifications should be in accordance with the ACGIH® Publication No. 2094, ''Industrial Ventilation—A Manual of Recommended Practice'' wherever applicable.

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